

Testimony of Thomas A. Farley, MD, MPH, Commissioner New York City Department of Health and Mental Hygiene

before the

New York City Council Committee on Health

on

Preconsidered Introduction No.

December 4, 2013

City Council Chambers New York, New York Good morning, Chairperson Arroyo and members of the New York City Council Committee on Health. I am Dr. Thomas Farley, Commissioner of the New York City Department of Health and Mental Hygiene. Thank you for the opportunity to comment on this Preconsidered Introduction, a bill that would amend the Smoke-Free Air Act by prohibiting electronic cigarette use in all places where smoking conventional cigarettes is prohibited. This legislation will help address electronic cigarette use, which is growing rapidly among both youth¹ and adults² and poses a threat to the progress we have made in reducing smoking in New York City.

Since 2002, the Bloomberg Administration and the City Council have worked hard to reduce smoking and protect all New Yorkers from the harmful effects of tobacco. Perhaps the single most effective policy change that has been made has been amending the Smoke-Free Air Act, which has not only protected nonsmokers from second-hand smoke but also radically changed the social acceptability of smoking. We also made cigarette taxes the highest in the nation, produced public awareness campaigns warning about the risks of smoking, and offered direct assistance to tens of thousands of New Yorkers to help them quit. With your help, last month we became the first major city in the United States to increase the age of sale for cigarettes to 21 and one of the first jurisdictions in the country to prohibit redeeming discounts on tobacco products. To address the growing trade in illegal cigarettes, we also increased our ability to enforce against tax evasion, which will help ensure high cigarette prices and level the playing field for honest retailers. As a result of these efforts, the smoking rate of adult New Yorkers has fallen by more than a quarter³ and the smoking rate of teenagers has been cut in half.⁴ We have estimated that this decline in smoking is preventing thousands of unnecessary deaths in New York

¹ Centers for Disease Control and Prevention. Notes from the Field: Electronic Cigarette Use Among Middle and High School Students — United States, 2011–2012. Morbidity and Mortality Weekly Report 2013;62(35):729-30.

² McMillan et al. Three Year Trends in the Use Of Emerging Tobacco Products. Presented at 141st APHA Annual Meeting; 2013 November 5; Boston, MA.

³ New York City Department of Health and Mental Hygiene. Community Health Survey 2001-2012.

⁴ New York City Department of Health and Mental Hygiene. Youth Risk Behavior Survey 2001-2011.

City, contributing to our significant gains in life expectancy.⁵ However, our adult smoking rate has leveled off in the last two years, the youth smoking rate has remained stagnant for several years, and smoking is still the number one cause of preventable death in New York City. For these reasons, we are constantly seeking new ways to discourage youth from starting to smoke and assist adult smokers in quitting. Even more important, we feel we must protect the gains we have worked so hard to achieve and prevent smoking rates from rising again.

Electronic cigarettes, commonly called e-cigarettes, are nicotine delivery devices that emit vapor and are designed to look like conventional cigarettes. Among United States high school students, electronic cigarette use more than doubled between 2011 and 2012, from 4.7 percent to 10 percent.⁶ In 2012, more than 1.78 million middle and high school students nationwide tried electronic cigarettes.⁷ Sales of these products have doubled in just two years from nearly \$300 million in 2011 to \$600 million in 2012,⁸ and are expected to reach \$2 billion in 2013.⁹ All of this country's big cigarette companies are now producing and heavily marketing e-cigarettes.

A key point for the hearing today is that e-cigarettes are so new that we know very little about them. We cannot answer many of the important questions that health experts have about their short-term, long-term, and indirect effects. Electronic cigarettes are not regulated by any federal agency. Because there are no government reporting requirements for e-cigarettes, there is

⁶ Centers for Disease Control and Prevention. Notes from the Field: Electronic Cigarette Use Among Middle and High School Students — United States, 2011–2012. Morbidity and Mortality Weekly Report 2013;62(35):729-30.

⁵ Li W, Maduro G, Begier EM. Life Expectancy in New York City: What Accounts for the Gains? New York City Department of Health and Mental Hygiene: Epi Research Report, March 2013; 1-12.

⁷ Centers for Disease Control and Prevention. Notes from the Field: Electronic Cigarette Use Among Middle and High School Students --- United States, 2011–2012. Morbidity and Mortality Weekly Report 2013;62(35):729-30.

⁸ CBSNews.Com. Booming E-cigarette industry raises questions on safety, regulation. July 22, 2013. Last accessed November 25, 2013. Available at:

<u>http://www.absnews.com/#3001-505263_052-577394842//hoarning-a-ciganette-industry-naises-questions-on-suffety-regulation/</u>
⁹ Wieczner, Jenn. The Wall Street Journal. 10 Things E-Cigarettes Won't Tell You. November 10, 2013. Last accessed
November 25, 2013. Available at: http://arthine.wsj.com//news/antiidles/SB00000044240527/023044448204577918440522939008302

no way of knowing the levels of nicotine or amounts or kinds of other chemicals they deliver to the lungs of users.¹⁰ The Food and Drug Administration (FDA) has found that some electronic cigarettes contain toxins and carcinogens and has expressed concern about their safety.^{11,12} Some studies suggest that electronic cigarettes release emissions containing volatile organic compounds¹³ and fine particulate matter,^{14,15} which are associated, in large enough concentrations, with respiratory problems.

Electronic cigarettes have not been subjected to any long-term scientific studies and their impact on health over time is unknown. What we do know with certainty is that most of these devices contain nicotine, a highly addictive substance, and many electronic cigarettes look virtually identical to and mimic the action of smoking a conventional cigarette.

I am sure you will hear later today from e-cigarette advocates that e-cigarettes, by delivering nicotine to addicted smokers, help those smokers quit. Based on this argument, they believe health experts should condone or actually promote e-cigarette use. And initially the FDA tried to regulate e-cigarettes as drug delivery devices. But remarkably, it was the electronic cigarette industry itself that sued the FDA over this, arguing in court that electronic cigarettes were not drug delivery devices but instead were tobacco products and should be regulated as tobacco products. And in 2010, the federal court agreed with them.¹⁶ In an Associated Press article on this legislation last week, a representative of the Tobacco Vapor Electronic Cigarette Association

 ¹¹ FDA warns about health risks posed by e-cigarettes. Last accessed November 27, 2013. Available at: <u>http:///www.fdta.gov//FouConsumens//Consument/Updates//uccm11734001.htm</u>
 ¹² Food and Drug Administration. Evaluation of e-cigarettes. May 4, 2009. Last accessed November 27, 2013. Available at:

¹⁰ FDA and Public Health Experts Warn About Electronic Cigarettes, Jul. 22, 2009. Available at: http:///www.fda.gov/%20NicwsEvents/Nicwstroom/PressAnnouncements/mcm173222.htm

¹² Food and Drug Administration. Evaluation of e-cigarettes. May 4, 2009. Last accessed November 27, 2013. Available at: http:///www.fila.gov/klowunloads/klings/sciencenescandh/uccmn173250.pdff

¹³ Schripp T, Markewitz D, Uhde E, et al. Does e-cigarette consumption cause passive vaping? Indoor Air 2013;23:25–31.

¹⁴ Schripp T, Markewitz D, Uhde E, et al. Does e-cigarette consumption cause passive vaping? Indoor Air 2013;23:25–31.

¹⁵ Zhang Y, Sumner W, Chen D-R. In Vitro Particle Size Distributions in Electronic and Conventional Cigarette Aerosols Suggest Comparable Deposition Patterns. Nicotine & Tobacco Research 2013;15(2):501-508.

¹⁶ Sottera, Inc. v. Food and Drug Administration, 627 F.3d 891 (D.C. Cir. 2010).

reiterated this position, saying that e-cigarettes should be regulated as tobacco products. By the industry's own logic, then, e-cigarette use should be discouraged by health experts and prohibited in places where use of conventional cigarettes is prohibited.

In addition, there are reasons to question the claim that e-cigarettes help smokers of conventional cigarettes quit. The use of electronic cigarettes, particularly in places where smoking is prohibited, may actually have the opposite effect, helping smokers <u>avoid</u> quitting by acting as a "bridge" – that is, helping them maintain nicotine levels in their blood until they have an opportunity to smoke a conventional cigarette again.

Several e-cigarette companies are now running advertisements, including ads on television, with attractive models and celebrities, glamorizing the act of smoking in a way that we have not seen since conventional cigarette ads were banned from television in the early 1970s. I view this marketing as highly irresponsible and dangerous because it may entice children to experiment with smoking.

Allowing the use of electronic cigarettes in places where smoking is prohibited could accentuate this problem, making the act of smoking conventional cigarettes socially acceptable again and undermining the enormous progress of tobacco control efforts over the past few decades. The impact of the social acceptability should not be underestimated; children and young adults are heavily influenced by whether they feel a behavior is viewed positively by their peers. If smoking becomes more socially appealing or even glamorous again we can be virtually certain that smoking rates in teenagers will rise. Another concern is that young people who experiment with electronic cigarettes may become addicted to nicotine and then switch over to smoking conventional cigarettes.

5

Finally, allowing use of e-cigarettes indoors may make it difficult to enforce the Smoke-Free Air Act against conventional cigarettes, because e-cigarettes and conventional cigarettes can look so much alike. New Yorkers have come to enjoy and greatly benefit from smoke-free restaurants and bars. We do not want to return to a day in which smoking conventional cigarettes in these places is allowed, simply because restaurant and bar staff can't easily distinguish them from e-cigarettes.

Various jurisdictions around the country have prohibited the use of electronic cigarettes in areas where smoking is prohibited, including New Jersey, Utah, North Dakota, Boston and various counties in New York, California and Kentucky. Last week, Chicago announced that it is pursuing similar legislation.

Because of these concerns, prohibiting the use of electronic cigarettes in areas where smoking is restricted is a prudent step. While more research is needed on the health effects of electronic cigarettes, waiting to act could jeopardize the progress we have made over the last 12 years.

Thank you for the opportunity to testify. I am happy to answer any questions.

6





Testimony – In Support

Preconsidered Introduction to amend the administrative code of the city of New York, in relation to the regulation of electronic cigarettes.

Submitted by:

American Heart Association / American Stroke Association Robin Vitale, Senior Director, Government Relations 122 East 42nd Street, 18th Floor, New York, NY 10168

Date: December 4, 2013

To: New York City Council Committee on Health, Council Member Maria del Carmen Arroyo, Chair

Thank you, Chair Arroyo and the members of the NYC Council Committee on Health for this opportunity to provide testimony regarding the potential regulation of electronic cigarettes in New York City, by adding these nicotine-delivery devices to the city's existing Smoke Free Air Act.

More than a decade ago, the American Heart Association / American Stroke Association supported the city's goal to protect New Yorkers from the effects of tobacco smoking by helping to pass the city's smoke-free law. In our role as the nation's oldest and largest voluntary organization dedicated to building healthier lives, free of cardiovascular diseases and stroke, it was critical that we restrict smoking from our public workplaces. Unfortunately, the use of tobacco remains the leading preventable cause of heart disease and stroke, our city's number one and number four causes of death respectively. As a result, in 2011, we once again supported the expansion of the Smoke Free Air Act to include the city's public parks, beaches and pedestrian plazas. Our goal in this effort two years ago was to impact the social norms achieved by seeing people smoke, particularly in these areas used for recreation by our young people.

Our most recent work with the city to pass the new laws to improve the enforcement of the city's high excise tax, the second highest in the nation, as well as restrict the sale of tobacco and electronic cigarettes to people under the age of 21 are all strong indicators of New York's intention to promote a heart-healthy environment. Based upon this focus to protect public health, it is appropriate that the Council should turn its attention to this burgeoning trend of electronic cigarette use and the possible impact they could have on the enforcement of the existing law and encouraging continued tobacco addiction in our city.

Many of these products are manufactured to resemble traditional cigarettes, in appearance, functionality or both. Indeed, the appeal as shared by users is largely based on not only the provided nicotine, but the satiation effect of using the device orally and emitting a vapor into the air. This mimicry of traditional cigarettes, if used indoors where smoking is banned, can easily lead to confusion and confrontation by New York business owners. The potential for this dynamic to weaken the city's decade-long ban on smoking in workplaces is quite clear and is the greatest motivating factor to support this proposal.

There have been numerous misleading comments made about the presumed safety of electronic cigarettes. These devices are often marketed as a safe alternative to smoking with little impact on the user. These claims have not been substantiated by any public health authority. The American Heart Association supports the regulation of these products by the Food and Drug Administration and looks forward to the growth of scientific knowledge that can be achieved by such oversight.¹ Regardless, as we currently know very little about the long-term effects of using electronic cigarettes, we believe it is entirely necessary for the Council to alter the city's law to restrict the use of these products.

Most recently, the results of the National Youth Tobacco Survey yielded alarming news. Researchers from the Centers for Disease Control and Prevention found that the percentage of high school students who had used electronic cigarettes doubled in just one year (from 4.7% in 2011 to 10% in 2012.)² This troubling reality should heighten our concern as the CDC also confirms in this research that 90% of our nation's smokers begin during their teenage years. Additionally, the Youth Tobacco Survey also showed that one in five middle school students have used electronic cigarettes without ever using a tobacco product.² This data speaks to the potential for electronic cigarettes to serve as a gateway mechanism for future nicotine addiction. Lastly, the survey results don't indicate that electronic cigarettes are steering kids away from tobacco use as more than 76% of middle and high school students who used e-cigarettes within the past 30 days also smoked an actual cigarette during that time.²

Efforts to prevent and improve outcomes for heart disease and stroke patients remain a pivotal concern as the American Heart Association pursues our 2020 goal of both a 20 percent improvement in cardiovascular health for *all* Americans and a 20 percent reduction in cardiovascular and stroke deaths. Efforts to strengthen the city's Smoke Free Air Act and curb potential nicotine addiction in our young people are appreciated and certainly warranted as we target the leading preventable cause of these diseases – tobacco use.

The American Heart Association is proud to work in partnership with the New York City Council and the administration of the NYC Department of Health and Mental Hygiene as we continue to encourage New York smokers to quit and help protect NYC kids from tobacco industry tactics.

I welcome any questions you may have.

¹ http://newsroom.heart.org/news/fda-must-act-now-on-e-cigarettes-says-american-heart-association

² CDC National Youth Tobacco Survey http://www.cdc.gov/tobacco/data_statistics/surveys/nyts/



Testimony of Michael Seilback

Re: Expansion of Smoke-Free Air Act to include use of electronic cigarettes (Preconsidered Int. No. ____)

December 4, 2013

Good morning, my name is Michael Seilback and I am the Vice President, Public Policy & Communications for the American Lung Association of the Northeast. Thank you Chairwoman Arroyo and members of the committee for this important hearing.

When New York City passed its Smoke-Free Air Act, 10 years ago – it was a monumental achievement which removed cigarettes and secondhand smoke from our bars and restaurants. This law was replicated across the country, and around the world and helped propel New York forward to major reductions in smoking rates.

In recent months, we have seen a major increase in the use of electronic cigarettes, e-cigars, e-hookahs and similar products across the City. For the purpose of this legislation, I will use the term e-cigarette to refer to all of these products. Patrons of our smokefree bars, restaurants and workplaces are increasingly being exposed to secondhand emissions from electronic cigarettes. We hear complaints about e-cigarette use from New Yorkers across the city ranging from the Subway, to bars and restaurants, sporting events, concerts, public libraries, even in the hearing rooms of 250 Broadway.

This legislation would amend the Smoke-Free Air Act to restrict the use of ecigarettes anywhere in New York City that smoking tobacco products is prohibited. The American Lung Association strongly supports the preconsidered intro.

The American Lung Association is very concerned that we don't know what's in ecigarettes or what the health consequences of them might be. The American Lung Association is troubled that they may be starting kids on the path of a lifetime nicotine addiction and in addition to local laws, we are calling on the Obama Administration take action.

Currently, e-cigarettes are completely unregulated by the federal government, and the products vary in their makeup, nicotine level and design.

According to the FDA, electronic cigarettes, or e-cigarettes, are devices that allow users to inhale a vapor containing nicotine or other substances. Unlike traditional cigarettes, e-cigarettes are generally battery-operated and use an atomizer to heat a refillable cartridge that then releases a chemical-filled vapor.

Nearly all e-cigarettes contain nicotine that is derived from tobacco. In 2010, federal courts ruled that e-cigarettes could be regulated as tobacco products under FDA's Center for Tobacco Products, particularly since e-cigarette manufacturers "assert that their electronic cigarettes qualify as a tobacco product."

E-cigarettes are often available in flavors that may appeal to children and teens, including cotton candy, bubble gum, chocolate, strawberry and mint. Additionally, the e-cigarette industry is using Big Tobacco's playbook when it comes to marketing their products. We see ads making the products appear sexy and cool; we see ads telling smokers to revolt against being pushed outside and urging them to use e-cigarettes indoors; we see celebrity endorsers, implied health claims, and discounting and couponing.

Recent data from the CDC shows that youth usage has doubled in the last year. And of those youth, 76% of those kids also are using tobacco, as well.

Additional and on-going research is needed to understand the full public health impact of e-cigarettes, including their impact on youth initiation, whether current smokers are switching to these products instead of quitting or are using them in conjunction with regular cigarettes.

But what do we know? The health consequences of the use of e-cigarettes and the secondhand e-cigarette emissions that they give off are unknown. There is currently no scientific evidence establishing the safety of ecigarettes. No brand of e-cigarettes has been found by FDA to be safe and effective in helping smokers quit.

In initial lab tests conducted in 2009, FDA found detectable levels of toxic cancer-causing chemicals. Additional initial studies have found formaldehyde, benzene, and carcinogens in secondhand e-cigarette emissions.

If that wasn't reason enough to prohibit their use indoors, the use of ecigarettes in public places and workplaces may also complicate efforts to enforce and comply with smokefree laws.

The American Lung Association and its partners have urged the Obama Administration and FDA to move forward without delay to begin overseeing these products to determine the public health impacts of their use. We are hopeful we will see a proposed rule before the end of the year – but we estimate that it will be at least 12-18 months more until we see a final rule & FDA's oversight authority begin.

You will likely hear from vocal advocates of e-cigarette use today. Let's be clear on a few things.

1- The FDA has not approved e-cigarettes as a safe or effective method to help smokers quit. There are seven therapies approved by the U.S. Food and Drug Administration in combination with individual, group or phone cessation counseling that are the most effective ways to help smokers quit. Until and unless the FDA approves a specific e-cigarette for use as a tobacco cessation aid, the American Lung Association does not support any direct or implied claims that e-cigarettes help smokers quit.

2- This legislation will not prohibit New Yorkers from using this product. It will simply replicate our existing smokefree law and ask them to use the product in places where traditional smoking is permitted.

3 – NONE of the health claims – direct or implied – that you will here today have been verified by FDA, the Centers for Disease Control and Prevention, or any other federal health agency.

The American Lung Association strongly supports the proposed legislation and urges the Council to pass it.

For more information contact: Michael Seilback, Vice President, Public Policy & Communications for the American Lung Association of the Northeast, 631.415.0946 or <u>mseilback@lungne.org</u>.



Testimony of Michael A. Hernández President-Elect, Public Health Association of New York City

Public Hearing of the New York City Council Submitted to NYC Council Committee on Health, Maria del Carmen Arroyo, Chair Proposal to Regulate Electronic Cigarettes December 4, 2013

Thank you, Chair Arroyo, and the members of the Council Committee on Health for this opportunity to discuss a critical public health concern. My name is Michael Hernández and I currently serve in the role of President-Elect for the Public Health Association of New York City, or PHANYC.

Founded in 1936, PHANYC has provided a vital resource to link public health professionals, students of public health programs and our city's decision-makers together to help advance thoughtful health policies for our city. PHANYC has grown to be one of the largest affiliates of the American Public Health Association.

The policy agenda for PHANYC is quite robust as it seeks to cover various aspects of public health that impact our metropolitan area. As you are keenly aware, tobacco control has been a priority on our agenda due to the tremendous burden the tobacco industry has caused. Tobacco use is the leading preventable cause for many diseases in New York, including the biggest threats to our mortality – heart disease, cancer, stroke and lung disease. While the city has been proactively working to restrict and regulate tobacco use, the tobacco industry has concurrently been seeking avenues to attract new smokers while keeping current smokers addicted to their products.

Electronic cigarettes now threaten to serve the tobacco industry's purpose. Electronic cigarettes are battery-powered devices that provide users with a vapor filled with nicotine and other additives. These additives may provide a fruit or candy flavor to the e-cigarette, or may enhance the aerosol effect to the vapor emitted by the user.

The use of child-friendly flavors should serve as an immediate red flag that industry is hoping to attract new users while simultaneously maintaining those who may otherwise be motivated to quit their nicotine addiction. Compounded with the alluring advertisements featured on television and in magazines, and it is clear that electronic cigarettes have borrowed the marketing plan of Big Tobacco from decades past.

It must be emphasized that the Food and Drug Administration has not approved e-cigarettes as an effective method to help smokers quit. The U.S. Public Health Service maintains that the seven therapies approved by the FDA, in combination with individual or group cessation counseling is the most effective way to help smokers quit. ¹ In light of the current guidelines, and the lack of regulation from our federal government partners, PHANYC strongly supports this effort by New York City to add electronic cigarettes to the existing Smoke Free Air Act.

Contact Information: Michael A. Hernández President-Elect, Public Health Association of New York City (PHANYC) info@phanyc.org / www.phanyc.org

¹ <u>http://www.ahrq.gov/professionals/clinicians-providers/guidelines-</u> recommendations/tobacco/clinicians/treating_tobacco_use08.pdf

MEMORANDUM

TO: Health Committee, New York City Council

FROM: David Schwartz, Gotham Government Relations & Communications

DATE: December 4, 2013 (Public Hearing)

Re: Testimony in Response to Proposed Regulation of Electronic Cigarettes

OVERVIEW

& COMMUNICATIONS

We have come to you in order to advocate against the recent electronic cigarette regulations that have been proposed by City Council. Based on the available information and scientific studies, these proposed regulations are not only premature, but have also been too hastily set in motion.

How can a device that has been deemed by scientific studies to control tobacco usage, be controlled the same way as tobacco? The long-term effects of electronic cigarettes and its ingredients are unknown, so passage of this type of regulation would be premature. The legislation in question even admits that the long-term effects of electronic cigarette devices require further study and that the FDA has yet to regulate it. They also claim that some devices have been found to contain trace amounts of toxins and carcinogens. And they even claim that these devices may interfere with smokers' attempts to quit. However, while the language of the legislation alludes to potential negative characteristics and attempts to treat electronic cigarettes similarly to the way tobacco is regulated – nowhere does it acknowledge the widespread benefits of electronic cigarettes and the fact that they are an inherently different product, separate and distinct from tobacco.

It would be incredibly premature to treat electronic cigarettes identical to tobacco. It is especially troublesome when the federal government has yet to weigh in on the proper way to approach electronic cigarette regulation. We are not suggesting that electronic cigarettes be free from regulation, but rather insist that it be reasonably regulated. For example, we were never opposed to increasing the age of those who can purchase these devices, since these products are meant only for adult consumers. However, restricting the use of electronic cigarettes in public locations such as bars and restaurants around New York City would prevent the average adult consumer the ability to freely utilize an alternative to tobacco. Under the circumstances, it would be unreasonable. Electronic cigarettes are completely distinct from tobacco cigarettes; therefore, they should be regulated differently.

We urge you to regulate commensurate with harm and base your decisions on sufficient scientific evidence. There is simply a lack of adequate information and conclusive studies to draw such a close comparison between electronic cigarettes and tobacco. Studies even show that rather than interfering with smokers' attempts to quit, electronic

cigarettes encourage smokers to quit by allowing for a substitute that does not present the same dangers as tobacco cigarettes. And the truth is that electronic cigarettes have become well-known as an alternative to smoking and people recognize that it is an inherently different product. In fact, even products such as smokeless tobacco, nicotine patches and nicotine gum are regulated differently than combustion based cigarettes, which demonstrates the regulatory differences between these inherently different products.

As you work to understand this issue, please keep the following in mind:

- Electronic cigarettes encourage economic growth
- While the FDA has discovered trace amounts of tobacco-specific nitrosamines in some electronic cigarettes, they contain the same trace levels as the FDA-approved nicotine patch.
- Studies show that electronic cigarettes are just as good as the nicotine patch and other cessation products.
- The vapor from electronic cigarettes has no smell that affects other patrons or employees in any establishment
- The FDA was set to issue regulations by October 31st, but have they have yet to offer guidance on how these devices must be regulated – they are still expected to issue their findings.

At this time, all studies are simply postulations and there are clearly arguments for either side of this issue. Therefore, it would be incredibly premature to treat electronic cigarettes similarly to tobacco, until more substantial information is made available. We ask you, if you must regulate this device, please regulate commensurate with the harm for the time being or at least until the federal government has given us guidance on this issue.

RESEARCH and STUDIES

1. Lancet Medical Journal

This article in the Lancet Medical Journal unveiled the first major piece of research to show that e-cigarettes can benefit tobacco smokers. This study has demonstrated that electronic cigarettes work about as well as nicotine patches in helping smokers kick the habit, researchers report. E-cigarettes helped people smoke fewer cigarettes overall, even if they didn't quit completely. Although these findings are not enough to make public health experts embrace the concept of e-cigarettes, it's enough to make them look more closely at whether there may be some benefit to them.

2. University of Catania

One of the latest studies concerning electric cigarettes was conducted by Italy's University of Catania. The study was published in the journal PLOS One.

"Researchers at the University of Catania closely monitored and followed 300 smokers during the course of 2 years. Before participating in the study, all 300 smokers agreed to give electronic cigarettes a try. The University wanted to determine the effect e-cigs had on smokers by monitoring their reactions. It's no secret that thousands of people make the switch from cigarettes to e-cigs each year, but there's very little clinical data revealing actual statistics, and this is why the University set out on this path.

So, what effect did e-cigs have on the 300 smokers? According to the report published in PLOS, approximately 8.7% were no longer smoking cigarettes after 1 year. This is a huge jump that even surprised researchers. Smoking cessation products like nicotine patches and gum have a much lower success rate, even though they are marketed specifically to help smokers kick their bad habit.

Another key point of the study that's worth mentioning is that 4% of those 300 participants quite smoking after trying e-cigs without any nicotine. It's unclear to researchers what's causing these smokers to quit without nicotine, but some believe it's related to the oral fixation of placing a device that looks almost identical to a cigarette up to your lips. Unlike nicotine gum and patches, e-cigs provide the same habitual movements and motion as smoking a traditional cigarette. Users are able to satisfy those same habitual cravings by using an e-cig rather than smoking a cigarette." (http://e-cigaretteblog.vaporvixxen.com/post/54438671729/new-study-highlights-potential-benefits-of-e-cigs#.Uhg109J97Xw)

"I think the main message of the study is that we can use these products as an extraordinary tobacco control tool," Dr. Riccardo Polosa, the new study's senior author from the University of Catania, told Reuters Health." http://www.reuters.com/article/2013/06/24/us-e-cigarette-idUSBRE95N1C720130624

The entire study can be viewed through the following link: <u>http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0066317</u>

3. Drexel University School of Public Health

"A study just released by Professor Igor Burstyn, Drexel University School of Public Health, confirms that chemicals in electronic cigarettes (e-cigarettes) pose no health concern for users or bystanders. This is the first definitive study of e-cigarette chemistry and finds that there are no health concerns based on generally accepted exposure limits."

"By reviewing over 9,000 observations about the chemistry of the vapor and the liquid in e-cigarettes, Dr. Burstyn was able to determine that the levels of contaminants e-cigarette users are exposed to are insignificant, far below levels that would pose any health risk. Additionally, there is no health risk to bystanders. Proposals to ban e-cigarettes in places where smoking is banned have been based on concern there is a potential risk to bystanders, but the study shows there is no concern."

Source: http://blog.casaa.org/2013/08/new-study-confirms-that-chemicals-in.html

The entire study can be viewed through the following link: http://publichealth.drexel.edu/SiteData/docs/ms08/f90349264250e603/ms08.pdf

4. University of Hawaii Cancer Center

"A new study by the University of Hawai'i Cancer Center finds young people who want to quit smoking are turning to e-cigarettes."

"More than 1,500 smokers from different ethnic backgrounds were surveyed. Researchers found 13% of them turned to electronic smoking devices to try to kick their habit.

'We found that people who had used other nicotine replacement therapy that had been approved by the FDA – they were two to four times more likely to have tried electronic cigarettes to quick smoking,' said Dr. Pallav Pokhrel."

Source: <u>http://www.hawaiinewsnow.com/story/22906320/uh-cancer-center-study-finds-young-people-turn-to-e-cigarettes-to-quit</u>

A online version, published ahead of the print American Journal of Public Health, can be viewed through this link: http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2013.301453

5. Journal of the American Medical Association

"Dr. Neal Benowitz, who served on the FDA's Tobacco Products Scientific advisory committee, co-authored a July 15 report on e-cigs posted on the Journal of the American Medical Association's website."

"Benowitz said e-cigs 'likely pose less direct hazard to the individual smoker than tobacco cigarettes and might help smokers quit smoking or reduce harm by smoking fewer tobacco cigarettes.""

Source: Winston-Salem Journal (July 28, 2013).

6. Fraunhofer Institute for Wood Research WKI in Braunschweig

Dr. Tobias Schripp is scientist at Fraunhofer WKI and co-author of the study.

"In general, the emissions of VOCs and ultrafine particles when smoking an e-cigarette were lower than the equivalent emissions from a standard cigarette", said Schripp

"Additionally, the researcher and his colleagues were unable to find any formaldehyde emissions from the e-cigarette. Regular cigarettes, on the other hand, surpassed the guideline value of 0.1 ppm (parts per million) for indoor air quality under the given test requirements. Vaporized propylene glycol was given off from both tobacco cigarettes and e-cigarettes. Pulmonologists are afraid this solubilizing agent can bother the airways when inhaled in big quantities."

Source: Medical News Today (December 8, 2012).

7. American Journal of Health Behavior

"A new study being published in the *American Journal of Health Behavior* suggests that electronic cigarettes might encourage hard-core tobacco puffers to significantly cut back on traditional cigarettes, even when they say they don't want to.

The pilot study found that of 28 adult smokers—none of whom were interested in quitting—25, or nearly 90 percent, reduced their use of tobacco cigarettes during a week in which they smoked e-cigarettes from leading maker NJOY.

Nearly one-third of those smokers cut their tobacco cigarette use in half, and four of the participants told researchers that they were smoking no traditional cigarettes at all by the end of the weeklong trial of NJOY Kings.

Overall, the mean reduction in participants' cigarettes smoked per day was 39 percent, according to the study.

The research report also found that the e-cig users' nicotine absorption was comparable to that with nicotine-replacement products approved by the Food and Drug Administration. The report noted that 'these results suggest that this [NJOY] product delivered enough nicotine to suppress craving."

Source:

http://www.cnbc.com/id/100966001?__source=yahoo%7Cfinance%7Cheadline%7Chead line%7Cstory&par=yahoo&doc=100966001%7CSmoking%20cigs%20could%20cut%20 to

FOR THE RECORD



December 3, 2013

Maria del Carmen Arroyo, Chair Committee on Health 250 Broadway Suite 1768 New York, NY 10007

Dear Chairperson del Carmen Arroyo and Honorable Members of the Committee:

I write today in strong support of the proposed legislation to include electronic cigarettes (ecigarettes) in New York City's clean indoor air law. This amendment would eliminate the risk of exposure to toxic chemicals found in e-cigarettes, ease enforcement of existing smoking laws and continue to send the message that smoking indoors in New York City is not the norm.

In December 2011, the Boston Board of Health passed an amendment to our city's tobacco laws to prohibit use of e-cigarettes in workplaces and prohibit sales of e-cigarettes to minors. In the years prior to the Board's vote, we had heard from youth that they were able to purchase e-cigarettes in Boston's convenience stores and from employers that they were seeing an increase in the use of e-cigarettes indoors. E-cigarettes raise a number of unanswered health and safety concerns. For instance, FDA has found that e-cigarettes contain cancer causing agents along with other chemicals, including diethylene glycol – a common ingredient in antifreeze. They deliver amounts of nicotine that are inconsistent with their labeling and vary widely from puff to puff.¹ In addition, there is mounting evidence that e-cigarettes are being used in addition to cigarettes, rather than as a substitute. Despite these documented risks, e-cigarettes were and continue to be unregulated by the state and federal government.

¹ FDA (2009-05-04). <u>"Evaluation of e-cigarettes"</u>. Food and Drug Administration (US) – center for drug evaluation and research. Retrieved 2009-05-04.; Zezima, Katie (2009-07-23). "Analysis Finds Toxic Substances in Electronic Cigarettes". The New York Times. Retrieved 04 26 2010

Like cigarettes, e-cigarettes expose bystanders to second-hand vapors. The use of e-cigarettes produces vapors that quickly disperse into the surrounding air when exhaled by a user. Little to no research has been conducted on the composition of these vapors, and therefore little is known about the toxicity of second-hand exposures and risks incurred by bystanders when an e-cigarette is in use.² Assuming that the exhaled vapor contains the same or similar constituents as the solution, the use of these products in workplaces exposes employees to nicotine and other known toxins and carcinogens.

Nicotine delivery products, particularly e-cigarettes, undermine workplace smoking laws, as well as the public health gains attributable to these laws. Several studies have found that smoke-free workplace policies increase the success rates of employees who attempt to quit, and that employees of workplaces that maintained smoke-free policies were as much as two times as likely to quit.³ Such policies also reduce the number of cigarettes smoked by workers who do continue to smoke.⁴

Studies also show that smoke-free workplace policies have effects that extend beyond the affected workplaces to the general population. In two studies, smoking rates fell by 11% in one year after the implementation of workplace smoking restrictions along with other evidence-based tobacco control strategies.⁵ Encouragingly, smoke-free laws also contribute to decreased smoking among youth. A Massachusetts study conducted by Michael Siegel and colleagues found that youth living in towns with smoke-free restaurant laws were less than half as likely to establish smoking behaviors than youth living in towns with weak restaurant smoking restrictions.⁶ There is evidence that this drop in youth smoking is caused by a decrease in the visibility of smoking, resulting in a change in the perception by youth of social norms about

² Electronic cigarettes are unsafe and pose health risks, UC Riverside Study Finds. <u>http://www.njgasp.org/e-</u>

cig study UC Riverside 12-3-2010.pdf Accessed October 25, 2011. ³ Bauer JE, Hyland A, Li Q, Steger C, Cummings M. A longitudinal assessment of the impact of smoke-free worksite policies on tobacco use. American Journal of Public Health 2005;95(6):1024-9.

⁴ Glasgow RE, Cummings KM, Hyland A. Relationship of worksite smoking policy to changes in employee tobacco use: findings from COMMIT. Community Intervention Trial for Smoking Cessation. Tobacco Control 1997;6(Suppl 2):S44-S48; Moskowitz JM, Lin Z, Hudes ES. The impact of workplace smoking ordinances in California on smoking cessation. American Journal of Public Health 2000;90(5):757-61; Burns DM, Shanks TG, Major JM, Gower KB, Shopland DR. Restrictions on smoking in the workplace. In: Population Based Smoking Cessation: Proceedings of a Conference on What Works to Influence Cessation in the General Population. Smoking and Tobacco Control Monograph No. 12. Bethesda (MD): U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute, December 2000:99-128; Fichtenberg CM, Glantz SA. Effect of smoke-free workplaces on smoking behaviour: systematic review. British Medical Journal 2002;325(7357):188; Bauer JE, Hyland A, Li Q, Steger C, Cummings M. A longitudinal assessment of the impact of smoke-free worksite policies on tobacco use. American Journal of Public Health 2005;95(6):1024-9; National Cancer Institute. Population Based Smoking Cessation: Proceedings of a Conference on What Works to Influence Cessation in the General Population. Smoking and Tobacco Control Monograph No. 12. Bethesda (MD): U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, 2000. NIH Publication No. 00-4892; Task Force on Community Preventive Services. The Guide to Community Preventive Services: What Works to Promote Health? New York: Oxford University Press, 2005.

⁵ Frieden TR, Mostashari F, Kerker BD, Miller N, Hajat A, Frankel M. Adult tobacco use levels after intensive tobacco control measures: New York City, 2002-2003. American Journal of Public Health 2005;95(6):1016-23: State of Delaware. Delaware's smoking rate decreased by 11 percent in 2003 [press release]. Dover (DE): State of Delaware, Office of the Governor, July 2, 2004.

⁶ Siegel M, Albers AB, Cheng DM, Biener L, Rigotti NA. Effect of local restaurant smoking regulations on progression to established smoking among youths. Tobacco Control 2005; 14(5):300-6.

smoking. Another Massachusetts study, conducted by the same author, found that in towns with strong restaurant smoking regulations, youth were more likely to perceive a lower prevalence of adult smoking. They were also more likely to perceive that adults in their town disapproved of smoking.⁷

E-cigarette use in the workplace directly undermines these workplace smoking laws because they cause confusion about whether smoking is actually prohibited in the workplace. Further, when people see an e-cigarette being used in a workplace, it can be a trigger for those who are early in their cessation to want to smoke again.

Boston began implementation of our updated workplace law in January 2012 and to date, we have not had any violations. We have changed our mandatory workplace signage to reflect the change in the law and have had very few complaints about the new regulation. We do, however, continue to experience numerous violations of the prohibition on selling e-cigarettes to youth, which is an indication both of the demand for e-cigarettes and a need to educate the public about the risks associated with these products. We hope that you act favorably on this legislation and I encourage you to contact me if you have any questions.

Sincerely,

Barbara Ferrer

Barbara Ferrer, PhD, MPH, MEd Executive Director

⁷ Albers AB, Siegel M, Cheng DM, Biener L, Rigotti NA. Relation between local restaurant smoking regulations and attitudes towards the prevalence and social acceptability of smoking: a study of youths and adults who eat out predominantly at restaurants in their town. *Tobacco Control* 2004a;13(4):347–55.



Highly accessed fresh look at tobacco harm reduction: the case for the electronic cigarette	Open Acces	
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scale smoking cessation. Surveys document that most smokers would like to quit, and many have made repeated efforts to do so. However, conventional smoking cessation approaches require nicotine addicted smokers to abstain from tobacco and nicotine entirely. Many smokers are unable – or at least unwilling – to achieve this goal, and so they continue smoking in the face of impending adverse health consequences. In effect, the status quo in smoking cessation presents smokers with just two unpleasant alternatives: quit or suffer the harmful effects of continuing smoking. But, there is a third choice for smokers: tobacco harm reduction. It involves the use of alternative sources of nicotine, including modern smokeless tobacco products like snus and the electronic cigarette (E-cig), or even pharmaceutical nicotine products, as a replacement for smoking. E-cigs might be the most promising product for tobacco harm reduction to date, because, besides delivering nicotine vapour without the combustion products that are responsible for nearly all of smoking's damaging effect, they also replace some of the rituals associated with smoking behaviour. Thus it is likely that smokers who switch to E-cigs will achieve large health gains. The focus of this article is on the health effects of using an E-cig, with consideration given to the acceptability, safety and effectiveness of this product as a long-term substitute for smoking.

Keywords: Tobacco; Harm reduction; Snus; Electronic cigarettes

Introduction

Tobacco smoking is a global pandemic, affecting an estimated 1.2 billion people, that poses substantial health burdens and costs. With nearly six million deaths annually, smoking is the single most important cause of avoidable premature mortality in the world [1], mainly from lung cancer, coronary heart disease, chronic obstructive pulmonary disease and stroke [2,3]. As also underscored by the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC), the key to reducing the health burden of tobacco in the medium term is to encourage cessation among smokers [4].

Unfortunately, smoking is a very difficult addiction to break, even for those with a strong desire to quit. It has been shown that approximately 80% of smokers who attempt to quit on their own relapse within the first month of abstinence, and only about 5% achieve long term abstinence [5]. Moreover, currently available smoking cessation medications such as nicotine replacement therapy, the antidepressant bupropion and the partial agonist of the a4β2 nicotinic acetylcholine receptor, varenicline, at best double or triple this quit rate under the ideal circumstances of an experimental setting but have had low uptake and inferior efficacy in the community [6-8]. Furthermore, varenicline and bupropion have come under increasing scrutiny due to reports of serious adverse events that include behaviour change, depression, self-injurious thoughts, and suicidal behaviour [9]. The Tobacco Advisory Group of the Royal College of Physicians acknowledges that the development of addiction includes modifications in behaviour together with changes in brain structure and function that impair the ability to achieve and sustain abstinence. They note that some of these changes may not be entirely reversible [10]. Lastly, even tobacco control policies - particularly when not integrated and well supported by adequate funding - are not very effective [11].

Consequently, many smokers will keep smoking because, when given only the options of smoking or completely giving up nicotine, many will not give it up. Bearing in mind that nicotine *per se* does not cause much risk when separated from inhaling smoke, it is important to consider that a third option is also available to smokers; the reduction of smoking-related diseases by taking nicotine in a low-risk form. Tobacco harm reduction (THR), the substitution of low-risk nicotine products for cigarette smoking, is likely to offer huge public health benefits by fundamentally changing the forecast of a billion cigarette-caused deaths this century [12].

Value of harm reduction as a tobacco control strategy

The history of THR may be traced back to 1974, with the publication of a special article in the Lancet by British tobacco addiction research expert Michael A.H.

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Russell [13]. There are many and varied approaches to THR. Broadly, these can be categorised into two groups: (I) non-tobacco interventions aimed at decreasing tobacco consumption, and (II) alternative tobacco products. THR empowers smokers to gain control over the consequences of their nicotine addiction and at its simplest it is non intrusive and solely educational, therefore having a strong ethical rationale [14]. The strategy is cost-effective and accessible today to almost all smokers. Harm reduction is particularly compelling for nicotine because so many people have such a strong propensity for using it.

Most scientists and commentators agree that complete tobacco cessation is the best outcome for smokers, and any efforts to make available safer products need to be part of a comprehensive tobacco control strategy aimed at minimising tobacco use through cessation and prevention [15]. Opponents of THR often claim that providing safer alternatives sidetracks smokers from quitting completely. However, refusing to provide truthful information about and access to safer alternative sources of nicotine dissuades smokers from quitting the most harmful method of obtaining nicotine - inhaling smoke.

Quit rates may be improved by advancing physicians' understanding of predictors of success in smoking cessation [16], and some have purported that it may be better to focus efforts on developing and improving pharmacologic therapies than to promote safer alternatives such as smokeless tobacco [17,18]. Currently, however, there is a growing trend in physicians' indifference or scepticism towards the efficacy of smoking cessation programs [19]. Moreover, the use of ' pharmaceutical cessation aids [20] and behavioural support [21] have led to limited success in cessation, and it has been argued that the majority of current smokers will continue to smoke without acceptable safer alternatives [22]. Therefore, the case for an effective THR strategy is legitimate.

Avoiding confusion about true health consequences of nicotine use

When considering harm reduction as a tobacco control strategy it is important to separate the risk associated with inhaling smoke from that of taking nicotine. As Russell noted 30 years ago, "There is little doubt that if it were not for the nicotine...people would be little more inclined to smoke than they are to blow bubbles or light sparklers" [13], "The rapid absorption of nicotine from snuff confirms its potential as an acceptable and relatively harmless substitute for smoking".... "Switching from cigarettes to snuff would substantially reduce the risk of lung cancer, bronchitis, emphysema, and possibly coronary heart disease as well, at the cost of a slight increase in the risk of cancer of the nasopharynx (or oral cavity in the case of wet snuff)" [23]. Nicotine fulfils all the criteria of an addictive agent (including psychoactive effects, drug-reinforced behaviour, compulsive use, relapse after abstinence, physical dependence, and tolerance) by stimulating specialized receptors in the brain which produce both euphoric and sedative effects [24]. Individuals who have emotional dysfunctions or attention deficits are more likely to start smoking and less likely to quit. Nicotine has beneficial effects on attention, concentration, and mood in many smokers; these individuals may be depending on nicotine as a means of self-medication [25].

Are there important associated adverse health consequences of nicotine intake? The landmark work, Nicotine Safety and Toxicity, edited by Neal Benowitz, considered the potentially harmful effects of nicotine as well as its benefits [26]. After reviewing the evidence, the authors concluded that nicotine presents little if any cardiovascular risk, and that nicotine has not been shown to be carcinogenic. It is has been reported that nicotine may be potentially harmful during pregnancy, but probably less harmful than continued smoking [27-29]. There are data suggesting that nicotine may be beneficial in treating ulcerative colitis [30] and Tourette syndrome [31]. Other conditions for which nicotine is being considered as treatment include memory impairment, attention deficit disorder, depression, and Parkinson's disease [32]. Regarding long-term use, even though nicotine is a potential toxin, it appears to be well-tolerated during weeks and months of nicotine medication therapy without evidence of serious adverse health effects [10]. Using the multi-criteria decision analysis method previously used by the Independent Scientific Committee on Drugs (ISCD) to rank the harms of drugs used in the UK, a working group of international nicotine experts convened by the ISCD considered the potential harms of a wide range of nicotine containing products based on sixteen parameters of harm to individuals and harm to others. Not only conventional cigarettes were judged to be by far the most harmful form of nicotine containing product, but e-cigarettes were ranked as similar in harm to nicotine patches [33]. By and large, nicotine *per se* does not cause much risk when separated from inhaling smoke.

Current tobacco harm reduction products

Pharmaceutical nicotine products have been used as potential long-term cigarette substitutes. It has been reported that about 20 percent of smokers who quit with nicotine gum used it for more than one year, even though it was available only by prescription [34]. None of the currently available products deliver nicotine to the brain at a dose and rate similar to smoking. But this inadequacy is due to a philosophical aversion to nicotine addiction, not to technical inefficacy; a 1995 study found that high-dose transdermal nicotine was safe and effective for heavy smokers [35,36]. To be realistic alternatives, contemporary nicotine products need to be as readily available as cigarettes, competitively priced, socially acceptable and approved for regular long-term recreational use rather than as short-term cessation aids [22]. But these products would also be addictive.

A convincing example of a successful THR strategy is that of Swedish snus. Snus is a type of finely ground moist snuff that delivers significant levels of nicotine (Figure 1). Snus does not produce any of the toxic combustion products and it is manufactured in a way that produces low levels of carcinogenic tobacco-specific nitrosamines (TSNAs) [37,38]. In Sweden, where snus has progressively replaced cigarette smoking over the past 20 years [35], substantial reductions in smoking prevalence have been reported [39]. Although Sweden's tobacco control policies have undoubtedly contributed to this decline, the popularity of snus has played a major role. The much steeper decline in smoking prevalence observed among males than females is likely to be due to greater snus use in males [40]. Snus prevalence in Swedish males rose from 10% in 1976 to 23% in 2002 [41]. From the period 1990–1995 to the period 2002–2007, smoking prevalence decreased from 26 to 10% among men [42]Interestingly, the Swedish population prevalence of tobacco use has remained relatively steady at around 40%, but with 58% of daily tobacco users now taking snus instead of smoking cigarettes [43]. As a result of this, tobacco-related mortality in Sweden is among the lowest in the Western world [44]. Studies provide quantitative evidence that health risks of using snus is lower than smoking for lung, oral, and gastric cancers, for cardiovascular disease, and for all-cause mortality [45].



Figure 1. Snus smoke-free tobacco. Snus is an oral tobacco product that comes in a pouch of some sort, designed to be placed between the gums and upper lip. Snus is not chewed and requires no spitting. The standard pouch holds 1 gram of finely ground tobacco. Snus is regulated as a food in Sweden, and thus held to strict quality standards. Swedish snus was developed to greatly reduce TSNA content, and research shows that snus does not increase the risks of cancer of any type.

The Swedish experience has been replicated in Norway, which shares a border with Sweden and is culturally similar [46]. The 2005 California Tobacco Survey shows that smokers in that state are not receptive to using oral smokeless tobacco as a substitute for cigarette smoking [47]. One possible explanation for this phenomenon is that U.S. smoker's perceptions of smokeless products are incorrect; indeed they are sceptical of the idea that snus is safer than cigarettes [48]. Misleading information disseminated by government agencies and non-profit health organizations has made American consumers [49,50] and health professionals [51] believe that smokeless tobacco is as harmful as, if not even more harmful than, smoking. Providing complete and truthful information could make U.S. smokers more receptive to switching to this much less harmful alternative.

The issue of abuse liability has been recently used by opponents of THR to warn about potential risks of smokeless tobacco products. Hatsukami et al. [52] concluded that smokeless tobacco appears to have slightly lower abuse liability, with possibly lower severity of addiction or dependence compared with smoking and greater ease of cessation. They also concluded that it may be possible that switching from cigarettes to smokeless tobacco would increase the potential for cessation from all tobacco products. Fagerström and Eissenberg came to similar conclusions in a recent comparison of dependence among smokers, smokeless tobacco users

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and users of medicinal nicotine [53]. Many former smokers in Sweden have quit through using snus, suggesting it may be a more effective cessation aid, and a more attractive long-term alternative to cigarettes, than pharmaceutical nicotine because its nicotine delivery and social aspects are similar to those of smoking [38,39,54]. Three small clinical trials support the role of smokeless tobacco as a cessation option for smokers. After reporting reduced TSNA exposure among smokers given an American snus product or Ariva (a dissolvable pellet), Mendoza-Baumgart et al. [55] concluded that this low-nitrosamine smokeless tobacco product has strong potential as a harm reduction tool. In 2010 Caldwell et al. [56] tested the acceptability of Swedish snus, nicotine gum and Zonnic (a pouch containing 4 milligrams of nicotine embedded in microcrystalline beads) among naive smokers in New Zealand. They reported that all three products significantly reduced craving for cigarettes, and all three enabled subjects to reduce their smoking significantly, with Zonnic and snus ranked higher than nicotine gum for both quitting and reducing smoking. Hence, it is not surprising that dissolvable tobacco products led to a significant reduction (approx. 40%) in cigarettes per day, no significant increases in total tobacco use, and significant increases in two measures of readiness to quit in a recent pilot randomized study [57].

The issue of abuse liability has been also used by anti THR supporters to warn about potential risks of e-cigarettes. However, in a recent randomized controlled trial of 300 smokers [58], only 26.9% of those who switched to e-cigs resulting in complete smoking abstinence were still using the product by the end of the observational period (week-52) with the 73.1% of users stopping vaping as well. That many regular vapers were able to free themselves also from the behavioral component of smoking that was being reproduced by vaping the product under investigation, indicates that the e-cigarettes are not very "addictive".

Emerging tobacco harm reduction products: electronic cigarettes

Use of electronic cigarettes (E-cigs) may prove to be an even more attractive long-term alternative because of their similarities to smoking, including the hand-tomouth repetitive motion and the visual cue of a smoke-like vapour.

According to the WHO Study Group on Tobacco Product Regulation, E-cigs are categorized as electronic nicotine delivery systems (ENDS), devices designed for the purpose of nicotine delivery to the respiratory system where tobacco is not necessary for their operation [59]. Awareness and use of E-cigs has increased exponentially in the past four years. These devices, which are manufactured and sold by several different companies, consist of a lithium battery, electronic components, an atomizer, and a cartridge that holds a liquid solution composed of water, propylene glycol, flavourings, and nicotine (Figure 2). Their popularity appears to be related to the close similarities to smoking, the fact that they can be used in smoke-free places, the competitive price, and the perceived potential for harm reduction [60].



Figure 2. Structure of a standard entry model electronic-cigarette (e-Cigarette). The e-Cigarette is a battery-powered electronic nicotine delivery device (ENDD) resembling a cigarette designed for the purpose of providing inhaled doses of nicotine by way of a vaporized solution. The product provides a flavor and physical sensation similar to that of inhaled tobacco smoke, while no smoke or combustion is actually involved in its operation. It is composed of the following key components: (1) the inhaler - also known as 'cartridge' (a disposable plastic mouthpiece - resembling a tobacco cigarette's filter containing an absorbent material saturated with a liquid solution of propylene glycol and vegetable glycerin in which it may be dissolved nicotine); (2) the atomizing device (the heating element that vaporizes the liquid in the mouthpiece and generates the mist with each puff); (3) the battery component (the body of the device - resembling a tobacco cigarette - which houses a lithium-ion rechargeable battery to power the atomizer). The body of the device also houses an electronic airflow sensor to automatically activate the heating element upon inhalation and to light up a red LED indicator to signal activation of the device with each puff. The LED indicator also signals low battery charge.

Cigarette smokers will keep smoking because of their addiction and when given the options of smoking or completely giving up nicotine, many will not give it up. This rigid dichotomous scheme may be now considered legacy of the past as many of them would be better off using nicotine in a low-risk form. E-cigs may be an additional tool for reducing tobacco related harm when used to target smokers for whom current cessation programmes have had only limited success [61]. E-cigs also may be attractive to inveterate smokers who consider their tobacco use a recreational habit that they wish to maintain in a more benign form, rather than a problem to be medically treated [62].

Toxicological characterization of e-cigarettes

The available evidence indicates that e-cigarettes do not raise serious health concerns and can be considered a much safer alternative to conventional smoking [63-<u>66</u>].

Detailed toxicology characterization of e-cigarette liquid and vapour using gas chromatography mass spectrometry (GC-MS) demonstrates that their primary components are water, propylene glycol (PG), glycerin, and nicotine [67]. In an independent study, Laugesen tested E-cig mist for over 50 priority-listed cigarette smoke toxicants and found none [64]. This report only revealed traces (8.2 ng/g) of TSNAs in the "high" nicotine cartridge of a Ruyan brand E-cig. However, it must be noted that this amount is equal to the quantity reported to be present in a nicotine medicinal patch [61] (Table 1).

Table 1. Summary data of maximum tabacco-specific nitrosamine levels in various cigarettes and nicotine-delivery products includine electronic cigarettes (ng/g, except for nicotine gum and patch that are ng/gum piece and ng/patch) - Modified by Khan Z et al. J Public Health Policy 2011

FDA-commissioned testing of e-cigarette cartridge fluids found diethylene glycol in one of the 18 e-cigarette cartridges tested [68]. Formaldehyde, acetaldehyde, and acroleine (potentially toxic carbonyl compounds) have been detected in e-cigarette vapour in 12 brands of e-cigarettes but at levels substantially lower than in cigarette smoke. These compounds may be formed by the oxidation of propylene glycol or glycerol when in contact with the heating coil.

Cahn and Siegel [61] reviewed the results of 16 laboratory analyses of E-cig liquid, including the FDA's Report noted above . TSNAs were reported in two studies, but at trace levels, which are similar to those found in a nicotine patch, and, most importantly, about 500-fold to 1400-fold lower than TSNA levels measured in regular cigarettes (E-cigs containing only 0.07-0.2% of the TSNAs present in cigarettes) (Table 1).

It must be however noted that the e-cigarette industry is now adopting improved manufacturing standards. According to American e-liquid Manufacturing Standards Association (AESMA), liquids produced before 2013 were largely inaccurate, whereas newest products have substantially improved in term of purity, consistency and accuracy of nicotine content.

For example, [69] in a recent analysis of 20 refill liquids of 10 of the most popular brands have shown that the nicotine content in the bottles corresponded closely to the labels on the bottles with levels of nicotine degradation products being 1-2% for most samples. Also, this analysis did not detect ethylene glycol nor diethylene glycol; for several brands the levels of impurities were above the level set for nicotine products in the European Pharmacopoeia, but below the level likely to cause harm.

E-cigarette vapour contains a number of potentially toxic compounds. Testing on some devices has found tobacco-specific nitrosamines (TSNAs) [70]) and polycyclic aromatic hydrocarbons present in cartridge fluid, but generally in very low levels, similar to those in nicotine replacement therapy [64,68,71].

Cadmium, lead and nickel have also been detected in vapour but in trace levels only, comparable with levels found in Nicorette inhaler [72]. Metal and silicate

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particles were detected in fluid and vapour from e-cigarette cartomisers obtained from one manufacturer over several years, leading to exposure to amounts of these particles equal to or higher than users of tobacco cigarettes might typically experience [73].

In essence, these products appear to be much safer than tobacco cigarettes and comparable in toxicity to conventional nicotine replacement products. Of note, retailers have already sold hundreds of thousands of E-cigs with no evidence that these products have endangered anyone when used as directed. Although there is no indication that E-cigs are any more an immediate threat to public health and safety than traditional cigarettes, which are readily available to the public, the current data is insufficient to conclude that E-cigs are safe in absolute terms, and further studies are needed to comprehensively assess their safety, particularly in the long term.

E-cigarette studies

The E-cig is a very hot topic that has generated considerable global debate, with authorities wanting to ban it or at least regulate it. Consequently, a formal demonstration supporting the efficacy and safety of these devices in clinical trials would be of utmost importance.

One of the earliest clinical trials of electronic cigarettes was conducted at the University of Auckland, New Zealand. Forty adult smokers of 10 or more cigarettes per day were randomized to use an E-cig containing 16 mg of nicotine or 0 mg of nicotine (placebo), a Nicorette nicotine inhalator, or their own brand cigarette. The 16 mg E-cig alleviated desire to smoke after overnight abstinence, was well tolerated and exhibited a pharmacokinetic profile more like the Nicorette inhalator than a tobacco cigarette [74]. In a small preliminary study of 16 smokers comparing two brands of E-cigs to the participants' own brand, Elssenberg reported that 10 puffs from either brand delivered little to no nicotine compared with 10 puffs from the regular brand [75]. A response to this letter pointed out that each puff from an electronic cigarette delivers approximately 10% of the nicotine found in a puff of cigarette smoke [76]. Therefore E-cigs users need to take more puffs than smokers to raise blood nicotine levels. Final results of Eissenberg's study for 32 participants confirmed that no measurable levels of nicotine or carbon monoxide were detected in E-cigs users. However, both brands effectively suppressed nicotine abstinence symptoms [72]. Recently Vansickel and Eissenberg studied blood nicotine levels and among subjects who used E-cigs according to a standard protocol after 12 hours of abstinence [78]. All subjects were former smokers who had quit smoking 11 months earlier and were veteran vapers. Blood nicotine levels increased from 2 nanograms per milliliter (ng/ml) at baseline to 10 ng/ml within 5 minutes of the first puff, and to 16 ng/ml at the end of the ad lib period of use. These levels are very similar to those produced by cigarette smoking, suggesting with an elarning curve effect has to be taken into account when discussing clinical studies with E-cigs. Canadian researchers examined the reinforcing effects of E-cigs with and without nicotine on 11 volunteers. Participants reported a reduction in craving,

Japanese researchers conducted a safety assessment of E-cigs with 32 smokers and found that following the treatment, no abnormal changes in blood pressure, hematological data, or blood chemistry and no severe adverse events were observed [62]. In a prospective proof-of-concept study, we monitored for 6 months possible modifications in smoking habits of 40 smokers not willing to quit who experimented with a 7.4 mg nicotine/cartridge E-cig [60]. Combined sustained smoking reduction and smoking abstinence was shown in 22/40 (55%) participants, with an overall 88% fall in cigs/day. Mouth and throat irritation, and dry cough were common, but diminished substantially by the end of the study. Participants' perception and acceptance of the product was good.

That these results could be maintained for at least 24 months by adopting newer more efficient models as improved smoking sensation aids [81] indicates that these products have potential for efficient long-term substitution for smoking.

In a recent prospective 12-month randomized control design study (ECLAT study) we have just collected the data of E-cigs with 7.2 mg, 5.4 mg and 0 mg nicotine cartridges to measure smoking reduction or abstinence in 300 smokers unwilling to quit Declines in cig/day use and eCO levels were observed at each study visits in all three study groups (p,0.001 vs baseline), with no consistent differences among study groups. Smoking reduction was documented in 22.3% and 10.3% at week-12 and week-52 respectively. Complete abstinence from tobacco smoking was documented in 10.7% and 8.7% at week-12 and week-52 respectively. A substantial decrease in adverse events from baseline was observed and withdrawal symptoms were infrequently reported during the study [58].

In another recent randomized controlled trial, Bullen and coll. [82,83] randomised 657 adult smokers wanting to quit to 16 mg nicotine e-cigarettes (as needed), 21 mg nicotine patches (one per day), or placebo e-cigarettes (no nicotine, as needed) in a 4:4:1 ratio. Participants, who all lived in Auckland, New Zealand, could access the national Quitline (a telephone counselling service), but received no additional support. At 6 months, 7.3% participants in the nicotine e-cigarettes group had achieved biochemically verified abstinence, compared with 5.8% participants in the patches group, and 4.1% in the placebo e-cigarettes group. However, the statistical power was insufficient to conclude superiority of nicotine e-cigarettes to patches or to placebo e-cigarettes. As for other clinical studies with e-cigarettes, adverse events were very mild.

Several surveys [84-86] paint a picture of the typical e-cig consumer as a long-term smoker who tried repeatedly to quit. The median age of respondents ranges from late 30s to mid 40s. The percentage of respondents using e-cigs as a complete replacement for smoking ranged from 31% to 79%. Etter and Bullen found that 77% of daily users were former smokers, and 19% who were still daily smokers reduced their cigarettes per day from 25 to 15. The most-used flavour was tobacco, but 61% preferred various fruit flavours, coffee, vanilla, and chocolate [86]. Over 90% of respondents reported that their health has improved. When asked the main reason why they chose to use an e-cig, 64.6% selected "to continue to have a 'smoking' experience, but with reduced health risks." [85].

Discussion

E-cigs might be the most promising product for tobacco harm reduction to date. E-cigs deliver a nicotine vapour without the combustion products that are responsible for nearly all of smoking's damaging effects (Figure 3). Temperatures of approximately 1.000 °C are generated with each puff of a lit cigarette, and thousands of toxic chemicals are produced during the combustion process [87]. In contrast, E-cigs use vaporization, rather than combustion, and the low operating temperature of the atomizer (up to 160 °C, depending on the model) does not emit cigarette toxicants [64]. Therefore, the health risks are likely to be similar to those from smokeless tobacco, which has approximately 1% of the mortality risk of smoking [49]. E-cigs may contain nicotine, which contributes to nicotine addiction and helps sustain tobacco use. However, if sufficient numbers of smokers can transfer their nicotine dependence to a less-harmful delivery method, millions of lives could be saved. The positive aspects of E-cigs appear to outweigh the negative aspects (Table 2).



Figure 3. Medical Infograph. This Infograph compares the potential health risks of cigarette smoke with the health risks of vapor. Since e-cigarette liquid contains only propylene glycol, vegetable glycerin, flavorings, and nicotine, the resulting vapor is unlikely to present any more disease risk than medicinal nicotine products -- the risk of nicotine addiction. The many more toxic and carcinogenic ingredients in tobacco smoke are linked to numerous health problems.

Table 2. Positive and negative aspects of e-cigarettes

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Nonetheless, websites that provide information about the health risks of smokeless tobacco, have conflated these risks with the risks of smoking, misleading the public and smokers into believing that there is no potential for harm reduction by switching from smoked to smokeless products [49]. Yet, evidence continues to emerge that snus is an effective harm-reduction strategy [38]. Similar deceptive advice is being given to smokers who might be thinking about switching to E-cigs [39]. Foulds et al. [90] found that 78% of E-cig users they interviewed had not used any tobacco in the prior 30 days, but they still advised smokers to use proven treatments (e.g. counselling and FDA-approved drugs). This is a bizarre advice, in view of the fact that the subjects they interviewed had tried to quit smoking an average of nine times before taking up use of an E-cig, and two-thirds had tried to quit with an FDA-approved smoking cessation medication [90].

With the excuse of safeguarding public health and guiding regulatory strategies, extensive research on product design, toxicant exposure, abuse liability, youth initiation, and influence on cessation efforts has been advocated [91]. Thus it appears that the same tactics that are being used to keep less hazardous products such as snus from being widely adopted by smokers are being used to combat switching to E-cigs. None of the toxicological testing conducted in E-cigs has shown that users or bystanders are exposed to harmful levels of toxins or carcinogens. Any danger of toxicant contamination can be averted by forcing manufacturers to adopt a similar regulatory framework as for dietary supplements, provided that no claims are made about prevention or treatment of disease [92]. Under dietary supplement regulation, manufacturers must show that a product is not dangerous before introduction. Compliance with national good manufacturing practice policies would ensure that e-liquids are produced in a quality manner, do not contain contaminants or impurities, are accurately labelled, and are held under conditions to prevent adulteration. With regard to marketing and safety of e-cigarettes' electronics, batteries, and spare parts, these components are already regulated by existing directives.

There is no evidence that large numbers of non-smokers are purchasing or will purchase E-cigs and become addicted to nicotine. E-cigs eliminate exposure to the smoke toxicants responsible for nearly all smoking-related diseases. Thus even if 50% of the non-smoking population should decide to addict itself to nicotine via an E-cig, the associated disease risks, if any, would be minimal. Thus, "abuse liability" is a moot point in this context.

Furthermore, E-cigs represent a middle ground between nicotine maintenance using the most deadly of delivery mechanism, smoking, and the nicotine abstinence demanded by the tobacco control community [93]. Fears that smokers who "might have quit altogether" will instead switch to snus or E-cigs is further evidence that the tobacco control community believes that total abstinence is something that all smokers will eventually embrace, and perhaps come to love. However, research shows that many smokers are dependent on the beneficial effects of nicotine to combat symptoms of underlying conditions [10] and that long-term nicotine abstinence may result in long-term discomfort for many smokers [94].

Summary

The dream of a tobacco-free, nicotine-free world is just that—a dream. Nicotine's beneficial effects include correcting problems with concentration, attention and memory, as well as improving symptoms of mood impairments. Keeping such disabilities at bay right now can be much stronger motivation to continue using nicotine than any threats of diseases that may strike years and years in the future.

Nicotine's beneficial effects can be controlled, and the detrimental effects of the smoky delivery system can be attenuated, by providing the drug via less hazardous delivery systems. Although more research is needed, e-cigs appear to be effective cigarette substitutes for inveterate smokers, and the health improvements enjoyed by switchers do not differ from those enjoyed by tobacco/nicotine abstainers.

It is of paramount importance that government and trusted health authorities provide accurate and truthful information about the relative risks of smoking and alternatives to smoking. If the public continues to be misled about the risks of THR products, millions of smokers will be dissuaded from switching to these much less hazardous alternatives. One of us recently wrote that, "It's time to be honest with the 50 million Americans, and hundreds of millions around the world, who use tobacco. The benefits they get from tobacco are very real. It's time to abandon the myth that tobacco is devoid of benefits, and to focus on how we can help smokers continue to derive those benefits with a safer delivery system" [95].

In the absence of regulatory standards, it is important that currently marketed products are of high quality. For example, the hardware should be reliable and should produce vapour consistently. The liquids should be manufactured under sanitary conditions and use pharmaceutical grade ingredients, and labels should contain a list of all ingredients and an accurate and standardized description of the nicotine content.

According to a recent article by CDC researchers, the proportion of U.S. adults who have ever used electronic cigarettes more than quadrupled from 0.6% in 2009 to 2.7% in 2010 with an estimated number of current electronic cigarette users of about 2.5 million [96]. Although rigorous studies are required to establish THR potential and long term safety of electronic cigarettes, these figures clearly suggest that smokers are finding these products helpful. If they were ineffective one would not expect the market to take off as it is. Most importantly, even if this THR product proves to be effective for only 25% of the smoking population, it could save millions of lives world-wide over the next ten years.

Competing interests

R.P. is Professor of Medicine and he is supported by the University of Catania, Italy. He has received lecture fees and research funding from GlaxoSmithKline and Pfizer, manufacturers of stop smoking mediactions. He has also served as a consultant for Pfizer and Arbi Group Srl (Milano, Italy), the distributor of CategoriaTM e-Cigarettes. R.P.'s research on electronic cigarettes is currently supported by LIAF (Lega Italiana AntiFumo). B.R.'s research is supported by unrestricted grants from tobacco manufacturers to the University of Louisville, and by the Kentucky Research Challenge Trust Fund. P.C. and C.R. are Assistant Professors and they are supported by the University of Catania, Italy. M.M is researcher and she is supported by the University of Catania, Italy. They have no relevant conflict of interest to declare in relation to this work.

Authors' contributions

All authors revised the article critically for important intellectual content and approved its final version.

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Testimony of American Cancer Society Cancer Action Network to the New York City Council, Committee on Health December 4, 2013 • New York, NY

Re: Statement in support of Preconsidered Int. No. _____ (Gennaro, Quinn, Arroyo) to amend the administrative code in relation to the regulation of electronic cigarettes.

Chair Arroyo, members of the health committee, thank you for the opportunity to testify today. My name is Michael Davoli and I represent the American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan, advocacy affiliate of the American Cancer Society. We are pleased to be able to speak in support of legislation that will help preserve the integrity of New York City's landmark Smoke Free Air Act by prohibiting the use of electronic cigarettes where smoking is otherwise prohibited.

New York City has been a national leader in its commitment to protecting youth and adults from the deadly impact of tobacco use. In fact, we just celebrated the 10 year anniversary of the passage of the Smoke Free Air Act, a bold act of leadership which had tremendous positive effects on the health of New Yorkers and an impact around the globe by influencing other locales to go smoke-free. Further, New York City has passed numerous laws to protect the public from the hazards of secondhand smoke (*Smoke Free Parks and Beaches, and Smoke-Free Hospital Grounds*) and to change social norms around smoking. Allowing the use of electronic cigarettes or e-cigarettes in public spaces undermines these effective Smoke Free laws and creates confusion for business owners, among the public and in enforcement efforts.

Over the last several years, there has been a dramatic growth in the marketing and sale of ecigarettes and in the claims being made by e-cigarette manufacturers, as well as a proliferation in the various types of e-cigarettes being sold. Despite the dramatic rise in the use of ecigarettes, very little is known about their actual health risks or their impact on youth tobacco use or whether they are effective in helping smokers quit. No federal agency currently regulates how e-cigarettes are made or how and to whom they are marketed and sold. ACS CAN supports New York City applying its laws governing cigarettes and other tobacco products to e-cigarettes. We applaud the Council's leadership in proposing the regulation of electronic cigarettes in the same manner as traditional cigarette smoking under the Smoke Free Air Act.

Electronic Cigarettes should not be exempt from the Smoke Free Air Act.

Because electronic cigarette use simulates the behavior of smoking, use of these products complicates enforcement of the Smoke Free Air Law, and weakens its effectiveness. Denormalizing smoking, in addition to reducing exposure to secondhand smoke, is a key rationale for secondhand smoke laws in public places.¹ Product advertisements show e-cigarettes being used in areas where smoking is prohibited—touted for their ability to be "smoked anywhere". The use of e-cigarettes in this manner undermines the city's successful efforts to create a smoke-free environment, modeling healthy behavior, especially for children. Not only does this behavior deteriorate the social norms that the city has worked hard to institute, but it can be a trigger to smoke for smokers who are trying to quit. Use of an e-cigarette in public places normalizes the action of smoking.

Additionally, the use of these products, which often resemble traditional cigarettes, and produce a visible cloud when exhaled, are causing confusion for the public and enforcement officials alike. Business operators, striving to follow existing law shouldn't have to become experts at differentiating between cigarettes and e-cigarettes. If it looks like someone is smoking in a public space where it is prohibited, it should be treated as such. This confusion around enforcement has already led some businesses to voluntarily declare that use of electronic cigarettes is prohibited in their establishments. Furthermore, 3 states and more than 100 localities have enacted provisions to their smoke free laws, similar to this proposal, to deal with this growing problem².

Growing evidence shows electronic cigarettes are a growing problem among youth.

The use of e-cigarettes is increasing, including among youth. A recent Centers for Disease Control and Prevention (CDC) report (*National Youth Tobacco Survey, reported in Sept 5, 2013 Morbidity and Mortality Weekly Report*) shows that in the United States from 2011 to 2012 just one year—the percentage of youth (middle and high school students) using e-cigarettes more than doubled. Furthermore, more than 75% of the youth surveyed who used e-cigarettes also smoked conventional cigarettes. As well, 1 in 5 who used e-cigarettes had never tried traditional cigarettes. This could indicate that e-cigarettes are a gateway to traditional tobacco products.

The e-cigarette industry is using many of the marketing techniques created and perfected by big tobacco companies to addict youth; and to date they remain completely unregulated. From candy and fruit flavors like cotton candy and gummy bears, attractive packaging and designs, to targeted print, television and online advertising, and free giveaways of "starter kits," these products are luring our youth, portraying smoking behavior as glamorous, and taking a page right out of Big Tobacco's marketing manual. In fact, every major tobacco company now offers an electronic cigarette.

¹ U.S. Department of Health and Human Services (HHS), Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General, HHS, U.S. Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012.

² Americans for Non-Smokers Rights. <u>http://www.no-smoke.org/</u>

Since there is no regulation of these products at all, including packaging, we are further concerned that children could ingest toxic, potentially lethal amounts of nicotine (which happened in May, killing a toddler as reported here <u>http://www.timesofisrael.com/police-investigating-toddler-death-from-nicotine-overdose/</u>).

Electronic cigarettes vary widely since they are not yet subject to regulation or standardization. They are readily available for purchase at an ever growing number of stores in the city and the devices used to add nicotine to the product are available in a variety of forms, vials or cartridges, or liquid drops (often called "juice"). Again, these doses are not regulated at all. In fact there are large variations among the products of their strength and dosage. Users do not have any way of knowing how much nicotine they are getting, and there is currently no method for evaluating what is in the various products offered, or whether they are being accurately labeled. An FDA study in July of 2009 found that the amounts of nicotine actually in the products were not the same as what was advertised on the products³. Since e-cigarettes currently have no oversight at all, users have no way of knowing exactly what it is they are inhaling. This poses serious concerns about health and safety.

More research and regulation is needed on electronic cigarettes.

There simply isn't enough high-quality, objective scientific evidence yet to know whether ecigarettes are safe or effective. And there is currently no scientific evidence to back up the electronic cigarette industry's claims that their products are safe. The FDA conducted a limited study in July of 2009 and found that several e-cigarette products and numerous cartridges contained carcinogens and toxic chemicals, including the ingredients found in anti-freeze.⁴ More research on e-cigarettes is needed to determine what ingredients they contain, how they are being used, and what effect they have on users. ACS CAN has concerns about the potential public health effects of e-cigarettes and significant additional research is needed on these products and how they are used.

ACS CAN supports the inclusion of electronic cigarettes in the NYC Smoke Free Air Act. These amendments won't prohibit e-cigarettes, but simply regulate them like other tobacco products. People of appropriate age will continue to be free to use them, just not in places where smoking is prohibited.

Effective regulation is absolutely essential to guard against these risks and prevent e-cigarettes from creating a new generation of youth tobacco users, increasing the overall number of people addicted to nicotine, convincing current tobacco users not to quit or re-glamorizing the act of smoking. The New York City Council can ensure that history does not repeat itself with a new generation of products, by passing this intro and maintaining the integrity of its landmark Smoke Free Air Act.

³ U.S. Food and Drug Administration. Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA. July 22, 2009. Available online at

http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm.

⁴ Eissenberg, T, "Electronic nicotine delivery devices: ineffective nicotine delivery and craving suppression after acute administration," *Tobacco Control* 19:87-88, 2010

From the desk of ...

Rachel Sica 592 Vanderbilt Avenue, Apt 3L Brooklyn, NY 11238

December 4, 2013

Testimony in Support of the proposal to regulate electronic cigarettes

Submitted to: New York City Council, Committee on Health, Maria del Carmen Arroyo, Chair

To the members of the Council Committee on Health:

Thank you for this opportunity to share my thoughts about the possible regulation of electronic cigarettes in New York City. As a recent graduate of Sarah Lawrence College with a Master's degree in Health Advocacy, and a Brooklyn resident, the use of e-cigarettes in our city is a serious concern for me, and in my opinion is a detriment to our public health efforts.

It is very important to emphasize that there is no independent, peer-reviewed research that confirms the claims of the e-cigarette industry. While they may believe there is a health benefit, the greatest way to reduce your risk for disease is to completely quit your addiction through scientifically-approved cessation therapies.¹

As these devices are not currently regulated by the Food and Drug Administration, they are able to be manufactured, used and marketed however the industry deems fit. It is shocking, as a public health professional, to see celebrity endorsers featured in advertisements on television and glossy magazine covers. It seems to me that the e-cigarette industry has simply reversed time and utilized the same marketing game plan that tobacco used fifty years ago.

These advertisements, coupled with the fruit and candy flavoring that is available to use in many ecigarette devices, seems to be directly targeting our young people. The recent data analysis achieved by the CDC from the National Youth Tobacco Survey cements these concerns. Of the middle and high school students who reported having used an electronic cigarette, 76% of those students also smoked a traditional cigarette in the same timeline.² E-cigarettes are clearly not helping these young people to quit; rather they are sustaining nicotine addiction and possibly introducing a new generation to tobacco use.

¹ <u>http://no-smoke.org/learnmore.php?id=645</u>

² CDC National Youth Tobacco Survey <u>http://www.cdc.gov/tobacco/data_statistics/surveys/nyts/</u>

E-cigarettes are manufactured to often resemble traditional cigarettes. From the lighted tip to the vapor that is emitted, this similarity can easily cause confusion for any bar or restaurant owner who is rightfully trying to enforce the existing Smoke Free Air Act.

The proposal being considered today would simply create a level playing field among the legal addictive products, whether they possess tobacco or just nicotine. Many of these businesses should already be accustomed to our tobacco control policies as Altria (owner of Philip Morris), Lorillard and Reynolds American are all investing heavily in e-cigarette manufacturing.³ By adding e-cigarettes to the list of products restricted by the New York City Smoke Free Air Act, we can once again prioritize our health over the business of the tobacco industry.

I look forward to your support of this proposed regulation.

³ <u>http://www.mcclatchydc.com/2013/11/26/209666/as-feds-ponder-future-of-e-cigarettes.html</u>



E-cigarette Facts

Studies available at www.VapersClub.com

-<u>E-cigarettes do NOT produce smoke</u>. They steam liquid in the same way a fog machine does. The liquid base is the same base sometimes used in asthma inhalers and the base liquid is considered to be GRAS (Generally Recognized as Safe) by the FDA.

-A number of studies show that vaporization of e-liquid in an electronic cigarette does not emit toxic levels of the hazardous chemicals that are released from the combustion of tobacco. (see attached studies and also additional studies at www.VapersClub.com/science.php)

-A peer-reviewed study concluded that "for all byproducts measured, electronic cigarettes produce very small exposures relative to tobacco cigarettes. The study indicates no apparent risk to human health from e-cigarette emissions based on the compounds analyzed."

- Another peer-reviewed study concluded "Our findings are consistent with the idea that substituting tobacco cigarettes with e-cigarettes may substantially reduce exposure to selected tobacco-specific toxicants. E-cigarettes as a harm reduction strategy among smokers unwilling to quit, warrants further study."

-Asking those who have switched to e-cigarettes for their health to stand in an area where people are permitted to smoke cigarettes violates their right to a smokefree environment.

-Asking vapers to use e-cigarettes outdoors gives the impression that the vapor is toxic. This might make smokers unlikely to want to switch to e-cigarettes, which are much less hazardous than inhaling smoke.

-Many people supporting this bill will state that "we don't know " what is in e-cigarette vapor, but this is simply not true anymore. Data has been provided to them, and to you, that shows what is in e-cigarette vapor.

-Indoor use bans on e-cigarettes have been rejected in most of the states that have proposed them.

-A ban on indoor use of e-cigarettes would be nearly impossible to enforce as they produce no odor and when the inhale is held for more than 4 seconds, no visible vapor is exhaled.

-Making laws based on appearance rather than science sets a bad precedent for future legislation.

Quotes from Public Health Experts

"First, an e-cigarette does not involve the 'inhaling, or exhaling of smoke.' Smoke is defined as 'the gaseous products of burning carbonaceous materials made visible by the presence of small particles of carbon.' To be sure, one definition of smoke is 'fume or vapor often resulting from the action of heat on moisture.' That, however, is not the way the term smoke is commonly understood. Statutes should be construed under their "ordinary and plain meaning.' Water vapor containing traces of particulate matter, such as water evaporating from a tea kettle, is not ordinarily understood to be 'smoke.' An e-cigarette does not function in manner of a traditional cigarette because it functions electrically rather than via combustion of a material such as tobacco. Therefore, the vapor emitted by an e-cigarette would not fall within the definition of 'smoke' or 'smoking' in § 15.2-2820. Second, an e-cigarette is battery powered and is not 'lighted' as that term is commonly understood. No flame is involved in its operation."

- Kenneth T. Cuccinelli, VA Attorney General

http://www.vaag.com/OPINIONS/2010opns/10-029-Peace.pdf

"Smokers smoke because they are addicted to nicotine in cigarettes, but it is the smoke, not the nicotine, which causes a long list of diseases, including lung cancer, heart disease, stroke and emphysema." — New York State Health Commissioner, Richard Daines, M.D.

"Nicotine is the addictive ingredient in cigarettes that keeps smokers hooked, but it's not the ingredient that harms smokers' health," emphasized Ursula Bauer, Ph.D., M.P.H, director of the state's Tobacco Control Program. "With safe nicotine products, smokers can give up the smoke without giving up the nicotine."

- Ursula Bauer, Ph.D., M.P.H, director of the New York State Tobacco Control Program

http://www.health.state.ny.us/press/releases/2008/2008-01-28 commissioner_petitions_fda_to_make_nicotine_therapies_easy_to_buy.htm

"Second hand mist from an e-cigarette is not smoke at all, and does not contain any substance known to cause death, short or long term, in the quantities found. It becomes invisible within a few seconds, and is not detectable by smell.

— Dr. Murray Laugesen, Health New Zealand, foremost expert on electronic cigarettes http://www.healthnz.co.nz/ECigsExhaledSmoke.htm

"All that's happening is you're heating up a liquid to the point of becoming a vapor. So referring to it as smoke doesn't make sense at all. Therefore, considering it subject to a smoking ban doesn't really make sense, either."

— Dr. David Baron, Chief of Staff at UCLA Medical Center, from a video interview http://www.youtube.com/watch?v=pnVsVhystFw&feature=PlayList&p=CE289D5633179547&playnext= 1&playnext_from=PL&index=10 "As one who experiences severe headaches, sneezing, watery eyes and other sinus problems from exposure to very little secondhand tobacco smoke (a key reason I've been an outspoken smokefree indoor policy/law activist since 1986), I'm delighted and relieved to report that I experienced NO adverse reactions during or after my mega exposure to e-cigarette vapor."

- William T. Godshall, Executive Director, Smokefree Pennsylvania, from a report on attending a conference for electronic cigarette consumers

"There is no existing evidence that e-cigarettes pose a risk for nonsmokers. The nicotine exposure from the exhaled vapor produced is likely to be extremely small and there is no reason to think that it poses a danger for nonsmokers. But there is certainly no evidence to suggest that it poses a hazard."

— Dr. Michael Siegel, Professor of Social and Behavioral Sciences, Boston University School of Public Health, who also has 20 years of experience in Tobacco Control (TobaccoAnalysis.blogspot.com)

"The claim that the trivial amount of vapor would be much of a risk seems ridiculously far-fetched."

- Dr. Carl Phillips, TobaccoHarmReduction.org

and the angle

"There is substantial and compelling scientific research documenting that consuming the ingredients in ecigarettes (nicotine, propylene glycol, water and flavors) is vastly safer than burning tobacco and inhaling 3000+ toxic by-products. Claiming that e-cigarettes are dangerous for non-smokers is about as credible as claiming that air travel is dangerous for people who never set foot in an airplane."

— Dr. Brad Rodu, Professor of Medicine at the University of Louisville http://www.ecigarettedirect.co.uk/campaign/scientists-dispel-ASH-junk-science.html

RESEARCH ARTICLE

Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality

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Abstract

Context: Electronic cigarettes (e-cigarettes) have earned considerable attention recently as an alternative to smoking tobacco, but uncertainties about their impact on health and indoor air quality have resulted in proposals for bans on indoor e-cigarette use.

Objective: To assess potential health impacts relating to the use of e-cigarettes, a series of studies were conducted using e-cigarettes and standard tobacco cigarettes.

Methods and materials: Four different high nicotine e-liquids were vaporized in two sets of experiments by generic2piece e-cigarettes to collect emissions and assess indoor air concentrations of common tobacco smoke by products. Tobacco cigarette smoke tests were conducted for comparison.

Results: Comparisons of pollutant concentrations were made between e-cigarette vapor and tobacco smoke samples. Pollutants included VOCs, carbonyls, PAHs, nicotine, TSNAs, and glycols. From these results, risk analyses were conducted based on dilution into a 40 m³ room and standard toxicological data. Non-cancer risk analysis revealed "No Significant Risk" of harm to human health for vapor samples from e-liquids (A-D). In contrast, for tobacco smoke most findings markedly exceeded risk limits indicating a condition of "Significant Risk" of harm to human health. With regard to cancer risk analysis, no vapor sample from e-liquids A-D exceeded the risk limit for either children or adults. The tobacco smoke sample approached the risk limits for adult exposure.

Conclusions: For all byproducts measured, electronic cigarettes produce very small exposures relative to tobacco cigarettes. The study indicates no apparent risk to human health from e-cigarette emissions based on the compounds analyzed.

Keywords: E-cigarette, e-cig, ecigarette, ecig, emissions, vaping, nicotine vaporizer, SHS, secondhand vapor, SHV, eliquid, e-liquid, vapor, TSNA, VOC, PAH, DEG, PG, carbonyl, glycerine, cancer risk, risk estimate, exposure assessment, tobacco smoke, risk assessment, toxicity, indoor air quality, inhalation

Introduction

Introduced in the United States in 2007, electronic cigarettes (e-cigarettes) have quickly become a popular substitute for traditional tobacco cigarettes (Ayers et al., 2011). This substitution appears to be due to health concerns of smokers, increased cost of tobacco cigarettes, and indoor smoking restrictions (Etter & Bullen, 2011). A number of surveys and studies have shown that a substantial number of smokers significantly reduce tobacco use and/or transition completely from

tobacco cigarettes to electronic cigarettes. (Bullen et al., 2010; Etter, 2010; Etter & Bullen, 2011; Foulds et al., 2011; McQueen et al., 2011; Polosa et al., 2011; Siegel et al., 2011). Currently, there are only two states that have a statewide ban on e-cigarette use in places where smoking is prohibited. However, dozens of municipalities and counties have discussed and/or introduced pending legislation that would ban the use of e-cigarettes where smoking is prohibited. Prior studies have examined e-cigarettes and e-liquids using

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Gas Chromatography/Mass Spectrometry (GC/MS) to assess the nature and concentrations of pollutants generated from e-cigarettes with different e-liquids (FDA, 2009; Laugesen et al., 2008; Trehy et al., 2011; Lauterbach et al., 2012). Although studies have provided information on the pollutants that could be generated from the vapors, there are no peer reviewed studies that assessed the impact of these air pollutants on overall indoor air quality and exposures.

Experimental methods

Setup

An e-cigarette comes in either two pieces or three pieces and uses a battery that is activated either manually or pneumatically to heat a metal coil (atomizer) that vaporizes the e-liquid in a cartridge (Figure 1). Three piece e-cigarettes have a cartridge which holds the e-liquid to be vaporized, a heating element called an atomizer and a battery to activate the heating element. In two piece e-cigarettes the atomizer and cartridge are combined and called a cartomizer. Two sets of measurements (phases I and II) were made using standard, pneumatic pressure-activated, two-piece e-cigarettes.

A fully charged and tested battery was used for each sample collected. Twelve new cartomizers were filled to capacity with 1.8mL of e-liquid each from four different-liquid bottles labeled A, B, C and D (three samples from each bottle) using sterile 18 gauge syringes. The four popular e-liquid brands were tobacco flavored and extra high nicotine strength, the highest commonly used level of nicotine (24 mg/mL or 26 mg/mL depending on manufacturer). The same liquid samples were used for both phase I and II. All four liquids and actual tobacco cigarettes (Marlboro Red) were used in both phases. Each brand was studied in triplicate in phase I. In phase II, the e-liquids were repeated three times, but the cigarettes were only duplicated due to some filter cassettes being damaged during shipping. During both phase I and phase II, blank samples were collected using the same setup as for the actual tests without any cigarette or e-cigarette in the smoking machine. These samples were to assess any baseline gaseous species that may be present as a result of off-gassing from the polyethylene bag. No off-gassing from the bag was evident based on the low values obtained from the analyses of the blank samples (Table 1).

Figure 2 shows the experimental setup. Polyethylene glove bags (37" L × 37" W × 25" H; Glas-Col, Terre Haute, IN) were used for collection. Around one hundred and ten liters of commercial zero air were introduced as the dilution air. A Single Cigarette Smoking Machine meeting FTC and ISO requirements as suggested by Lauterbach et al. (2012) (SCSM; CH Technology, Westwood, NJ) was connected to the bag. The e-cigarettes and tobacco cigarettes were connected to the smoking machine to simulate the smoking. Although studies have shown slightly increased levels of some VOCs analyzed in this study in the exhaled breath of nonsmokers (Wallace & Pellizzari, 1995; Gordon et al., 2002), these studies suggest such emissions are likely due to environmental factors such as exposure to gasoline or environmental tobacco smoke (ETS). Schripp et al. (2012) measured VOC levels of exhaled vapor or smoke from an e-cigarette user and cigarette smoker respectively and their results were comparable to our findings. Based on these results, the authors make the assumption that although there may have been lower levels of some compounds assessed in e-cigarette vapor if the vapor had first been inhaled and partially absorbed by the e-cigarette user, it is unlikely there would be significantly higher levels of most of the compounds tested for.

For each e-cigarette trial, 50 puffs of 50 mL per puff (4 s/puff, every 30 s) were used. For the tobacco cigarettes, the puff lasted 2 s with the smoke volume as 35 mL as per the Federal Trade Commission (FTC) protocol (Bradford et al., 1936; Ogg, 1964; International Standards Organization [ISO], 2000). The increased duration of puff for the e-cigarettes was based on direct

Table 1. Phase I and II pollutants sampled for and media for sampling

sampling.		
Pollutant	Filter type/coating	Method of analysis
Nicotine	Na ₂ SO ₄	GC/NPD
TSNAs	Teflon	GC/MS
PAHs	XAD	GC/MS
PG	XAD	GC/MS
DEG	XAD	GC/MS
VOCs	Multisorbent Tubes	HS-GC/MS
Carbonyls	Quartz Filter	HPLC-UV

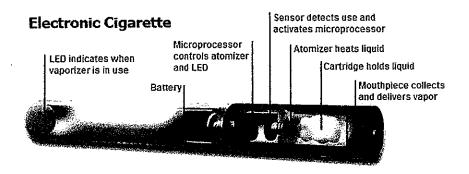


Figure 1. Image of cross section of e-cigarette components.

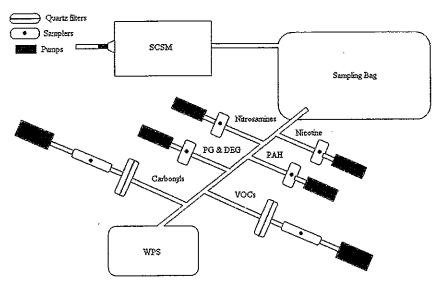


Figure 2. Illustration of the setup for capturing the pollutants after the vapor or smoke was released from the smoking machine. (See colour version of this figure online at www.informahealthcare.com/iht)

observation of e-cigarette use at a gathering for e-cigarette users where puff length average was found to be 4 s. Longer puff duration was also used by Lauterbach et al. (2012). This study was a target compound analysis of tobacco smoke-specific pollutants. Six different types of pollutants were sampled: Nicotine, tobacco specific nitrosamines (TSNAs) (N'-nitrosonornicotine (NNN), N'nitrosoanatabine (NAT), N'nitrosanabasine (NAB), and 4-(methylnitrosamino-1-(3-pyridyl)-1-butanone(NNK)), polyaromatic hydrocarbon's (PAHs), glycols (propylene glycol/PG and diethylene glycol/DEG), volatile organic compounds (VOCs) and carbonyls (i.e. formaldehyde, acrolein, acetaldehyde). The flow rates through these samplers were 265 mL/min, 250 mL/min, 235 mL/min, 250 mL/min, 180 mL/min and 200 mL/min, respectively. For the first four species, filter cassettes were prepared by a certified laboratory according to the protocol described by Hammond et al. (1987). The glycol sampler used an XAD-4 impregnated quartz filter using a procedure similar to that described by Lewtas et al. (2001). A 47 mm quartz filter (Pall, Quartz 47mm, 2 µm pore size, USA) was placed in front of the sampling tube for VOCs and carbonyls to remove particles. The filter was replaced for each trial. Preconditioned thermal desorption tubes (SUPELCO, USA) were used to collect VOC samples. Sorbent tubes (catalog #226-119; SKC, Eighty Four, PA) and the filters in ChemDisk Personal Samplers (Assay Technology, USA) were used for carbonyl collection in the two phases, respectively. The latter impregnated filters were used for phase II as prior to beginning phase II there was a shortage of the sorbent tubes used in phase I. The sorbent tubes and impregnated filters used 2,4-dinitrophenylhydrazine (DNPH) to collect carbonyls for an EPA TO-11 type analysis. Each species had its own sampling pump. A Wide Range Particle Spectrometer (WPS) (Model 1000 XP, MSP Corporation, Shoreview, MN) was used to measure particle number size distributions. The WPS is designed to sample particle ranges from 10 nm to 10 um. The total WPS flow rate was 1 LPM of which 0.3 LPM was for the differential mobility analyzer (DMA) aerosol flow and 0.7 LPM was for the laser particle spectrometer (LPS) aerosol flow. The sampling bag was changed after each trial. In addition, the smoking machine was cleaned with ethanol to prevent any cross contamination between the samples.

After sampling, the cassettes used for nicotine, nitrosamines (NNN, NAT, NAB, NNK), polyaromatic hydrocarbons (PAHs), propylene glycol (PG) and diethylene glycol (DEG) samples were packed in dry ice for shipment to the laboratory for analysis.

Analysis

VOCs and carbonyls

VOCs

VOC samples were stored in a freezer at -20°C before analysis. The concentrations of the VOC species were determined using a modified EPA Method TO-17 procedure (USEPA, 1999a). Using an Entech Model 5400 (Entech Instruments, Simi Valley, CA), the samples were individual thermally desorbed into silonized bottles. Conventional thermal desorption provides only one opportunity to make the measurement. However, by desorption into the equivalent of a canister, a second analysis can be performed if there are problems with the initial analytical run. The partial contents of the bottle were introduced to a cryogenic preconcentrator (Model 7100A, Entech Instruments), and then flash evaporated into and analyzed with a Finnigan Gas Chromatography-Ion Trap Mass Spectrometry (GC/MS, Trace GC with Polaris Q MS, ThermoFinnnigan, San Jose, CA).

Carbonyls

Each carbonyl sample was placed into a brown glass vial to avoid any photodecomposition and was

extracted with 1 mL of acetonitrile (ACN) for 1 h using a Standard Orbital Shaker (VWR, Model 3500, Houston, Texas). The extracts were then analyzed using the EPA TO-11HPLC/UV method (USEPA, 1999b). In brief, a 20 µL aliquot was injected to the HPLC/UV analysis system (Surveyor PDA Detector, Surveyor Autosampler, Surveyor LC Pump, Thermo Electron). A Nova-Pak C18 analytical column (3.9×150 mm, Waters, Milford, MA) was used for the separation of the carbonyl-DNPH derivatives. The mobile phase contains two mixed solutions: A = ACN/water 60/40 (v/v) and B = water/ACN/ tetrahydrofuran 60/30/10 (v/v/v). The LC pump setup was 100% B solution for 2 min, followed by linear gradient from 100% B to 100% A in 10 min and then 100% A for another 13 min. The mobile flow rate was 1 LPM and the samples were analyzed with UV detection at 365 nm.

Blank and 1 ppm standard were run every nine samples as the quality control. The extraction efficiency was determined as 95–105% in general for the target analyses by spiking a known amount of the standard mixture (Air Monitoring Aldehyde-DNPH Mix, AccuStandard, New Haven, CT) to the sample matrix. The relative standard deviation of the 7 repeated injections of a mid-level standard was around 2–10 % for all the target compounds.

PAHs

The PAHs to be quantified were naphthalene, acenaphthylene, acenapthene, fluorine, anthracene, henanthrene, fluoranthene, pyrene, benz(a)anthracene, chrysene, retene, benzo(b)fluoranthene benzo(k)fluoranthene, benzo(a)pyrene, indeno(1,2,3-cd)pyrene, dibenz(a, h) anthracene, and benzo(ghi)perylene. Samples were collected on Paliflex 2500QAT Quartz fiber filters, treated with ground XAD-4 resin. Serial dilutions of the stock standard were made in dichloromethane. The standards were run with PAH samples that were extracted and reduced from filters. Samples are extracted by sonication in dichloromethane, followed by evaporation to 0.5 mL. A Hewlett Packard 6890 gas Chromatograph equipped with a 5972 Mass Selective detector was used to perform the analysis. The column used is an Agilent Technologies part #122-5562, DB-5MS fused silica capillary column with the following specifications: length 60 m, diameter 250 μm, film thickness.25 μm. The inlet temperature was 300°C. The oven conditions were 80°C, increased by 5°C/ min to 300°C, hold for 20 min.

Nicotine

Samples were collected on Pallflex TX40HI20 Tefion coated fiber filters. Extraction of nicotine from treated filters was performed by liquid-liquid extraction of the filters by vortexing in NaOH and heptane. The 0.5 mL organic layer was removed from the solution and injected into the Gas Chromatograph. A Hewlett Packard 7890 Gas Chromatograph equipped with a Nitrogen Phosphorus detector was used to perform the analysis. The column used was an Agilent Technologies part #123-5012E, DB-5MS fused silica capillary column with the following specifications: length 15 m, diameter 320 μ m, film thickness.25 μ m. The inlet temperature was 235°C. The oven conditions were 60°C initially, hold for 4 min, increased by 10 C/min to 190°C, then 30°C/min to 225°C

Tobacco specific nitrosamines

The four nitrosamines to be quantified were N'-nitrosoanatabine, N'-nitrosoanabasine, 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone, and N'-nitrosonornicotine. The samples were collected using Pallflex TX40HI20 Teflon coated fiber filters (Hammond et al., 1987). Filters are extracted by sonication in methanol, followed by evaporation to 0.5 mL. A Hewlett Packard 7890 Gas Chromatograph equipped with a Nitrogen Phosphorus detector was used to perform the analysis. The column used was an Agilent Technologies part #123-5012E, DB-5MS fused silica capillary column with the following specifications: length 15 m, diameter 320 µm, film thickness 0.25 µm. The inlet temp was 300°C. The oven conditions were 80°C initially, increased by 15°C/ min to 140°C.

Glycols (DEG and PG)

Samples were collected on XAD-4 impregnated Pallflex 2500QAT Quartz fiber filters in phase I, and on XAD-4 impregnated Pallflex TX40HI20 Teflon coated fiber filters in phase II (Lewtas et al., 2001). The filters were extracted by sonication in methanol, followed by evaporation to 0.5 mL. A Hewlett Packard 6890 gas Chromatograph equipped with a 5972 Mass Selective detector was used to perform the analysis. The column used was an Agilent Technologies part #19091X-133, DB-WAX fused silica capillary column with the following specifications: length 30 m, diameter 250 μ m, film thickness 0.25 μ m. The inlet temperature was 250°C. The oven conditions were 70°C initially, hold for 2 min, increased by 10°C/min to 220°C.

Results

The values of the pollutant concentrations for the e-liquid vapor samples and the cigarette smoke samples are presented in the Table 2 and in more detail in the supplemental material (Tables S1–S6).

For all of the samples, average VOC concentrations measured during phases I and II were below the limit of detection with limited exceptions. Ethylbenzene, benzene, toluene, and m/p xylenes (BTEX) were above detection limits. Their measured concentrations were orders of magnitude higher in tobacco smoke relative to the e-liquid vapor. The latter 3 compounds were measured by Schripp et al. (2012) and the results were comparable. For most carbonyls, concentrations were found to be low for both phases I and II for samples A-D, with some exceptions, such as acetone, formaldehyde, and acetaldehyde. These 3 carbonyls, however, were orders of magnitude higher in tobacco smoke relative to e-liquid vapor. Findings

854 T. R. McAuley et al.

Table 2 Summary of the average concentrations	(ng/L) of sampled pollutant during phase I and II.
Tanie Z. Builling Vol ule average concented	(iig) L) of bampica pointening and a prime i and a

	Vapor Sample A		por Sample A Vapor Sample B		Vapor S	Vapor Sample C		Vapor Sample D		Blank E		Cigarette Smoke F	
	Phase I	Phase II	Phase I	Phase II	Phase I	Phase II	Phase I	Phase II	Phase I	Phase II	Phase I	Phase II	
VOCs	18.0	139.2	76.0	178.7	115.5	137.7	317.5	45.7	112.0	64.0	3566.3	6185.3	
Carbonyls	797.7	345.0	1112.0	376.3	809.3	357.5	973.7	360.5	1648.8	327.4	31865,2	11357.3	
PAHs	4.25	1.83	0.30	0.93	3.05	0.55	0.18	0.75	N/F	0.65	2.69	2.67	
Nicotine	905	1705	725	2144	538	8770	6794	5904	N/F	N/F	5039	48050	
TSNAs	N/F		18		18		15				121		
PG	2668	2254	37,785	56,133	120,000	54,993	77,390	88,365	1339	196	3,185	260	
DEG	N/F	N/F	3	N/F	511	N/F	143	N/F	16	N/F	13	N/F	

See Tables S1-S6 in the supplemental sections for additional information on specific pollutants, measured concentrations, and limits of detection (LOD).

are consistent with Schripp et al. (2012) and Lauterbach et al. (2012). Most PAHs were below the LOD for e-cigarette vapor but were above LOD for tobacco smoke. An anomaly was found with benzo(a)pyrene as it was found at similar levels in e-cigarette vapor, tobacco smoke, and the blank sample. Lautebach et al. (2012b) found contrasting results and noted benzo(a)pyrene was below their LOD for e-cigarette vapor but more than 40 times higher in tobacco cigarette smoke. Nicotine levels were also significantly higher in cigarette smoke than in the e-liquid vapor, typically by an order of magnitude or more. This result is corroborated by Laugesen et al. (2008), Lauterbach et al. (2012), and Trehy et al. (2011). Tobacco specific nitrosamines (N'-nitrosoanabasine, N'-nitrosoanatabine, 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone, and N'-nitrosonornicotine) quantified in e-cigarette vapor were also typically found at lower levels than tobacco smoke. The TSNA results for phase II were not included in the summary table because significant levels of TSNAs in the blank sample and atypically low levels of TSNAs in the cigarette smoke make this data set unreliable. Previous studies (Laugesen et al., 2008; FDA, 2009: Lauterbach et al., 2012) have shown levels of these TSNAs in e-cigarette vapor to be orders of magnitude lower than in tobacco cigarettes which is similar to our findings from phase I. DEG was detected in some samples, but below toxic levels as is corroborated by FDA (2009) and Lauterbach et al. (2012). The risk analysis of all the phase I and II measured pollutants is presented in the toxicology section.

Table 3 shows very low particle counts across all e-liquids tested. Figure 3 presents the average size distributions for all of the samples measured in the phase I experiments. Instrument problems with the WPS produced highly uncertain measurements for the phase II experiments and thus, they are not presented. The e-cigarette liquids include components like the glycols that can nucleate in the air to produce visible particles and provide the illusion of "smoke." Figure 3 shows at least two size modes are formed in the bag where there were essentially no pre-existing particles. It also shows that the particle number concentrations in the tobacco smoke are significantly higher than in the e-cigarette emissions (Figure 3). These results are in reasonable agreement with those of Schripp et al. (2012) where they diluted the emissions into a much higher volume resulting in modes with

Table 3. Total particle counts for phase I.

Idble 0. Total parada	Mean number	
Sample	concentration \pm SD (p/cm ³)	N (samples)
Vapor Sample A	1795±2315	79
Vapor Sample A	2015 ± 2361	79
Vapor Sample A	1654 ± 2067	79
Vapor Sample B	667 ± 1873	79
Vapor Sample B	635 ± 1800	79
Vapor Sample B	2115 ± 2329	79
Vapor Sample C	2119 ± 2378	79
Vapor Sample C	2287 ± 2472	79
Vapor Sample C	2963 ± 3122	79
Vapor Sample D	994±2023	79
Vapor Sample D	2019 ± 2040	79
Vapor Sample D	2057 ± 2218	79
Blank E	28±35	79
Cigarette Smoke F	21810 ± 55287	79
Cigarette Smoke F	21352 ± 50414	79
Cigarette Smoke F	19906 ± 48189	79

Phase II results are not presented due to complications with the WPS.

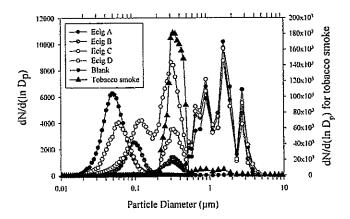


Figure 3. Overall particle number concentration (p/cm^3) and size distribution data for all vapor and smoke samples collected in phase I. (See colour version of this figure online at www. informahealthcare.com/iht)

different relative proportions. The Schripp et al. (2012) measurements were measurements of the size distribution after a smoker or e-cigarette user exhaled the aerosol and only measured particles <560 nm in diameter. These distributions are similar to those observed in the present study. These measurements indicate that e-cigarettes do not contribute significant particulate matter mass to the indoor environment.

The cigarette smoke particle number concentration was an order of magnitude higher than the highest concentration of any e-liquid (2963 ± 3122 , liquid C vs. $21,352 \pm 50,414$). Similar differences were found in Schripp et al. (2012). These results would be expected given the combustion of the tobacco.

Toxicology

An expert toxicology consulting firm assessed the impacts of the measured concentrations on indoor air quality for all of the pollutants. Air quality data collected during both phases was provided to the toxicologist after being converted to estimated air concentrations using a well-mixed standard room size of 40 m³. Indoor air quality analysis was conducted based on a dynamic system with estimated air changes per hour of 0.3. Risk analysis was conducted for all byproducts detected in vapor from e-liquids A-D, and cigarette smoke (F).

The Total Cumulative Hazard Indices (HIs) and Excess Lifetime Cancer Risks (ELCRs) values from the aforementioned Risk Analyses are presented in Supplemental Tables S7a and b & S8, respectively, for each vapor sample for e-liquids A-D and cigarette smoke (F) for phases I and II of the study. The HI and ELCR values were compared to acceptable Risk Limits of an HI of 1 for Non-Cancer Risks and an ELCR Risk Limit of 1×10^{-5} for Cancer Risks. In addition, based on individual Hazard Quotients and ELCRs (see *Calculation Addendum, supplemental material*), the percentage risk contributions by the individual analytes were calculated to identify either individual chemical or chemical class risk drivers and the results are presented in Supplemental Tables S7a and b and S8.

Based on the exposure assumptions listed in Tables S7a and b and S8 for child and adult subchronic, chronic, and lifetime inhalation exposures to the atmospheric concentrations of Non-Cancer and Cancer analytes detected in vapor from e-liquids A-D and cigarette smoke (F), for phases I and II of the study, the Non-Cancer Risk findings (Table S7a and b) for both subchronic and chronic exposures, revealed a condition of "No Significant Risk" of harm to human health for vapor from e-liquids A-D (i.e. no HI value >1). For the cigarette smoke, (F), phase I results, the child subchronic and chronic inhalation exposure HIs markedly exceeded the HI Risk Limit of 1 (i.e. HIs = 2 and 10, respectively). In addition, the HI value of 5 for adult chronic exposures to cigarette smoke (F) in phase I of the study also indicated a condition of "Significant Risk" of harm to human health via the inhalation route of exposure, as did the HI value of 2 for the cigarette smoke (F), phase II for chronic child exposures. It is important to note that the key risk drivers for subchronic exposures were acrolein, methacrolein and propionaldehyde and for chronic exposures, acrolein and methacrolein. In the case of acrolein and methacrolein, some degree of uncertainty may be associated with this

finding, since acrolein was used as the surrogate for the methacrolein inhalation RfCs.

For child and adult exposures to carcinogens in vapor from liquids A-D and cigarette smoke (F) (Table S8) no Cumulative ELCR exceeded the Cancer Risk Limit of 1×10^{-5} , with ELCRs ranging from 1×10^{-7} to 9×10^{-10} , except for F (cigarette smoke), where the phase I and phase II ELCRs for adult exposures approached the ELCR risk limit of 1×10^{-5} (i.e. ELCRs of 7×10^{-6} and 1×10^{-6} , respectively). In each instance the primary risk driver was acetaldehyde. However, based on the overall findings, neither vapor from e-liquids A-D, or cigarette smoke (F) analytes posed a condition of "Significant Risk" of harm to human health via the inhalation route of exposure.

Discussion

Electronic cigarettes have earned considerable attention by local, state, and federal agencies over the last few vears. Many legislators have issued warnings and/or proposed bans to prohibit the use of e-cigarettes in public places. In July 2009, the Food and Drug Administration (USFDA, 2009), issued a report (http://www.fda.gov/ ForConsumers/ConsumerUpdates/ucm173401.htm) voicing several concerns, such as potential for youth addiction and possible toxicity of e-liquid. The FDA issued this report without any evidence of youth use of e-cigarettes or health impacts from the use of or exposure to emissions from an e-cigarette. In this study emissions from e-cigarette use and tobacco cigarette use were analyzed to measure levels of the chosen pollutants. Analysis of the pollutant concentrations showed that the e-cigarette vapor was found to pose significantly lower risk than cigarette smoke under the same testing conditions. Since there is no combustion with e-cigarette use, as opposed to cigarette smoking, particle counts resulting from vapor production were expected to be low as found during phase I (Table 3). These results are uncertain since they could not be replicated in phase II due to instrumental problems. For the cigarette smoke, particle concentrations were an order of magnitude higher than concentrations found for the vapor samples as shown above (Table 2). These results are similar to those of Schripp et al. (2012) and tobacco cigarette smoke particle distributions in Li and Hopke (1993).

Total air emission concentrations for many pollutants were found to be very low. The toxicology data shown in supplemental material (Tables S7a and b and S8) provides scientific evidence that for all pollutants sampled during this study, the endpoints of concern for assessing overall risk revealed no discernible health impacts from exposures to the vapor produced by any e-liquid used in this study. ELCR values for mainstream cigarette smoke samples were fairly low. The authors believe that this was because the measurements did not include side stream smoke in the testing environment. This lack of ETS should be taken into account for levels of all compounds measured in cigarette smoke in this study with respect to indoor air quality. All risk analysis findings are based on a standard room size of 40 m³ taking into account dispersion of the pollutants and a well-mixed environment. There is no prior research that compares actual emissions data collected with an assessment of potential exposures. These findings assess only the actual emissions measured and associated risk analysis impacts, not potential adverse health impacts related to e-cigarette use.

To date, no study on e-cigarettes suggests a potential risk to bystanders of e-cigarette users. A recent study by Flouris et al. (2012) concluded that acute active and passive vaping of e-cigarettes did not influence complete blood count (CBC) indices in smokers and never smokers, respectively. In contrast, acute active and passive tobacco cigarette smoking increased the secondary proteins of acute inflammatory load for at least 1 h.

Some weaknesses of this study include not changing the tubes in consideration of the possibility of glycol adherence to Teflon tubes used for sample collection during phase I of the experiment and the WPS error during phase II of the experiment. Difficulty obtaining IRB approval in 2009 for human subject trials using previously unstudied products made use of a smoking machine necessary to conduct this study. As a result, data did not reflect real world use of e-cigarettes, where the human user is an intermediary between the vapor and the environment.

There are a number of possibilities for future research. As a result of a large data gap as to what chemical compounds and/or pollutants found in tobacco smoke are also found in vapor produced by e-cigarettes, this study was designed to assess similarities and differences between tobacco smoke and e-cigarette vapor. Constituents were then assessed based on their overall risk for potential health impacts based on measured concentrations during phase I and II. Future studies should include repeating the experiment with other flavors of e-liquid (including flavorless) to determine whether flavoring in e-liquid plays a part in levels of various pollutants, varied voltage e-cigarettes to investigate whether increased heat initiates pyrolysis or decomposition that increases the toxicity, various types of cartridges and atomizers to determine whether cartomizer filler (polyfil) affects levels of tested compounds, and additional brands of e-liquid to assess emissions from a greater variety of e-liquids. It may also be beneficial to repeat the current study using a multi-cigarette version of the smoking machine to see if higher concentrations of vapor may affect toxicity. Tobacco cigarettes produce side stream smoke continuously, but there is minimal side stream vapor with e-cigarette use. Therefore, it would be helpful to repeat the experiment with human subjects smoking or using the e-cigarette inside the testing environment for inclusion of side stream smoke for comparison to real world environment. This would also help determine the extent to which vapor components may be absorbed by the e-cigarette user, rather than being released into the ambient air (see Vansickel & Eissenberg, 2012).

Conclusions

The current study indicates that there are very low indoor air quality impacts from the use of an electronic cigarette based on the risk screening of measured emissions. It also indicates no apparent risk to human health from e-cigarette emissions based on the compounds analyzed. The authors recognize that future research assessing exposures to bystanders and users will be imperative for fully understanding the impacts from use of an electronic cigarette.

Acknowledgments

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Declaration of interest

National Vapers Club (NVC) has spent more than 3 years educating people about electronic cigarettes. This research was necessary to have more thorough information to present to scientific and political bodies who are struggling with regulation of a new product about which there is very little published scientific data. Funding was obtained by fundraising events held by NVC as well as individual donations by NVC members, and in part by e-cigarette retailers who contacted NVC to offer contributions. Although NVC funded this study, it had no control over the results. The scientists and independent contractors hired by the principal investigator were entirely responsible for collecting, analyzing and interpreting the data. Prior to data collection, no author or independent contractor who worked on this project had any financial interest in the outcome of this study. Subsequent to data collection, S. Babaian became part owner in a retail e-cigarette company.

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Levels of selected carcinogens and toxicants in vapour from electronic cigarettes

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Notes

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Levels of selected carcinogens and toxicants in vapour from electronic cigarettes

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ABSTRACT

Significance Electronic cigarettes, also known as ecigarettes, are devices designed to imitate regular cigarettes and deliver nicotine via inhalation without combusting tobacco. They are purported to deliver nicotine without other toxicants and to be a safer alternative to regular cigarettes. However, little toxicity testing has been performed to evaluate the chemical nature of vapour generated from e--cigarettes. The aim of this study was to screen e-cigarette vapours for content of four groups of potentially toxic and carcinogenic compounds: carbonyls, volatile organic compounds, nitrosamines and heavy metals. Materials and methods Vapours were generated from 12 brands of e-cigarettes and the reference product, the medicinal nicotine inhaler, in controlled conditions using a modified smoking machine. The selected toxic compounds were extracted from vapours into a solid or liquid phase and analysed with chromatographic and spectroscopy methods. Results We found that the e-cigarette vapours contained some toxic substances. The levels of the toxicants were 9-450 times lower than in cigarette smoke and were, in many cases, comparable with trace amounts found in the reference product. Conclusions Our findings are consistent with the idea that substituting tobacco cigarettes with e-cigarettes may substantially reduce exposure to selected tobacco-specific toxicants. E-cigarettes as a harm reduction strategy among smokers unwilling to quit, warrants further study. (To view this abstract in Polish and German, please see the supplementary files online.)

INTRODUCTION

An electronic cigarette, also known as e-cigarette, is a type of nicotine inhaler, imitating ordinary cigarettes. Although the majority of e-cigarettes look similar to other tobacco products, such as cigarettes or cigars, certain types resemble pens, screwdrivers or even harmonicas. E-cigarettes contain nicotine solution in a disposable cartridge. The cartridge is replaced when the solution is finished or might be refilled by the ecigarette user. In contrast with ordinary cigarettes, which involve tobacco combustion, e-cigarettes use heat to transform nicotine solution into vapour. Processed and purified nicotine from tobacco leaves, suspended in a mixture of glycerin or propylene glycol with water, is vapourised. Nicotine present in such vapour enters the respiratory tract, from where it is absorbed to the bloodstream.¹⁻⁴

Distributors of e-cigarettes promote the product as completely free of harmful substances. The basis for

the claim of harmlessness of the e-cigarettes is that they do not deliver toxic doses of nicotine and the nicotine solution lacks harmful constituents. E-cigarettes are new products and, as such, require further testing to assess their toxic properties. Currently, the scientific evidence on the lack or presence of toxic chemicals in the vapour generated from e-cigarettes, and inhaled by their users is very limited. In August 2008, Ale Alwen, the Assistant Director-General for Non-communicable Diseases and Mental Health, stated that 'the electronic cigarette is not a proven nicotine replacement therapy. WHO has no scientific evidence to confirm the product's safety and efficacy. However, WHO does not discount the possibility that the electronic cigarette could be useful as a smoking cessation aid. The only way to know is to test.5 Douglas Bettcher, Director of the WHO's Tobacco Free Initiative stated that only clinical tests and toxicity analysis could permit considering e-cigarettes a viable method of nicotine replacement therapy.6

The majority of tests carried out on e-cigarettes until now consist of analysing the chemicals in the cartridges or nicotine refill solutions.7-18 The current tests show that the cartridges contain no or trace amounts of potentially harmful substances, including nitrosamines, acetaldehyde, acetone and formaldehyde. However, using e-cigarettes requires heating the cartridges and under such conditions chemical reactions may result in formation of new compounds. Such a situation takes place in the case of ordinary cigarettes, where a number of toxic compounds are formed during combustion. The US Department of Health and Human Services of the Food and Drug Administration agency carried out tests which showed the presence of trace amounts of nitrosamines and diethylene glycol in e-cigarette vapour. These tests were conducted in a manner which simulated the actual use of the products.¹⁹

We developed analytical methods and measured concentrations of selected compounds in the vapour generated by different brands and types of ecigarettes. We focused our study on the four most important groups of toxic compounds present in the tobacco smoke: carbonyl compounds, volatile organic compounds (VOCs), tobacco-specific nitrosamines and metals (table 1).

MATERIALS AND METHODS Electronic cigarettes and reference product (Nicorette inhalator)

Since the internet is currently the main distribution channel for the products, we searched price

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Chemical compounds	Toxic effects
Carbonyl compounds	
.Formaldehyde*, acetaldehyde*, acrolein*	 Cytotoxic, carcinogenic, irritant, pulmonary emphysema, dermatitis
Volatile organic compounds (VOCs)	· 이상 방법에 관광하는 것이 같은 것이 있는 것이 같은 것이 같은 것이 있다. 같은 것은 것은 것은 것은 것은 것은 것이 같은 것이 있다.
Benzene*; toluene*, aniline	Carcinogenic, haematotoxic, neurotoxic, irritant
Nitrosamines	
N'-nitrosonomicotine (NNN)*, 4-(methylnitrosoamino)-1-(3-pyridy))-1-butanone (NNK)*, N'-nitrosoethylomethyloamine	Carcinogenic
Polycyclic aromatic compounds (PAHs)	전 성영을 관심했는 일종 전신의 물건이 다.
Benzo(a)pyrene, benzo(a)anthracene, dibenzo(a)anthracene	Carcinogenic
Free radicals	
Methyl radical, hydroxyl radical, nitrogen monoxide	Carcinogenic, neurotoxic
Foxic gases	가 있는 것 같은 바람에 관광하는 것은 것이다. 것은 것은 것은 것을 많은 것이다. 것은 것을 다. 것은 것은 것은 것은 것은 것은 것은 것은 것 같은 것은
Carbon monoxide, hydrogen sulfide, ammonia, sulfur dioxide, hydrogen cyanide	Cardiovascular toxicants, carcinogenic; irritant
feavy metals	날 같은 한국 수별을 수 없다. 가지 않는 것은 것 같아요.
Cadmium (Cd)*, lead (Pb)*, mercury (Hg)*	Carcinogenic, nephrotoxic, neurotoxic, haematotoxic
Dther toxicants	그는 그는 것은 것을 위해 가는 것은 것은 것을 가지 않는다. 것은 것을 가지 않는다. 것은 것을 가지 않는다. 것은 것은 것은 것을 가지 않는다. 것은 것은 것은 것은 것을 가지 않는다. 것은 것을 가지 않는다. 것은
Carbon disulfide	Neurotoxic

*Indicates compounds analysed in this study.

comparison websites, online marketplace (Allegro.pl auction service) and internet discussion forums for e-cigarette users to identify the most popular brands of e-cigarettes distributed from within Poland. The searching was limited to web pages from Poland, and only Polish language was allowed for in retrieval options. Some 30 brands were identified. The brands were entered into Google.pl, and ranked according to the number of hits they generated. The number of hits in the search engine for the selected 30 models allowed selection of the 11 most popular e-cigarettes brands. Additionally, one e-cigarette model purchased in Great Britain was used in the study. All ecigarette models selected for the study were purchased online. Characteristics of the product tested in the study are shown in table 2.

The suitable cartridges of the same brand name were used for the study. They were purchased from the same sources as that of the e-cigarette and were matched to selected models. All cartridges were characterised by high nicotine content (16–18 mg). As a reference product the medicinal nicotine inhalator was used (Nicorette 10 mg, Johnson&Johnson, Poland). The inhalator for the study was purchased in one of the local pharmaceutical warehouses.

Generation of vapour from e-cigarettes and reference product

Vapour from e-cigarettes was generated using the smoking machine Palaczbot (Technical University of Lodz, Poland) as described previously.³ This is a one-port linear piston-like smoking machine with adjustable puffing regimes in a very wide range, controlled by computer interface.

Pilot samples demonstrated that it was impossible to generate vapour from e-cigarettes in standard laboratory conditions assumed for conventional cigarettes testing (International Organization for Standardization (ISO) 3808).²⁴ Inhalation of a volume of 35 ml anticipated in conventional cigarette standard is insufficient for activation of most of the e-cigarettes. Thus, we decided to generate vapour in conditions reflecting the actual manner of e-cigarettes using, determined based on the results of inhalation topography measurement among 10 'e-smokers', who declared that they regularly use e-cigarettes for a period

Table 2 Characteristics of products tested in the study

Product code	Brand name	Model	Cartridge type	Flavour	Labelled nicotine content (mg or mg/ml)	Measured nicotine content (mg) ³	Retailer	Country
EC01	Joye	510	Cartridge	Marlboro	4	4	Inspired s.c.	Poland
ECO2	Janty	eGo	Cartridge	Mariboro	16	5	Janty	Poland
EC03	Janty	Dura	Cartridge	Marlboro	16	5	Janty	Poland
ECO4	DSE	901	Cantridge	Regular	16	9	Fausee	Poland
EC05	Trendy	808	Cartridge	Trendy	18	2	Damhess	Poland
EC06	Nicore	M401	Cartridge	Mariboro	18	5	Atina Poland	Poland
EC07	Mild	201	Cartridge	Marlboro	18	19	Mild	Poland
EC08	Colinss	Age	Cartomizer	Camel	18	11	Colinss	Poland
EC09	Premium	PR111	Cartomizer	Tobacco	16	12	Premium	Poland
EC10	Ecis	510	Cartridge	Menthol	11	5	Arcotech	Poland
EC11	Dekang	Реп	Cartridge	Regular	18	18	Ecigars Polska	Poland
EC12	Intellicig	Evolution	Cartridge	Regular	8	8	Intellicig	UK

longer that 1 month.³ All testing procedures in this work were carried out using the same averaged puffing conditions: puff duration of 1.8 s, intervals between puffs of 10 s, puff volume 70 ml and number of puffs taken in one puffing session was 15. A total of 150 puffs were taken from each e-cigarette in 10 series of 15 puffs with intervals between series of 5 min each. Each e-cigarette was tested three times on three following days after batteries were recharged during nights. A fresh cartridge was placed on the e-cigarettes each day they were tested. Vapour was visibly being produced during the full 150 puffs taken from each product tested.

Analytical chemistry

Note: The details of the sample preparation and analysis are given in the online supplementary materials.

It was planned to absorb the analysed vapour components in bulbs containing an organic solvent (extraction to liquid) or on suitable sorbents (extraction to solid phase). This required the modification of the system described above, in such a manner to enable quick connection of desirable sorption system. Carbonyl compounds and organic compounds due to their volatility were trapped in tubes packed with solid adsorbent. Metals and nitrosamines in turn, which are characterised by lower volatility, were to be absorbed in two gas washing bottles with methanol (50 ml in each bottle). Both washing bottles were immersed in acetone-dry ice bath in order to avoid any losses of volatile solvent. A picture of the set for vapour generation from e--cigarette and metals or nitrosamines absorption is presented in online supplementary figure S2.

The samples, after the preparation and condensation procedure, were analysed using analytical methods with high specificity and sensitivity allowing detection of even trace amounts of analysed compounds. Figure 1 shows the sample preparation procedure; and all analytical methods are described in details in the online supplementary materials. The following carbonyl compounds were analysed in this work using high-performance chromatography with diode array detector liquid (HPLC-DAD): formaldehyde, acetaldehyde, acrolein, acetone, propionic aldehyde, crotonaldehyde, butanol, benzaldehyde, isovaleric aldehyde, valeric aldehyde, m-methylbenzaldehyde,

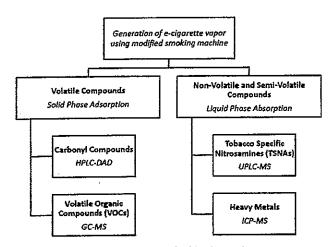


Figure 1 Analytical procedures applied in the study to test carcinogens and selected toxicants in vapour from e-cigarettes. GC-MS, gas chromatography-mass spectrometry; HPLC-DAD, high-performance liquid chromatography with diode array detector; ICP-MS, inductively coupled plasma-mass spectrometry; TSNA, tobacco-specific nitrosamine; UPLC-MS, ultra-performance liquid chromatography-mass spectrometry; VOC, volatile organic compound.

o-methylbenzaldehyde, p-methylbenzaldehyde, hexanal, 2,5dimethylbenzaldehyde. VOCs included benzene, toluene, chlorobenzene, ethylbenzene, m,p-xylene, o-xylene, styrene, 1,3-dichlorobenzene, 1,4-dichlorobenzene, 1,2-dichlorobenzene, naphthalene and were analysed with gas chromatography-mass spectrometry. Among tobacco-specific nitrosamines two compounds were measured: N'-nitrosonornicotine (NNN) and 4-(methylnitrosoamino)-1-(3-pyridyl)-1-butanone (NNK) with ultra-performance liquid chromatography-mass spectrometry. An inductively coupled plasma mass spectrometry technique was used to quantify following metals: cobalt (Co), nickel (Ni), copper (Cu), zinc (Zn), cadmium (Cd), lead (Pb), arsenic (As), chromium (Cr), selenium (Se), manganese (Mn), barium (Ba), rubidium (Rb), strontium (Sr), silver (Ag), thallium (Tl) and vanadium (V). All analytical methods used in this work were validated as per the International Conference on Harmonisation guideline Q2(R1).²⁵

Statistical analysis

Results were presented as mean \pm SEM levels of selected compounds in vapour generated from e-cigarettes (per 150 puffs). The study aimed to compare the results obtained for aerosol from Nicorette inhalator with the results obtained for all examined e-cigarette models. Due to the small size of the groups, the difference between the mean from two groups was assessed based on Student's t test. All statistical analyses were conducted using the software for statistical data analysis Statistica V9.0 (StaftSoft, Tulsa, USA). The significance level was established as p<0.05.

RESULTS

Carbonyl compounds

Among 15 carbonyls analysed, only 4 were found in vapour generated from e-cigarettes (table 3); and these compounds were identified in almost all examined e-cigarettes. The exception was one e-cigarette marked with code EC09, where acrolein was not detected. Three of the carbonyls have known toxic and irritating properties: formaldehyde, acetaldehyde and acrolein. The content of formaldehyde ranged from 2.0 μ g to 56.1 μ g, acetaldehyde from 1.1 μ g to 13.6 μ g, and acrolein from 0.7 μ g to 41.9 μ g per one e-cigarette (150 puffs). Trace amounts of formaldehyde, acetaldehyde and o-methylbenzaldehyde were also detected from the Nicorette inhalator. None of these compounds were detected in blank samples.

Volatile organic compounds

Among 11 VOCs analysed, only two were found in samples of vapour generated from e-cigarettes (table 3), and these compounds were identified in almost all examined e-cigarettes. The only one exception was e-cigarette marked with code EC02, where toluene and m,p-xylene were not detected. The content of toluene ranged from 0.2 μ g to 6.3 μ g per one e-cigarette (150 puffs). Although the m,p-xylene levels found in analysed samples of e-cigarette vapours ranged from 0.1 μ g to 0.2 μ g, it was also found on the same level in blank samples. In Nicorette inhalator in turn, none of the compounds analysed in that group were noted.

Tobacco-specific nitrosamines

Both nitrosamines analysed in the study were identified in all but three vapours generated from e-cigarettes (table 3). NNN was not found in e-cigarettes marked with codes EC01, EC04 and EC05 and NNK was not identified in products EC04, EC05 and EC12. The content of NNN ranged from 0.8 ng to 4.3 ng, and NNK from 1.1 ng to 28.3 ng per one e-cigarette

Compound	BS	Levels in va	apour from ele	ctronic cigaret	ites†		• • •		and a	a da Car				Reference produc
ang selarah sang sang sang sang sang sang sang sang		Product code	9					· · · ·				a de la come		
		EC01	EC02	EC03	EC04	EC05	EC06	EC07	EC08	EC09	EC10	EC11	EC12	Inhalator
Carbonyl compounds (µg)					· · ·									
Formaldehyde	ND	44.2±4.1*	23.6±8.7*	30.2±2.3*	47.9±0.2*	56.1±1.4*	35.3±2.7*	19.0±2.7*	6.0±2.0	3.2±0.8	3.9±1.5	23.9±11.1	46.3±2.1*	2.0±1.1
Acetaldehyde	ND	4.6±0.2*	6.8±3.2	8.2±2.5*	11.5±2.0*	3.0±0.2*	13.6±2.1*	11.1±3.3*	8.8±1.6*	3.5±0.3*	2.0±0.1	3.7±1.5	12.0±2.4*	1.1±0.6
Acrolein	ND	41.9±3.4*	4.4±2.5	16.6±2.5*	30.1±6.4*	22.0±1.6*	2.1±0.4*	8.5±3.6	0.7±0.4	ND	2.7±1.6	1.1±0.6	7.4±3.2*	ND
o-methylbenzaldehyde	ND	1.9±0.5	4.4±1.2*	3.2±1.0*	4.9±1.2*	1.7±0.1*	7.1±0.4*	1.3±0.8	5.5±0.0*	6.0±0.7*	3.2±0.5*	5.1±0.1*	2.2±0.6*	0.7±0.4
/olatile Organic Compound	ls (VOCs)	(µg)	1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -											
Toluene	ND	0.5±0,1*	ND	0.2±0.0*	0.6±0,1*	0.2±0.0*	ND	0.3±0.2	0.2±0.1	6.3±1.5*	0.2±0.1*	0.5±0.1*	0.5±0.0*	ND
p.m-xylene	0.1	0.1±0.0"	ND	0.1±0.0*	0.2±0.1*	0.1±0.0	ND	0.1±0.1	0.1±0.0	0.1±0.0*	0.1±0.0*	0.1±0.1*	0.1±0.0	ND
obacco-Specific Nitrosami	nes (TSN	As) (ng)												
NNN	ND	ND	2.7±2.2	0.8±0.8	ND	ND	0.9±0.4	4.3±2,4	1.9±0.3*	1.2±0.6	2.0±1.1	3.2±0.6*	1.3±0.1	ND
NNK	ND	2.0±2.0	3.6±1.8	3.5±1.8	ND	ND	1.1±1.1	21.1±6.3*	4.6±0.4*	28.3±13.2	2.1±2.1	13.0±1.4*	ND	ND
Aetals (µg)					in a tradition a									
Cd	0.02	0.17±0.08	0.15±0.03*	0.15±0.05	0.02±0.01	0.04±0.01	0.22±0.16	0.02±0.01	0.08±0.03	0.01±0.01	0.17±0.10	0.03±0.03	ND	0.03±0.01
Ni	0.17	0.28±0.22	0.29±0.08	0.21±0.03	0.17±0.07	0.14±0.06	0.11±0.06	0.23±0.09	0.26±0.10	0.19±0.09	0.12±0.04	0.11±0.08	0.11±0.05	0.19±0.04
Pb	0.02	0.06±0.01	0.06±0.03	0.07±0.01	0.03±0.01	0.05±0.01	0.03±0.01	0.04±0.01	0.57±0.28	0.09±0.04	0.06±0.02	0.04±0.03	0.03±0.03	0.04±0.01

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Values are mean±SEM. *Significant difference with Nicorette inhalator (p<0.05). †Units are µg, except for nitrosamines units are ng. BS, blank sample; ND, not detected; NNK, N'-nitrosonornicotine (NNN) and 4-(methylnitrosoamino)-1-(3-pyridyl)-1-butanone; NNN, N'-nitrosonornicotine; DL, detection limit.

(150 puffs). In Nicorette inhalator or in blank samples in turn, none of these compounds was noted.

Metals

Among 12 metals analysed in the study, cadmium, nickel and lead were identified, and were present in all vapours generated from e-cigarettes (except cadmium, which was not detected in a product of code EC12; table 3). The content of cadmium ranged from 0.01 μ g to 0.22 μ g, nickel from 0.11 μ g to 0.29 μ g and lead from 0.03 μ g to 0.57 μ g per one e-cigarette (150 puffs). The same metals in trace amounts were detected in Nicorette inhalator and in blank samples.

DISCUSSION

We examined vapours generated from 12 models of e-cigarettes for the presence of four groups of toxic compounds found in tobacco smoke. The Nicorette inhalator was used as a reference product. Such a choice was dictated by the premise that a therapeutic product like Nicorette inhalator should fulfil specified safety standards and should not contain significant levels of any of the analysed toxic compounds.

Our results confirm findings from the previous studies, in which small amounts of formaldehyde and acetaldehyde were detected in cartridges. 9 18 However, the presence of acrolein in a cartridge or nicotine solution has not been reported so far. Formaldehyde and acetaldehyde were also found in vapour exhaled to test chamber by volunteers who used e-cigarette filled with three various nicotine solutions.26 Recently, Uchiyama et al²⁷ demonstrated that vapour generated from a single brand of e-cigarette contained low levels of formaldehyde, acetaldehyde and acrolein. There is a possibility that acrolein is present in vapour only, since this compound may be formed as a result of heating glycerin which is a component of the solution. Pyrolysis of glycerin has been studied in steam with acrolein, formaldehyde and acetaldehyde observed as the major products.²⁸²⁹ These products appear to result from dehydration and fragmentation of glycerin. Although energy calculations of the dehydration of glycerin by the neutral mechanisms indicate that these processes can only occur at relatively high temperatures such as in pyrolysis or combustion, the addition of acids allows substantially lower dehydration temperatures.30

All three carbonyl compounds found in the study and discussed above have been shown to be toxic in numerous studies: formaldehyde is classified as carcinogenic to humans (group 1 by International Agency for Research on Cancer, IARC)³¹; acetaldehyde as possibly carcinogenic to humans (group 2B),³¹ and acrolein causes irritation to the nasal cavity, and damage to the lining of the lungs and is thought to contribute to cardiovascular disease in cigarette smokers.³² Exposure to carbonyl compounds found in vapour might cause mouth and throat irritation which is the most frequently reported adverse event among e-cigarette users.¹ ³³ A study by Cassee *et al*³⁴ showed that sensory irritation in rats exposed to mixtures of formaldehyde, acetaldehyde and acrolein is more pronounced than that caused by each of the compounds separately. Future studies should evaluate possible adverse health outcomes of short term and long term exposure to these compounds among users of e-cigarettes and people involuntarily exposed to exhaled vapours.

We found that the vapour of some e-cigarettes contains traces of the carcinogenic nitrosamines NNN and NNK, whereas neither was detected in aerosol from the Nicorette inhalator. The studies conducted previously reported the presence of NNN and NNK in ecigarette cartridges in amounts of 3.9–8.2 ng per cartridge,¹⁸ ¹⁹ which corresponds with the results on vapour obtained in the present paper. However some other studies have reported that some cartridges are free of nitrosamines.¹² This inconsistency of findings of various studies might be due to different analytical methodologies of variable sensitivity applied in the studies discussed above.

Two of the analysed VOCs were detected: toluene and m, p-xylene. None of the studies conducted until now reported the presence of these compounds in a cartridge, nicotine solution or e-cigarette vapour. None of these compounds were found in a study by Schripp *et al*²⁶ on passive exposure to e-cigarette vapours. Three toxic metals, cadmium, nickel and lead, were detected in the vapour of analysed e-cigarettes. Since the same elements were also detected in trace amounts in Nicorette inhalator and in blank samples it is possible that there were other sources of these metals. This limitation of the study does not allow us to conclude whether e-cigarette alone may be a significant source of exposure to these chemicals.

Recently, we published a study on tests for nicotine delivery of Polish and UK e-cigarette brands.³ Many of the same brands in that paper have also been included in this study and tested for toxicants delivery. It should be mentioned that the leading brands with the highest nicotine delivery did not have the highest yields for toxicant delivery. This is important as while selecting the brands for nicotine the worst brands for toxicants generally can be avoided.

The results allowed us to compare the content of harmful substances between various e-cigarette models and conventional cigarettes (based on literature data).³⁵ To compare levels of selected toxins in e-cigarette vapour and mainstream smoke of a conventional cigarette we assumed that users of e-cigarettes take on overage 15 puffs during one session of product use, and it would correspond to smoking one conventional cigarette. In our study the vapours from e-cigarettes were generated from 150 puffs (10 series of 15 puffs each). For comparison purposes, we assumed that 150 puffs of an e-cigarette correspond to smoking 10 cigarettes. The comparison of toxic substance levels between conventional cigarettes and e-cigarettes is presented in table 4.

Table 4 Comparison of toxins levels between conventional and electronic cigarettes

Toxic compound	Conventional cigarette (µg in mainstream smoke) ³⁵	Electronic cigarette (µg per 15 puffs)	Average ratio (conventional vs electronic cigarette)			
Formaldehyde	1.6–52	0.205.61	9			
Acetaldehyde	52-140	0.11-1.36	450			
Acrolein	2.4-62	0.07-4.19	15			
Toluene	8.3-70	0.02-0.63	120			
NNN	0.005-0.19	0.00008-0.00043	380			
NNK	0.012-0.11	0.00011-0.00283	40			

NNK, N'-nitrosonomicotine (NNN) and 4-(methylnitrosoamino)-1-(3-pyridyl)-1-butanone; NNN, N'-nitrosonomicotine.

As shown in table 4 levels of selected toxic compounds found in the smoke from a conventional cigarette were 9-450-fold higher than levels in the vapour of an e-cigarette. Smoking an ecigarette (also referred to as 'vaping') can result in exposure to carcinogenic formaldehyde comparable with that received from cigarette smoking. Formaldehyde was also found in the vapour of medicinal inhalators, at levels that overlapped with those found in e-cigarette vapour. Exposure to acrolein, an oxidant and respiratory irritant thought to be a major contributor to cardiovascular disease from smoking, is 15 times lower on average in e-cigarette vapour compared with cigarette smoke. The amounts of toxic metals and aldehydes in e-cigarettes are trace amounts and are comparable with amounts contained in an examined therapeutic product.

The results of the study support the proposition that the vapour from e-cigarettes is less injurious than the smoke from cigarettes. Thus one would expect that if a person switched from conventional cigarettes to e-cigarettes the exposure to toxic chemicals and related adverse health effects would be reduced. The confirmation of that hypothesis however, requires further studies involving people using e-cigarette devices.

The primary limitation of our research is that the puffing profile we used may not reflect actual user puff topography. Hua et al^{36} reported that e-cigarette users take longer puffs, and that puff duration varied significantly among e-cigarette brands and users. This suggests that actual doses of toxicants inhaled by e-cigarette users might be higher than measured in our study. Similarly to results of tobacco cigarette testing with smoking machines (International Organization for Standardization (ISO), Federal Trade Commission (FTC)) the values obtained in our study should be interpreted with caution. The other limitation of our research is that we have tested only 12 brands of e-cigarettes. There are numerous different brands in the market, and there is little information on their quality control.

CONCLUSIONS

The vapour generated from e-cigarettes contains potentially toxic compounds. However, the levels of potentially toxic compounds in e-cigarette vapour are 9-450-fold lower than those in the smoke from conventional cigarettes, and in many cases comparable with the trace amounts present in pharmaceutical preparation. Our findings support the idea that substituting tobacco cigarettes with electronic cigarettes may substantially reduce exposure to tobacco-specific toxicants. The use of e-cigarettes as a harm reduction strategy among cigarette smokers who are unable to quit, warrants further study.

What this paper adds

- Distributors of e-cigarettes promote the product as completely free of harmful substances. Currently, there is no comprehensive research on the presence of toxic chemicals in the vapour generated from e-cigarettes and inhaled by their users.
- This study of chemical composition of vapour generated from 12 brands of e-cigarettes revealed that the vapour
- contained some toxic substances.
- The levels of potentially toxic compounds in e-cigarette vapour were found to be from ninefold to almost 450-fold lower compared with smoke from conventional cigarettes, and in many cases comparable with trace amounts present in pharmaceutical preparations.

Contributors MLG and NB designed the study and wrote the paper. JK, MG and LK tested the products using smoking machine. AS and JK developed the analytical method and measured carbonyl compounds and VOCs. AP, MJC, and CRD developed the analytical method and measured metals. CH and PJ developed the analytical method and measured TSNAs. MLG and JK analysed the data. All contributors approved the final version of the manuscript.

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NYC COALITION FOR A SMOKE-FREE CITY

Testimony of Sheelah Feinberg

Executive Director

NYC Coalition for a Smoke-Free City

before the

New York City Council Health Committee

regarding

Expanding the Smoke-Free Air Act to Include E-Cigarettes

December 4, 2013

City Hall Council Chambers New York, NY 10007 Good morning and thank you Council Member Arroyo and members of the Health Committee for the opportunity to speak today.

My name is Sheelah Feinberg, and I am the Executive Director of the NYC Coalition for a Smoke-Free City, a program of Public Health Solutions. The Coalition is a public health advocacy group that has worked with over one hundred health and youth focused community groups across the five boroughs to raise awareness around tobacco control and prevention. We support neighborhood efforts for long-term change and believe that all New Yorkers have the right to breathe clean, smoke-free air where they live, work, and play.

The Coalition and its partners are grateful to have a City Council and Mayor who have demonstrated an unprecedented commitment to improving public health. Our combined efforts have yielded historic success. Thanks to a comprehensive approach that includes bold policies, higher cigarette taxes, hard-hitting media campaigns, and cessation services to help smokers quit, the percentage of adults smoking in New York City is now 15.5%¹ and the percentage of public high school students who smoke has fallen to 8.5%.² This means thousands of lives saved, increased life expectancy, and improved health for all New Yorkers.

Earlier this year, the Coalition celebrated the ten-year anniversary of the Smoke-Free Air Act. New York City was considered a public health pioneer when we made our bars and restaurants smoke-free. What was at the time considered a contentious public health initiative is now widely embraced not only in New York City but also in other cities, states, and even other countries. The Smoke-Free Air Act has since been expanded to include hospital entryways as well as public parks, beaches, and pedestrian plazas.

However, with the emergence of e-cigarettes, our successes may be compromised. In fact, youth use of e-cigarettes doubled last year,³ and we are concerned that this unregulated product will serve as a nicotine starter kit for a new generation of smokers.

In the absence of federal guidelines, state and local governments must decide how to approach the sale and use of e-cigarettes. Many states, including New York, have set minimum purchase ages for e-cigarettes to try to prevent teenagers from becoming addicted to nicotine. As we know, New York City is now the first major city in the US to increase the minimum purchase age for tobacco products, including e-cigarettes, to twenty-one.

Adding e-cigarettes to the Smoke-Free Air Act is both welcome and necessary. The driving force for the original legislation was strong science and research showing that secondhand smoke from combustible cigarettes is harmful. Research suggests that the

² Youth Risk Behavior Survey, 2011. New York City Department of Health and Mental Hygiene.

Community Health Survey, 2012. New York City Department of Health and Mental Hygiene.

³ CDC Morbidity & Mortality Weekly Report, 11/15/2013:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6245a2.htm?s_cid=mm6245a2_w

vapor emitted from e-cigarettes is not free of carcinogens.^{4,5} Beyond the uncertainty about the safety of exposure to the vapor, restaurant patrons and workers should not have to worry about determining whether a person is smoking a real cigarette or "vaping" an e-cigarette. E-cigarettes are designed to mimic the look of real cigarettes. Allowing e-cigarettes in areas where smoking is prohibited would not only complicate enforcement of the Smoke-Free Air Act, but it would also mean that "smoking" would be seen in places where is hasn't been allowed for years.

While some have claimed that e-cigarettes are safe and a cessation aide, the evidence to back both of these claims simply does not exist at this time. The Food and Drug Administration has not declared e-cigarettes to be an effective tool for quitting smoking; and there is no research showing that e-cigarettes have helped smokers quit long-term or break nicotine addiction altogether. Also, many e-cigarette users smoke regular cigarettes too.

Why act now? As stated previously, the use of e-cigarettes is on the rise. With marketing and flavoring of e-cigarettes falling outside the current restrictions on the tobacco industry, e-cigarette manufacturers are running numerous ads, including during this year's Super Bowl, and targeting youth with flavors such as gummy bear, bubble gum, and caramel apple. While adding e-cigarettes to the Smoke-Free Air Act will not address all of these concerns, we believe it will prevent the re-normalization of smoking in places like restaurants and playgrounds.

New York City is not alone in the pursuit of limiting use of e-cigarettes to where smoking is permitted: New Jersey, Utah, South Dakota, and a number of localities have added e-cigarettes to their smoke-free laws. Forty-one state Attorneys General have urged the FDA to regulate e-cigarettes the same way as other tobacco products.⁶ In addition, Chicago officials recently announced their intention to expand their city's definition of tobacco products to include e-cigarettes. Under the proposal being discussed today, if a New York City adult wants to use an e-cigarette, he or she still can wherever smoking is permitted.

In closing, despite great progress, tobacco use still causes hundreds of thousands of preventable deaths in the United States annually, including thousands of lives lost here in New York. For over twenty years, the NYC Coalition for a Smoke-Free City has been a proud supporter of tobacco control and prevention efforts. While we believe that much more should be done to prevent the aggressive promotion of nicotine addiction regardless of the delivery mechanism, adding e-cigarettes to the New York City Smoke-Free Air Act is an important step for protecting public health and reducing the ongoing negative effects of smoking.

Thank you.

⁴ FDA 2009: <u>http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm</u>

⁵ Indoor Air, 2012: http://onlinelibrary.wiley.com/doi/10.1111/j.1600-0668.2012.00792.x/pdf

⁶ National Association of Attorneys General Letter to FDA. 10/23/2013

http://www.naag.org/assets/files/pdf/signons/E%20Cigarette%20Final%20Letter%20w%20Florida.pdf



RICHARD H. CARMONA, M.D., M.P.H., FACS 17th Surgeon Ceneral of the United States (2002-2006)

December 3, 2013

My name is Richard Carmona, and I served as the 17th Surgeon General of the United States. As we approach the 50th anniversary of the first Surgeon General's Report linking smoking and cancer, the plague of tobacco-caused death and disability still persists, killing over 430,000 Americans per year, while disabling millions more with preventable chronic diseases at a cost of hundreds of billions of dollars annually.

As a child I suffered from recurrent bouts of bronchitis living with unaware, chain-smoking parents whose deaths were hastened by tobacco as their quality of life slowly and painfully diminished. During my tenure as Surgeon General, my colleagues and I published reports detailing the preventable harm done by tobacco, spoke frequently to the public and to Congress about the catastrophic health damage caused by tobacco, and even participated as an expert witness in the federal government's case against the tobacco industry. I am particularly proud of my authorship of the 2006 Surgeon General's report on secondhand smoke, in which I wrote: "The debate is over. The science is clear: secondhand smoke is not a mere annoyance, but a serious health hazard that causes premature death and disease in children and non smoking adults."

Yet despite my actions and those of my predecessors like Surgeon General C. Everett Koop, high cigarette taxes, Food and Drug Administration (FDA)-approved smoking cessation therapies, and the best educational efforts by public health professionals, nearly 20% of the adult population and one-third of our military service members continue to smoke. The Centers for Disease Control (CDC) reports that adult smokers usually know they are engaged in harmful behavior and 69% would like to reduce or quit smoking. However, each year only 6% of smokers succeed in quitting, and new smokers replace those who successfully quit. The history and data suggest that we need more viable alternatives in this fight against tobacco.

Vice Chairman Canyon Ranch Chief Executive Officer Canyon Ranch Health President Canyon Ranch Institute Distinguished Professor Zuckerman College of Public Health University of Arizona I believe that one such alternative is the electronic cigarette. Despite their unfortunate name, electronic cigarettes are not actually cigarettes. They contain no tobacco but rather deliver nicotine without all of the toxic, carcinogenic, and other disease-causing products of tobacco combustion. (For example, they produce no carbon monoxide (a particularly lethal constituent of secondhand tobacco smoke) and produce no sidestream emissions (a source of 85% of secondhand tobacco smoke)). The published research suggests there may be a significant role for electronic cigarettes in tobacco harm reduction strategies, since they provide smokers both with the nicotine they crave and the smoking rituals that they have grown accustomed too. Respected Wall Street analysts have opined that, within a decade, electronic cigarette sales could overtake tobacco sales. I recently joined the board of NJOY, the leading independent electronic cigarette company, because its ambitions are even higher — to obsolete the tobacco cigarette entirely.

I am extremely concerned that a well-intentioned but scientifically un-supported effort like the current proposal to include electronic cigarettes in New York's current smoking ban, could constitute a giant step backward in the effort to defeat tobacco smoking. This regulation, if passed, would disincentivize smokers from switching to electronic cigarettes, since NJOY's research indicates that many initially switch for reasons of convenience. It would also send the unintended message to smokers that electronic cigarettes are as dangerous as tobacco smoking with the result that many will simply continue to smoke their current toxic products. Legislative action that would keep smokers smoking would obviously have serious health consequences.

I know that we all share the same vision of a world without tobacco related illness and disease. I strongly encourage you to resist calls to include electronic cigarettes in the City's smoking ban, which I believe would be a major step backward in the effort to achieve this aim.

Sincerely,

Richard Carmona

Richard Carmona, M.D., M.P.H., FACS 17th Surgeon General of the United States

NYC | HOSPITALITY ALLIANCE

Committee on Health, New York City Council Wednesday, December 4, 2013 at 10:00 a.m. Council Chambers, City Hall, New York, NY

Comments of Andrew Rigie, Executive Director, New York City Hospitality Alliance on:

Preconsidered Int. No. - In relation to the regulation of electronic cigarettes.

My name is Andrew Rigie and I am the Executive Director of the New York City Hospitality Alliance, a trade association representing restaurants and nightlife establishments impacted by the proposal to regulate electronic cigarettes.

Since electronic cigarettes have grown in popularity, restaurant and nightlife establishments have begun developing policies to allow or restrict their use indoors by customers and employees. However, the majority of businesses with whom The Alliance spoke reported that the use of e-cigarettes is non-existent, or so limited and isolated, that they have not become an issue of concern. However, in establishments where their use may be prevalent, policies to manage them are being developed based on different considerations, such as the following:

- Many customers and employees are using e-cigarettes as a tool to quit smoking traditional cigarettes, in part due to their convenience. So businesses are trying to accommodate these people and support their efforts to quit.
- In certain cases e-cigarettes have reduced the amount of people smoking traditional cigarettes on the street in front of bars and clubs, which reduces sidewalk cluttering and in turn reduces noise complaints from neighboring residents.
- Because research affirming negative health effects from second hand vapor is not conclusive some businesses have not yet moved towards a complete e-cigarette ban.
- Businesses have voluntarily banned the use of e-cigarettes as a means to please non-e-cigarette users.

Although e-cigarettes have grown in popularity there is not a proliferation of their use in New York City eating and drinking establishments. Furthermore, The Alliance understands that the FDA is in the process of determining how to regulate electronic cigarettes and the scientific community is researching their health effects. Therefore, we believe that it is premature for the City Council to pass the considered ban. However, the New York City Hospitality Alliance supports the Council's efforts to monitor the growing body of research relating to health effects associated with the second hand vapor of electronic cigarettes.

Respectfully submitted,

AwRigie

Andrew Rigie Executive Director arigie@theNYCalliance.org



December 3, 2013

New York City Council Committee on Health New York City Hall 250 Broadway New York, NY 10007

Subject: Comments on Proposed Regulation of Electronic Cigarettes

Dear Chairperson Arroyo and Committee on Health Members:

As the legal counsel for the National Association of Tobacco Outlets, Inc. (NATO), a national retail tobacco trade association, I am submitting this letter on behalf of the association regarding the proposed ordinance to include electronic cigarettes within the terms and provisions of the New York City Smoke-Free Air Act.

Underlying Basis for Smoke-Free Air Act Not Applicable to Electronic Cigarettes

According to a press release dated December 30, 2002 and issued by Mayor Michael Bloomberg, the New York City Council enacted the Smoke-Free Air Act in 1995 to protect its "citizens from the dangers of secondhand smoke." Subsequently, the Smoke-Free Air Act was amended in 2002 and Mayor Bloomberg stated that in extending the 1995 smoking restrictions "to almost all restaurants, bars and places of business, New York extends the protections from secondhand smoke to all of its workers." In fact, in his press release, Mayor Bloomberg announced that "New scientific evidence reveals additional significant health risks of secondhand smoke." These statements about secondhand smoke made by Mayor Bloomberg were reiterated by the New York City Health Department in support of the adoption of the 2002 amendments to the Smoke-Free Air Act (See Briefing Book, "Smoke-Free Workplace Legislation Will Save Lives—and It Won't Hurt Business, New York City Department of Health, 2002).

While scientific evidence regarding secondhand smoke formed the basis for the adoption and subsequent amendment of the Smoke-Free Air Act by the New York City Council, electronic cigarettes do not emit secondhand smoke because no tobacco is burned when an electronic cigarette is used. Rather, electronic cigarettes users exhale a vapor and a study conducted by Professor Igor Burstyn of the Drexel University School of Public Health concluded that claims regarding chemicals found in e-cigarette vapor were detected only "in trivial levels that pose no health risk" and are far below current "workplace standards for involuntary exposures." In other words, the underlying basis supporting the initial adoption and previous amendment of the Smoke-Free Air Act does not support the adoption of a further amendment to include restrictions on the use of electronic cigarettes.

FDA Undertaking Comprehensive Approach to Regulation of E-Cigarettes

On November 6, 2013, in an interview published in New Public Health, Mitch Zeller, the Director of the U.S. Food and Drug Administration's Center for Tobacco Products, stated that the agency is creating a comprehensive "regulatory framework to regulate electronic cigarettes." According to Director Zeller, the first step in the FDA's regulatory framework for e-cigarettes will be a new set of proposed federal rules that are currently under review by the White House Office of Management and Budget. Once approved by the OMB, the FDA will issue the proposed rules for public comment and then final adoption. These proposed rules are a serious first step in regulating electronic cigarettes on a nationwide basis.

The second step of this regulatory process is the FDA's "enormous investment in research" on electronic cigarettes to answer questions about how these products work, what kind of nicotine is being delivered, and who is using electronic cigarettes. In fact, in a press release issued on September 19, 2013, the FDA and the National Institutes of Health announced a partnership to create fourteen Tobacco Centers for Regulatory Science with "\$53 million [in funding] in the first year and a potential total of more than \$273 million over the next five years" to generate scientific research on tobacco products. As Director Zeller explained, scientific evidence is necessary to support regulatory actions and these research centers were created for that purpose.

New York City Amendment to Smoke-Free Air Act is Premature

The consideration by the New York City Committee on Health of the proposed amendment to the Smoke-Free Air Act to include electronic cigarettes is premature. In contrast to the comprehensive science-based regulatory approach being undertaken by the FDA, the proposed amendment to the Smoke-Free Air Act is based on conjecture and speculation with several broad and general statements in the "Legislative Findings" section that the use of electronic cigarettes "may interfere with smokers' attempts to quit smoking", children "may become addicted to nicotine and then switch to smoking cigarettes", and that e-cigarettes "may increase the social acceptability and appeal of smoking." Sound public policy should be based on scientific data and factual information, not on unsubstantiated claims. For this reason, the Committee on Health should follow the process utilized in the past by the New York City Council and postpone any action on restricting e-cigarette use under the Smoke-Free Air Act until the necessary scientific research and factual evidence regarding e-cigarettes becomes available.

In conclusion, I urge the Committee on Health to consider waiting until the FDA issues and adopts its proposed regulations on e-cigarettes and conducts the necessary scientific research and study to support reasonable, effective regulations. Given the FDA's comprehensive approach to studying and regulating e-cigarettes, it is premature to recommend to the New York City Council that the amendment to the Smoke-Free Air Act be considered for adoption.

Sincerely,

Thomas A. Briant

NATO Executive Director and Legal Counsel



Wednesday, December 4, 2013

Testimony of Patrick Norberto Smoke-Free NYC Coordinator

Madam Chair, esteemed members of the Committee, good morning/afternoon and thank you. I am grateful for the opportunity to address the Committee on the promotion and use of electronic cigarettes. My name is Patrick Norberto and I am the SYEP Director of the YM-YWHA of Washington Heights and Inwood and the coordinator of the Y's Smoke-Free NYC efforts.

For nearly one hundred years The Y's mission has been to advocate for and work toward improving the quality of life of those who live in Northern Manhattan. To that end every program the Y runs - from caring for our youngest children to providing summer jobs for youth to helping our mature adults spend their golden years actively and productively engaged - offers a significant health and wellness component that aims to boost the quality of their lives.

The Y has long been a committed and active partner in the campaign for a Smoke-Free NYC. Our Lawrence A. & Mae L. Wien House was the first HUD-funded low-income senior housing facility to become 100% smoke-free.

Our staff and teens successfully lobbied a number of local retailers to remove or substantially rearrange their tobacco product displays so our children would not be bombarded with the deceitful message that smoking acceptable or, worse, cool!

It concerns us that these products are currently unregulated and being sold without full knowledge of their impact on the health of the smoker and those who are subjected to the second-hand smoke. More to the point is that to permit the use of e-cigarettes in places currently off limits to regular cigarettes would negate a much of the hard-won results of the Y and our partners across the city. It is critical, to the continued success of our efforts to make NYC smoke-free, that the Council act to equate e-cigarettes with cigarettes and other tobacco products. Let's keep e-cigarettes with the regular cigarettes out of the workplaces and public spaces. Let's continue to keep the health and well-being of our children and seniors a top priority.

Thank you

FOR THE RECORD

NEW YORK CITY COUNCIL HEALTH COMMITTE HEARING ON PROPOSAL TO BAN THE PUBLIC USE OF ELECTRONIC CIGARETTES December 4, 2013

A "PUBLIC COMMENT"

Please see footnotes for published backup to the following arguments.

Ladies and Gentlemen of the Health Committee:

The proposal to ban the use of electronic cigarettes is a perfect example of the kind of irrational, counterproductive and moronic "zero tolerance" than expels little boys from school for chewing pop-tarts into something that vaguely resembles a gun.

Irrational because the alleged rationale for banning smokers from public places was "secondhand smoke" and...there IS no smoke with electronic cigarettes! No odor. No litter. No ash. Just heated water vapor.

You might as well ban tea pots.

3...

The arguments advanced for such a ban are themselves irrational-- and untrue.

1). It's been said that "we don't know what's in them." We do.

In order of quantity in a Blu brand ecig: "Distilled water, FCC Grade Vegetable glycerine, Nicotine, Natural and artifical flavors, Citric Acid." Half the ecigs on the market use naturally occuring vegetable glycerine; others use propylene glycol (PG)

Both glycerine and PG and all the flavors are FDA approved as safe and PG itself is cleared for use in food, toothpaste, cosmetics and everyday medicines like cough syrup, inhaled nasal sprays and eye drops, to name just a few.

2) It's said the vapors pose a "risk" to nonsmokers. They don't.

The main constituent in the vapor is...water.

As for ambient nicotine...

OSHA says workers can breathe 500 micrograms per cubic meter of air (500 ug/m3) for 8 hours a day, 40 hrs a week without harm. Experiments with animals exposed to huge doses of ambient nicotine for 20 hrs a day for 2 years showed no ill effect. (1) Ambient nicotine measured in bars in St. Louis where people were smoking real cigarettes, ranged from 1.15 ug/m3 to a high of 32.4, and a German study showed about the same: Restaurants, 15 ug/m3;bars, 31; with a packed disco

coming in at 193 -- all well below OSHA's safe-zone of up to 500. (2) And the amount of nicotine exhaled from an e-cig is exponentially smaller than from a Marlboro, say.

As for propylene glycol...

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a government (NIOSH) study showed that even airport workers exposed to the vapors from 800 gallons of PG forced through high pressure hoses for 6 hour shifts showed no ill effects (3) and other studies similarly confirmed its safety through inhalation at doses impossible to replicate with e-cigs. (ibid)

Finally, published tests on e-cig vapor show it's perfectly safe: Dr. Michael Siegel, a Public Health professor at Boson Univ and an activist anti smoker, links to a New Zealand study that " reveals (again by actual measurement) that the toxic emissions score- which is a score based on levels of 59 priority toxicants- was zero for electronic cigarettes." (4)

Further, he cites a study which concludes that: " The exhaled vapor from electronic cigarette smokers contained mainly propylene glycol, glycerin, and small amounts of nicotine. There does not appear to be any major concern regarding any dangers of exposure to "passive vaping." The bottom line is that electronic cigarettes show great promise as an effective smoking cessation device that greatly reduces health risks for smokers and at the same time, helps protect nonsmokers by eliminating secondhand smoke." (5)

With that out of the way, let's get back to the main issue: counterproductive, punitive, and, yes, moronic.

3: Counterproductive to the supposed interests of Public Health

Because hundreds of thousands of smokers have attested to having either cut down or quit smoking actual cigarettes because of e-cigarettes. And here we thought getting New Yorkers to do so was the city's sworn goal. Well, guess not. The goal seems to be to punish the very people who are doing what you've tried so valiantly to tax and vilify and nag and banish and coerce them into doing.

And the vilification seems to know no bounds. Smokers are apparently so odious a lot that anyone who LOOKS like a smoker should be condemned and. further, condemned to a life of solitude. Where do we go from here? Anyone putting something cylindrical into his mouth is not to be seen by Children? (And how many children, pray tell, are in bars?)

Next you will outlaw sucking a ballpoint pen.

-3-

4. Such a ban is not in any way "helpful" to smokers as the Council seems to think.

People who did not quit smoking because of the original smoking ban-- but simply quit going out as much as they had (or quit going out at all)-- will not be made to quit by an e-cig ban that may simply be affording them a window to normal life. They will once again withdraw. Nor will this be notably "helpful" to the city's restaurants and bars many of which closed or had to lay off workers because of the first ban, and now what you're planning is to zap them yet again.

5. Enforcement problems? Please.

The idea that e-cigs would impede the enforcement of the laws against smoking a real cigarette is just plain silly. Touch the cold tip of an e-cigarette and you know it's an e-cig. And anybody complaining from somewhere across the room is certifiably hypochondriac. There IS no odor. There IS no smoke. There IS no negative health effect on others. They've been brainwashed by propaganda to fear the sight of anything that LOOKS like a cigarette, and it's that irrational fear-manufactured and drummed into their heads by the city-- that's truly unhealthy.

The council's public statement about e-cigarettes also exposes that the reason behind the ban on real cigarettes wasn't, after all, the secondhand smoke. It was done to turn smokers themselves into outcasts as a way to "help" them quit. And the sponsors now openly justify the ban on the smokeless cigarettes for a similar purpose. This is the kind of "help" that gets given by Nurse Ratched.

From here, I can imagine a ban on the public drinking of Coca Cola (even if "sugar-free" since it LOOKS like the real thing) so The Children [™] don't get any terrible ideas.

Linda Stewart New York City

Disclaimer:

I do not use e-cigarettes or work for any company that has anything to do with them, or any venue where e-cigs are smoked. I'm just an average citizen of NYC who detests the overbearing direction of city government.

I am also distressed that the news of this so-called "public hearing" was withheld from the public till Thanksgiving eve and no means are afforded for standard written statements.

Footnotes, next page

Footnotes:

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(1) "For the first time we report the effect on the rat of long-term (two years) inhalation of nicotine. The rats breathed in a chamber with nicotine at a concentration giving twice the plasma concentration found in heavy smokers. Nicotine was given for 20 h a day, five days a week during a 2-year period. We could not find any increase in mortality, in atherosclerosis or frequency of tumors in these rats compared with controls. Particularly, there was no microscopic or macroscopic lung tumors nor any increase in pulmonary neuroendocrine cells. Throughout the study, however, the body weight of the nicotine exposed rats was reduced as compared with controls. In conclusion, our study does not indicate any harmful effect of nicotine when given in its pure form by inhalation."-- "Longterm Effects of inhaled nicotine," Waldum et al. http://www.ncbi.nlm.nih.gov/pubmed/8614291

(2) Nicotine levels in bars w. cig smokers: http://cleanairquality.blogspot.com/2006/11/is-secondhand-smoke-healthhazard.html

(3) A NIOSH study on the inhalation exposure of airport personnel using PG deicers (800 gallons forced through high pressure hoses for a 6-hour shift) found...nothing of concern. Breathing zone air samples indicated exposures of up to 94 mg/m3 for one hapless worker, with the average in a range of from 10-21. The researchers concluded:

 [T]here was no hazard from overexposure to deicing fluid.
 Airborne exposure to propylene glycol was low and propylene glycol has low toxicity.--(cerhr, op cit)

In another experiment, subjects spent an hour in a tightly-sealed tent filled with 10% PG aerosol mist. Again, "very little enter[ed] the lung." And even that aside:

The short half-life before saturation of metabolism does

not allow the build-up of toxicologically relevant doses. (Bau, cerhr, op cit)

In a final experiment (a staged simulation of an airline disaster) using PG mist, irritation wasn't observed until exposure levels averaged (179-851) 309 mg/m3

http://cerhr.niehs.nih.gov/chemicals/egpg/propylene/PG-Report_Final.pdf

(4) Wahlberg I. Tobacco-specific Nitrosamines in Unburnt New Zealand Tobaccos. Report to Health New Zealand Ltd. Swedish Match, 2004. (Link) Also http://tobaccoanalysis.blogpot.com June 30, 2009

(5) Schripp T, Markewitz D, Uhde E, Salthammer T. Does e-cigarette consumption cause passive vaping? *Indoor* Air 2012. DOI:10.1111/j.1600-0668.2012.00792.x. also http://tobaccoanalysis.blogspot.com June 28, 2012



Citizens Lobbying Against Smoker Harassment

P.O. Box 1036 Brooklyn, New York 11234 917-888-9317

December 4, 2013

Testimony of Audrey Silk, Founder City Council Health Committee File #T2013-7248 Legislation to add e-cigarettes to NYC Smoke-Free Air Act

My name is Audrey Silk and I am the founder of NYC Citizens Lobbying Against Smoker Harassment (C.L.A.S.H.)

The New York City Human Rights Law

Administrative Code of the City of New York Title 8

Updated 6/01/13

§ 8-101 Policy. In the City of New York, with its great cosmopolitan population, there is no greater danger to the health, morals, safety and welfare of the city and its inhabitants than the existence of groups prejudiced against one another and antagonistic to each other because of their actual or perceived differences, [including those based on race, color, creed, age, national origin, alienage or citizenship status, gender, sexual orientation, disability, marital status, partnership status, any lawful source of income, status as a vietim of domestic violence or status as a victim of sex offenses or stalking, lawful occupation, whether children are, may be or would be residing with a person or conviction or arrest record.] The council hereby finds and declares that prejudice, intolerance, bigotry, and discrimination and disorder occasioned thereby threaten the rights and proper privileges of its inhabitants and menace the institutions and foundation of a free democratic state.

Excerpts From the Council Notice

1

One of our greatest achievements in combating the devastating effects of *smoking* was passing the Smoke-Free Air Act. SmokING? Curb smoking??? Nicotine?? Sends the wrong message?? Allowing smokers?? ALLOWING??

DOH's 2002 FAQ Sheet on the Smoking Ban

Q: This is America. Don't citizens have a right to smoke, even if it hurts them?

A: Yes, smokers are free to continue to smoke—as long as they don't expose others involuntarily to cancer-causing chemicals. American democracy has always created laws to protect society from threats to our health and safety. Sometimes limits must be imposed on the right of one individual to engage in **behavior that**, while acceptable if it affects the individual only, is harmful to others.

So which is it? But for the gratuitous addition at the very end of your notice (almost like an afterthought to cover your behinds) on e-cig exposure, it's clear – by going after harmless vapor – your entire aim is – and may I say *has been* – that smokers are NOT free to continue to smoke and that it's not acceptable. That you are intolerant of it and that if you're not on the approved protected list this will not be a free democratic state.

Hiding behind "for the children" you seek to conscript me against my will into your waron-smoking army to carry your message. If smoking a cigarette "sends a message" – YOUR words -- then we are talking about my freedom of speech. Can I stand on a street corner and give a speech about my belief that it's normal to smoke? [ACTUALLY ASK AND WAIT FOR ANSWER] Then, according to you, how is my smoking a lit cigarette or e-constant any different from speech that, when expressed another way, you would call protected?

When it comes to the issue of smoking you are everything you despise. You are the bullies you have zero tolerance for with your intolerance of a legal lifestyle that doesn't fit yours. You are the stop and friskers of the health police.

As a NYC police officer for 20 years I had more authority than any one of you. I could arrest any of you for my reasons and have all the authority in the world to cuff you and process you. That the DA's office would drop it and tell me to let you go makes no never mind. You will have been subjected to my authority.

But I DIDN'T do that. But this is what YOU now hypocritically do. Your version of Stop & Frisk whereby you have opted to use your authority to violate someone's civil liberties because YOU have deemed the legal behavior wrong, same as you accuse the NYPD of violating many who have been stopped and frisked because the cop felt it best and had the authority to do it.

You'll protest you're different. That smoking is a health issue. Bullshit. You're not only no different, you're worse. No one invites being shot or stabbed. No one. Unlicensed guns – surely also a "health" issue – are illegal. Cigarettes are legal and many choose that pleasure over personal risk.

Then again, in the case of e-cigs it isn't even a health issue. With your "it hasn't been proven not to be harmful" you're practicing asserting a pink elephant is in the room and then demanding that we prove it isn't or else we lock you up! In science you have to prove to me that the pink elephant is there. Especially when you've moved from your proper role of advisor into an impediment of freedom of movement – the choice to smoke or not smoke based on that advice.

I believe nothing other than that this hearing is a sham. A theatrical production put on for the appearance of democracy and the opposition is nothing more than pawns for the show. With no regard your notice goes out on the eve of a 4 day holiday when many leave town, leaving many only two days to prepare. You offered no means by which to submit testimony by mail, freezing those who work for a living out of the debate, unlike the proponents who are here on their organization's paid clock.

You already know this is a done deal. So I'm not here to plead with you. I'm here to have it on record what I think of you and have always asserted about the anti-smoker movement. That by cartoonishly going after e-cigarettes because they LOOK like a cigarette proves that all the bans have nothing to do with "protecting others" – a role that you can argue is the government's – and all to do with those in position of power forcing people to comply with their views and silence dissent (censor smoking or anything that looks like it) – a role that can only be argued is the government's in a non-democratic country.

December 4, 2013

Testimony of Michael Shannon Vice President, External Affairs and Associate General Counsel

Before the Committee on Health, New York City Council.

I am Michael Shannon, Vice President of External Affairs and Associate General Counsel and am testifying on behalf of blu eCigs, the leading electronic cigarette company in the country. I am speaking today in opposition to a proposal that would include electronic cigarettes in the City's Smoke-Free Air Act.

This proposal would impose unnecessary and unfair restrictions on people who have made the personal choice to switch to electronic cigarettes. We are troubled that this proposal disregards recent scientific research and the opportunity for electronic cigarettes to provide a meaningful alternative for tobacco harm reduction.

The proposed amendment is part of a larger debate that often confuses important distinctions between traditional combustible cigarettes and electronic cigarettes.

E-cigarettes allow users to inhale an odorless vapor containing nicotine rather than tobacco smoke. E-cigarettes contain no tobacco, and as a result produce a *water vapor* – that evaporates in a few seconds. E-cigarettes have no combustion and therefore no ash, no tobacco smoke, and no unpleasant smell or noxious fumes for bystanders.

In a recent speech, Mitchell Zeller, head of the FDA's Center for Tobacco Products, called e-cigarettes "very interesting." He added: "You can look at them in the abstract from a harm perspective and say, if it's not tobacco, if it's not combusting, then does it make sense to look at it as something that might be potentially less harmful than any combustible tobacco product that's out there?"

Making less harmful products available to smokers as soon as possible should be a top priority. For too many years, tobacco policy has been mired in an all or nothing philosophy. Under this approach, smokers are presented with just one alternative: quit. This attitude has hindered the implementation of a public health strategy designed to reduce tobacco-related disease. E-cigarettes are likely much less harmful than combustible cigarettes and regulatory actions should treat e-cigarettes as separate and distinct from traditional combustible cigarettes. Proposals that equate the two products, however, will discourage smokers of combustible cigarettes who want to switch to an alternative product.

One source of confusion between traditional and electronic cigarettes involves the constituents of the vapor. Let me address that directly.

Well-respected public health advocates have concluded that accumulating evidence indicates electronic cigarettes may be safer because virtually none of the potentially harmful chemicals present in cigarette smoke are present in the vapor of electronic cigarettes.

This year, Lorillard conducted a study looking into the constituents of the vapor from e-cigarettes. The analysis found that the harmful or potentially harmful constituents found in the vapor were at or below detectible levels. As compared to combustible cigarettes, the reduction in these harmful constituent classes were at or near 100%, with the testing equipment's detection limits often being the limiting factor for reaching 100%. Further, there was no difference between the ambient air compared to the vapor from electronic cigarettes. Lorillard hopes to publish this study next year.

There are good reasons to regulate e-cigarettes, such as to ensure the quality and safety of the **produce**. The FDA has announced that it intends to assert its authority to regulate electronic cigarettes under the Tobacco Control Act. We expect this rule to be out soon. Lorillard stands ready to work with the FDA and its experts to develop sensible regulations – sensible regulations that encourage smokers to switch to e-cigarettes, sensible regulations that distinguish e-cigarettes from traditional tobacco products, sensible regulations that recognize e-cigarettes are likely the most significant tobacco harm reduction product ever.

By extending New York City's cigarette smoking ban to include the use of ecigarettes, this amendment discourages e-cigarettes use and will lock in smokers of combustible cigarettes. Why would a smoker switch to an e-cigarette if he or she has to go outside to vape with cigarettes smokers? Why would they switch if they are saddled with the same social stigma associated with combustible cigarette smoking?

We believe policy should acknowledge the distinct differences between electronic cigarettes and traditional combustible cigarettes. E-cigarettes are not the same as combustible cigarettes. In fact, e-cigarettes have little in common with combustible cigarettes. Therefore, the policy for e-cigarettes should have very little in common with the policy for combustible cigarettes. I ask that you reject this proposal.

Thank you for your time and consideration.

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Testimony before the New York City Council in Opposition to Legislation to Amend the Administrative Code to Include Electronic Cigarettes Within the Smoke-Free Air Act of New York City

Testimony of David Graham, Sr VP of International Regulatory Affairs on behalf of NJOY, Inc. before □ the New York City Council Committee on Health in opposition to T2013-7248.

December 4, 2013

Chair, members of the committee, my name is David Graham, Senior Vice President International Regulatory Affairs for NJOY Electronic Cigarettes. NJOY is America's number 1 electronic cigarette company that is independent of the tobacco industry. Our mission is to obsolete combustible tobacco cigarettes. We are science-based, and committed to act in the public health interest. Personally, I have worked for over 20 years with products and policies to help smokers quit and co-founded multiple tobacco control-related public-private partnerships including advocacy <u>for</u> smoke-free policies at global, national, and local levels. Thank you for the opportunity to address you today. I will make 4 main points:

1. The scientific basis for restrictions on secondhand smoke from <u>combustible tobacco cigarettes</u> is unequivocal.

In 1986, the Surgeon General's report concluded that second hand smoke caused lung cancer amongst non-smoking adults and respiratory problems amongst children. In 2006 the then Surgeon General, Dr Carmona released a follow up report on the health effects of secondhand smoke. He said then: "The debate is over. The science is clear,: secondhand smoke is not a mere annoyance, but a serious health hazard that causes premature death & disease in children and non smoking adults."

NYC established its Smoke-Free Air Act with the primary intent to protect workers from exposure to second hand tobacco smoke. Additional benefits included positive effects on smoking behavior such as encouraging smoking cessation. Such leadership, <u>founded on firm science</u>, was admired worldwide.

2. The basis for the proposal to restrict the use of electronic-cigarettes in public places could not be more different. It <u>does not</u> meet the evidence-based standards of the NYC smoke free air act. <u>Regarding exposure</u>: No evidence is cited in the proposed legislation to confirm that exposure to secondhand vapor from e-cigarettes is harmful to workers or anyone else. E-cigarettes contain no tobacco but rather deliver nicotine without all of the toxic, carcinogenic, and other disease-causing products of tobacco combustion. (e.g. they produce no carbon monoxide (a particularly lethal constituent of secondhand tobacco smoke) and produce no sidestream emissions (a source of 85% of secondhand tobacco smoke)).

NJOY has conducted testing for Harmful & Potentially Harmful Constituents (HPHC) according to FDA standards, and, other than nicotine, no detectable levels of HPHC were found in mainstream vapor of NJOY e-cigarettes. Further research is underway to assess secondhand exposure from the use of NJOY electronic cigarettes, and compare this to the exposure that would occur from conventional cigarettes.

<u>Regarding the effects of e-cigarettes on smoker behavior</u>. References to negative effects in the proposed bill are entirely speculative, without a clear base of evidence, and take no account of the potential for positive effects.

The Bill says that e-cigarettes: MAY INTERFERE with smokers' attempts to quit by making it easier for them to maintain their nicotine addiction.

• However, e-cigarettes POTENTIALLY PROMOTE smokers' attempts to quit by making an

Technical Report

Peering through the mist: What does the chemistry of contaminants in electronic cigarettes tell us about health risks?

Igor Burstyn, PhD

Department of Environmental and Occupational Health School of Public Health Drexel University 1505 Race St., Mail Stop #1034 Philadelphia, PA 19102 USA Tel: 215.762.2909 | Fax: 215.762.8846 igor.burstyn@drexel.edu

Abstract

The aim of this paper is to review available data on chemistry of aerosols and liquids of electronic cigarettes and to make predictions about compliance with occupational exposure limits of personal exposures of vapers (e-cigarette users) to compounds found in the aerosol. Both peer-reviewed and "grey" literatures were accessed and more than 9000 observations of highly variable quality were extracted. Comparisons to the most universally recognized workplace exposure standards, Threshold Limit Values (TLVs), were conducted under "worst case" assumptions about both chemical content of aerosol and liquids as well as behavior of vapers. The calculations reveal that there was no evidence of potential for exposures of e-cigarette users to contaminants that are associated with risk to health at a level that would warrant attention if it were an involuntary workplace exposures by approaching half of TLV. The vast majority of predicted exposures are <<1% of TLV. Predicted exposures to acrolein and formaldehyde are typically <5% TLV. Considering exposure to the aerosol as a mixture of contaminants did not indicate that exceeding half of TLV for mixtures was plausible. Only exposures to the declared major ingredients -- propylene glycol and glycerin -- warrant attention because of precautionary nature of TLVs for exposures to hydrocarbons with no established toxicity. Comparing the exposure to nicotine to existing occupational exposure standards is not valid so long as nicotinecontaining liquid is not mislabeled as nicotine-free. It must be noted that the quality of much of the data that was available for these assessment was poor, and so much can be done to improve certainty in this risk assessment. However, the existing research is of the quality that is comparable with most workplace assessments for novel technologies. In summary, an analysis of current state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to contaminants of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. However, the aerosol generated during vaping as a whole (contaminants plus declared ingredients), if it were an emission from industrial process, creates personal exposures that would justify surveillance of health among exposed persons in conjunction with investigation of means to keep health effects as low as reasonably achievable. Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.

Keywords: vaping, e-cigarettes, tobacco harm reduction, risk assessment, aerosol, occupational exposure limit

Introduction

Electronic cigarettes (also known as e-cigarettes) are generally recognized as a safer alternative to combusted tobacco products (reviewed in [1]), but there are conflicting claims about the degree to which these products warrant concern for the health of the vapers (e-cigarette users). A vaper inhales aerosol generated during heating of liquid contained in the e-cigarette. The technology and patterns of use are summarized by Etter [1], though there is doubt about how current, complete and accurate this information is. Rather conclusive evidence has been amassed to date on comparison of the chemistry of aerosol generated by electronic cigarettes to cigarette smoke [2-8]. However, it is meaningful to consider the question of whether aerosol generated by electronic cigarettes would warrant health concerns on its own, in part because vapers will include persons who would not have been smokers and for whom the question of harm reduction from smoking is therefore not relevant, and perhaps more importantly, simply because there is value in minimizing the harm of those practicing harm reduction.

One way of approaching risk evaluation in this setting is to rely on the practice, common in occupational hygiene, of relating the chemistry of industrial processes and the emissions they generate to the potential worst case of personal exposure and then drawing conclusions about whether there would be interventions in an occupational setting based on comparison to occupational exposure limits, which are designed to ensure safety of unintentionally exposed individuals. In that context, exposed individuals are assumed to be adults, and this assumption appears to be suitable for the intended consumers of electronic cigarettes. "Worst case" refers to the maximum personal exposure that can be achieved given what is known about the process that generates contaminated atmosphere (in the context of airborne exposure considered here) and the pattern of interaction with the contaminated atmosphere. It must be noted that harm reduction notions are embedded in this approach since it recognizes that while elimination of the exposure may be both impossible and undesirable, there nonetheless exists a level of exposure that is associated with negligible risks. To date, a comprehensive review of the chemistry of electronic cigarettes and the aerosols they generate has not been conducted, depriving the public of the important element of a risk-assessment process that is mandatory for environmental and occupational health policy making.

The present work considers both the contaminants present in liquids and aerosols as well as the declared ingredients in the liquids. The distinction between exposure to declared ingredients and contaminants of a consumer product is important in the context of comparison to occupational or environmental exposure standards. Occupational exposure limits are developed for unintentional exposures that a person does not elect to experience. For example, being a bread baker is a choice that does not involve election to be exposed to substances that cause asthma that are part of the flour dust (most commonly, wheat antigens and fungal enzymes). Therefore, suitable occupational exposure limits are created to attempt to protect individuals from such risk on the job, with no presumption of "assumed risk" inherent in the occupation. Likewise, special regulations are in effect to protect persons from unintentional exposure to nicotine in workplaces (http://www.cdc.gov/niosh/docs/81-123/pdfs/0446.pdf; accessed July 12, 2013), because in environments where such exposures are possible, it is reasonable to protect individuals who do not wish to experience its effects. In other words, occupational exposure limits are based on protecting people from involuntary and unwanted exposures, and thus can be seen as appropriately more stringent than the standards that might be used for hazards that people intentionally choose to accept.

By contrast, a person who elects to lawfully consume a substance is subject to different risk tolerance, as is demonstrated in the case of nicotine by the fact that legally sold cigarettes deliver doses of nicotine that exceed occupational exposure limits[9]: daily intake of 20 mg of nicotine, assuming nearly 100% absorption in the lungs and



Back to CASAA.org Main

FRIDAY, AUGUST 9, 2013

New study confirms that chemicals in electronic cigarettes pose minimal health risk

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PHILADELPHIA, Aug. 8, 2013/PRNewwire-USNewswire – E-cigarette users can breathe a little easier today. A study just released by Professor Igor Burstyn, Drexel University School of Public Health, confirms that chemicals in electronic cigarettes (e-cigarettes) pose no health concern for users or bystanders. This is the first definitive study of e-cigarette chemistry and finds that there are no health concerns based on generally accepted exposure limits.

E-cigarettes are devices that heat a nicotine solution to create an aerosol (called "vapor") that the user inhales, similar to smoking a cigarette. They are used as a low-risk substitute for smoking by millions of former smokers, and their increasing popularity seems to account for the current downward trend in smoking in the U.S. and some other countries. While experts agree that the risks posed by e-cigarettes are significantly less than those posed by smoking, there had been some debate about how much lower the risk was.

By reviewing over 9,000 observations about the chemistry of the vapor and the liquid in e-cigarettes, Dr. Burstyn was able to determine that the levels of contaminants e-cigarette users are exposed to are insignificant, far below levels that would pose any health risk. Additionally, there is no health risk to bystanders. Proposals to ban e-cigarettes in places where smoking is banned have been based on concern there is a potential risk to bystanders, but the study shows there is no concern.

This was the first study funded by the by The Consumer Advocates for Smokefree Alternatives (CASAA) Research Fund. CASAA, the leading consumer advocacy group promoting the availability and use of low-risk alternatives to smoking, is an all-volunteer, donation-funded organization. CASAA President Elaine Keller said of the study, "Over the years, there have been a lot of small studies of e-cigarette liquid and vapor, but those studies were either ignored or misinterpreted. Those that showed even the slightest contamination were used for propaganda by those who object to e-cigarettes because they look like



ABOUT CASAA

Our mission is to ensure the availability of effective, affordable and reduced harm alternatives to smoking by increasing public awareness and education; to encourage the testing and development of products to achieve acceptable safety standards and reasonable regulation; and to promote the benefits of reduced harm alternatives.

CONTENTS

- ▼ 2013 (122)
 - November (4)
 - October (8)
- September (11)
- August (26)

R.J. Reynolds launching TV commercial to promote V...

French e-cigarette study, media misrepresent facts...

Call to Action! Union City, CA May BAN E-Cigarett...

Anti-'vaping' legislation goes adrift

Wall Street Journal clarifies report of FDA "onlin...

Vero council delays vote to ban flavored tobacco (...

Call to Action: Please participate in the CASAA E-...

CASAA helps defeat California e-cigarette use ban

Canton toughens stance against smoking

Chicago Tribune CASAA "Letters to the Editor"

Helaine Baruch 251 West 87 – Apt52 New York, NY 10024

Testimony in Support of the proposal to regulate electronic cigarettes Submitted to: New York City Council, Committee on Health, Council Member Arroyo, Chair

December 4, 2013

To the members of the Council Committee on Health:

As a resident of Manhattan, and an advocate for strong tobacco control in our city, I would like to take this opportunity to thank our City Council for the tremendous leadership you have provided our city. Beginning more than a decade ago with the passage of the Smoke Free Air Act to the approval of two new laws in October which will serve to protect more New Yorkers from tobacco addiction-related diseases, your legacy speaks volumes for your support of public health.

Throughout today's hearing, you have heard compelling arguments about why electronic cigarettes must be regulated. There is no conclusive scientific evidence that there is a redeeming quality to these devices. The potential they offer to sustain a person's addiction to nicotine as opposed to encouraging them to quit completely is an over-riding concern.

However, I am here today to share with you a personal anecdote about my own experience of witnessing someone using an e-cigarette and the level of confusion I fear they could cause for business owners if they remain unregulated.

I was out with friends over the holiday weekend when I noticed someone near me, inside the restaurant, had starting smoking an e-cigarette. As someone who is passionate about breathing clean air, I politely asked if they could refrain from using the device near me. The response I received was an attempt to explain that they were just breathing out 'vapor.'

Much to their surprise, I reminded them that these devices were unregulated by the FDA and therefore we could not be 100% sure what they were releasing into the air. Furthermore, early studies have indicated that possible carcinogens and other toxic chemicals are found in their e-cigarettes.¹

While the conversation I had this past week was civil enough, the potential is great for confrontations to not end as well. It's not fair for us to burden business owners with the responsibility of deciphering if a patron is using an e-cigarette or a regular cigarette. And lastly, the best proven method for someone to curb their addiction is to seek approve cessation services which New York City often provides via the Department of Health and Mental Hygiene. By adding e-cigarettes to our city's Smoke Free Air Act, we are able to address all three concerns!

¹<u>http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm173327.htm</u>

Good Morning. I would like to present my case against the banning of e-cigarettes in public places.

Section 1 of this proposed bill concludes with "The Council therefore finds that prohibiting the use of electronic cigarette devices in public places and places of employment will protect the health of the citizens of New York City, facilitate enforcement of the Smoke-Free Air Act and protect youth from observing behaviors that could encourage them to smoke."

As for the health of the citizens of New York City, I propose that the use of electronic cigarettes doesn't pose a risk to public health. Although the harm to the user is debatable it has been established by the National Institute of Health that exposure to second hand vapor poses "no significant risk" to human health. The study, titled "Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality." States that "risk analyses were conducted based on dilution into a 40 m³ room and standard toxicological data. Non-cancer risk analysis revealed "No Significant Risk" of harm to human health for vapor samples". Keep in mind that this study was conducted indoors, in the outdoors, e-cigarette vapor would be even more diluted, posing even less of a health risk. Banning electronic cigarettes in workplaces and public areas would do nothing to affect public health.

It is important that the City of New York continues its enforcement of the Smoke-Free Air Act. Luckily the use of electronic cigarettes doesn't interfere with this act. Smoking is defined by the Smoke-Free Air Act as "inhaling, exhaling, burning or carrying any lighted cigar, cigarette, pipe, or any form of lighted object or device which contains tobacco." Because electronic cigarettes are neither lit or contain tobacco, they do not interfere with the act's prohibition of smoking in "public places" and "places of employment."

Finally, the number of new Yorkers that use electronic cigarettes is a mere fraction of those who use tobacco products such as cigarettes. A child is likely to see 10 people smoking on the streets of New York before he or she sees someone using an electronic cigarette. There are some amazing parents in New York City and I'm sure that just by talking to their child for a few minutes they can explain the harms of using tobacco and nicotine products. Thank you

I have provided a handout packet containing additional details from the aforementioned studies. Thank you for your time and I hope this information has helped clarify some of the misconceptions about electronic cigarettes. Thank you WARNING: You don't have to smoke to die from it. Second-hand smoke kills.

Executive Summary

Overview

Second-hand smoke causes illness in more than 40,000 New Yorkers and kills approximately 1,000 New Yorkers *every year*. Although the current New York City smoke-free law guarantees the right to a safe, smoke-free workplace for *some* employees, loopholes in the law may leave as many as a million workers—especially bar and restaurant workers—unprotected from second-hand smoke. Closing those loopholes could save 11,000 lives in New York City and won't hurt business.

Tobacco—The Leading Epidemic of Our Time (Fact Sheet 1)

- ◆ Cigarettes are the #1 cause of premature death in the United States. From 1995 to 1999, smoking caused more than 440,000 premature deaths each year.
- Smoking is also the #1 cause of preventable death in New York City, killing more than one New Yorker every hour—twice as many as AIDS, alcohol, murder, and suicide combined.
- More than a million New Yorkers smoke and, unless urgent action is taken, nearly 100,000 New Yorkers will die from tobacco-related diseases over the next 10 years, nearly half before they're 65 years old.
- Smoking costs Americans more than \$157 billion a year in health-care costs, decreased productivity, and lost earnings.

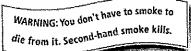
Second-Hand Smoke Kills (Fact Sheet 2)

- Second-hand smoke—the smoke we breathe from other people's cigarettes—causes cancer, heart disease, and many other illnesses. This has been verified by the U.S. Environmental Protection Agency, the Surgeon General, the Centers for Disease Control and Prevention, the International Agency for Research on Cancer, and the World Health Organization.
- Second-hand smoke contains many of the chemicals classified by the U.S. Environmental Protection Agency as "Group A" carcinogens, such as arsenic, benzene, and vinyl chloride.
- Second-hand smoke is a leading cause of death in the U.S., killing more than 40,000 people each year, including approximately 1,000 New Yorkers.
- The number of cancer deaths caused by second-hand smoke is higher than the total number of cancer deaths caused by asbestos, radionuclides, arsenic, benzene, vinyl chloride, radiation, pesticides, hazardous waste sites, chemicals found in drinking water, industrial chemicals, contaminated sludge, and mining waste *combined*.
- ◆ Just 30 minutes of exposure to second-hand smoke produces some of the same physical reactions as would occur from smoking.
- ◆ Second-hand smoke causes illness, such as ear infections in children, asthma, and respiratory infections, in more than 40,000 New Yorkers every year.





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Closing the Loopholes in New York City's Smoke-Free Law Could Save 11,000 Lives (Fact Sheet 3)

- New York City's current smoke-free law may leave as many as one million workers unprotected from second-hand smoke.
- ♦ Wait staff, cooks, and bartenders have the highest level of exposure to second-hand smoke of any occupational group—up to 2 to 6 times higher than people who work in offices. In an 8-hour shift, bartenders inhale the same amount of cancer-causing chemicals from second-hand smoke as if they'd smoked more than half a pack of cigarettes.
- Bar and restaurant workers are 50% more likely to get lung cancer than other workers, even after taking their own smoking habits into account.
- ◆ Extending the smoke-free workplace law could save 11,000 lives in New York City, including 4,000 non-smokers currently exposed to second-hand smoke at work, and 7,000 smokers who otherwise would have died from a tobacco-related illness (among the 22,000 smokers expected to quit if the law is strengthened).
- ◆ Studies indicate that 10% to 20% of smokers would quit if smoking were prohibited in their workplace. Even among those who continue to smoke, average consumption would decrease by 6% nearly 100 million fewer cigarettes smoked every year in New York City.
- ♦ New York City voters support stronger smoke-free workplace laws—eliminating smoking in all offices, restaurants, and bars—by a margin of 3 to 1.

Smoke-Free Workplace Laws Don't Hurt Business (Fact Sheet 4)

- Smoke-free workplace laws have had either a neutral or positive effect on business. Studies analyzing objective economic measures such as sales and employment figures have found no negative economic impact.
- Even the tobacco industry admits that smoke-free workplace laws don't hurt business: "...the economic arguments often used by the industry to scare off smoking ban activity were no longer working...These arguments simply had no credibility with the public, which isn't surprising when you consider that our dire predictions in the past rarely came true." —Internal document, Philip Morris, 1994.
- Smoke-free workplace laws do not hurt tourism. Europeans and other foreign nationals have lower per capita tobacco consumption rates than Americans. Market share analyses of international tourism indicate that smoke-free workplace policies do not change travelers' choice of destination.



The risks and benefits of long-term use of nicotine replacement therapy products

Verbal Comments

David T Sweanor J.D. Adjunct Professor Faculty of Law University of Ottawa Canada

Introduction

I have worked as a public health advocate on tobacco issues for nearly 30 years, and been a key player in the setting of many global precedents in tobacco control. These include issues of tobacco taxation, control of contraband, smoke-free policies, marketing restrictions, package health warnings, sales restrictions and product regulation. I have also been active, but not nearly as successful, in promoting policies that facilitate smoking cessation. I believe that efforts to motivate smokers to quit need to be inextricably linked to efforts that facilitate cessation if we are to achieve public health goals, and that the failure to offer viable options to dissonant smokers is a failure of health policy and a denial of the rights of smokers.

A Sufficient Case for Action on Longer Term Use of Medicinal Nicotine

There have been ongoing discussions - for decades - on the potential public health benefits of giving nicotine without the smoke. I have personally been involved in meetings, conferences, published papers and media interest in this issue since the 1980s. My position is that it is time to move beyond talk, to recognize that the health gains that can be achieved are truly enormous and that consumers have a right to the least toxic products that a sensibly regulated market can provide.

While there is a lot of science on the relative risk of different forms of nicotine delivery I think a lot of the attention to laboratory science, and the constant refrain of 'what if's' about potential harm obscures the bigger picture of the potential we have to dramatically reduce an overwhelming cause of death and disease. In fact at this stage I think we are better served looking not to esoteric areas of bench science, but to the ancient Greeks and logos – the ability to reason to a conclusion.

In a hopefully succinct overview, my reasoning is as follows:

- 1) We know, without doubt, that smoking cigarettes is an enormous cause of illness and death, from causes that include cancers, lung disease and cardiovascular disease.
- 2) We know that nicotine dependence will not simply be eliminated anytime soon that an 'abstinence only' approach to the drug is simply not viable. Nicotine is used, like other drugs, for a combination of social reasons, addiction and self-medication. Many millions of these people will continue their use of nicotine, and in the absence of viable alternative delivery systems millions of future deaths will result.
- As with any other cause of injury or disease, reducing the harm from nicotine use can be accomplished by a combination of four distinct areas of intervention. Measures can be taken aimed at:
 - a. Preventing the onset of the dangerous activity.
 - b. Cessation of the activity.
 - c. Protection of third parties from harm caused by the activity.
 - d. Reducing risks of those who engage in the activity.

- 4) There have been many successful interventions based on the first three of these four areas of intervention but the failure to properly integrate the fourth leg of public health interventions is like going to a race track and betting on a three legged horse.
- 5) Yet we know that it is possible to obtain nicotine with massively reduced risk to the user, and the virtual elimination of risks to bystanders. Reducing risk is not merely theoretical. We know this not just because we can predict, from our knowledge of human health, that getting a drug without decades of sucking smoke into the lungs is sure to be less toxic than getting it with that smoke. We can also look at the data to date on the risks of longer term use of NRT. But, most convincing of all, we can look at the very long history of a very big market for non-combustion based nicotine delivery in Sweden.
- 6) With over a million snus users, and with this use going back many decades, Sweden is a tremendously important case study of the ability to deliver nicotine with reduced risk. The results are astounding in that it is clear that the absence of smoke appears to virtually eliminate the major causes of the death and disease currently associated with tobacco use.
- 7) The Swedish health data also help us answer questions on potential risks. Experiments from various scientific disciplines regularly raise questions about potential risks from nicotine. But a simple look at Swedish health data can tell us that these theoretical concerns do not translate into significant actual health risks.
- 8) Because cigarette smoking is such an enormous cause of death and disease, anything even a small fraction of that risk could not fail to be noticeable in population health statistics. The 'what if' questions about some huge as yet unrecognized cause of disease from nicotine itself, given the very high quality of the Swedish health data, is on par with positing what if there has been an elephant living in one's backyard for many years and it is just that no one has noticed it yet.
- 9) With tobacco-based Swedish snus being so low in relative risk, the only basis for believing that this is not sufficient proof of concept for health gains to be achieved from greater provision of long term medicinal nicotine must logically be that there is a fear that a purer form of nicotine might somehow be much more dangerous. Yet there is no logical basis for holding that a product with fewer toxins might somehow be more toxic, and those who hold such a view should, but typically do not, show logical consistency by advocating that smokers use snus instead.
- 10) The reputed 'success' of tobacco control efforts look very poor when compared to other public health efforts where there was a viable way to reduce use. It did not take decades to reduce by half the prevalence of the use of leaded paint or leaded gasoline. Faced with the inescapable fact that 'it's the smoke, stupid', the failure to offer alternative delivery systems for nicotine has been a public health disaster.
- 11) In the absence of consumer-acceptable medicinal nicotine products for long term use it is not that smokers are left with no choices, just that they are left with far less reasonable ones. They already choose different brands of cigarettes in the mistaken belief that they can reduce their risks. They can choose from a wide variety of smokeless tobacco products. They can choose from a similarly wide variety of unregulated alternative products like electronic cigarettes. Dissonant smokers are not prevented from trying to reduce their risks; merely from making informed choices from a range of viable alternatives.
- 12) We know that, at the very least, a huge majority of this disease burden is a direct cause of the inhalation of smoke. Repeated inhalation of smoke into the lungs is a very bad thing for the human body. By way of analogy, if most people obtained caffeine by smoking tea leaves the way most currently get nicotine by smoking tobacco leaves, it too would be an enormous cause of ill health. Imagine what we would recommend to a land where the major form of caffeine intake was through smoking tea leaves, and then treat cigarette smokers here with the same respect.



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> New York City Council Committee on Health

Testimony of Kevin O'Flaherty Director of Advocacy, Northeast Region Campaign for Tobacco-Free Kids

In Support of Proposed Inclusion of E-Cigarettes in Current Smokefree Law

New York, NY December 4, 2013

Introduction

Smoke-free laws that protect everyone's right to breathe clean air in most workplaces and public places now cover a majority of the U.S. population. These laws have been a huge public health success—implemented with ease and high compliance and saving lives and health care dollars. They not only protect Americans from the thousands of chemicals in secondhand smoke; they also create an environment that discourages smoking among kids and encourages smokers to quit. Allowing the use of electronic cigarettes (e-cigarettes) in workplaces and public places threatens to reverse much of the improvement in public health that smoke-free laws have brought about.

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E-cigarettes are currently unregulated by the Food and Drug Administration (FDA) or any other health agency. They are relatively new and come in a dizzying variety of characteristics, contents, and flavors. Because of the many unknowns about their harm to individual users and non-users, as well as about their impact on youth smoking and discouraging quitting, it is extremely premature to allow the use of e-cigarettes in workplaces and public places. In addition, allowing their use in these places will complicate enforcement of smoke-free laws.

<u>The risks of e-cigarettes are too unknown to allow their use in workplaces and public places.</u>

While e-cigarettes may be less harmful than conventional cigarettes, little is known about the impact of exposure to the inhaled or exhaled vapor. Because they are not currently regulated by the FDA, there are no product standards or even a requirement for ingredient disclosure; and the wide variety of products on the market makes the risks even more uncertain. Some studies have identified chemicals in the nicotine solution and vapor from e-cigarettes.

- According to the FDA, because the safety and efficacy of e-cigarettes have not been fully studied, consumers currently have no way of knowing whether ecigarettes are safe for their intended use, how much nicotine or other potentially harmful chemicals are being inhaled during use, or if there are any benefits associated with using these products.¹
- A 2009 analysis by the FDA found that some e-cigarette cartridges contained diethylene glycol, a toxic substance also used in antifreeze, as well as some nitrosamines, which are carcinogens.²
- Several of the products themselves include warnings that inhaled nicotine is "very toxic."³
- Studies show that e-cigarettes produce more than just nicotine vapor and water. The vapors generated by e-cigarettes have been found to contain toxins, including formaldehyde, acetaldehyde, acrolein, volatile organic compounds like benzene and toluene, tobacco-specific nitrosamines, and metals like cadmium,

nickel, and lead.⁴ Though levels of these compounds are generally lower than those found in mainstream cigarette smoke, they still are among those identified as harmful or potentially harmful substances by the FDA.⁵

• At least one study has found that the use of e-cigarettes releases chemicals and ultrafine/fine particles, including volatile organic compounds and nicotine, into the air.⁶ This raises concerns about the effects of "passive vaping." As one researcher notes, "...while not polluting as a conventional cigarette, the e-cigarettes *are* putting detectable levels of several significant carcinogens and toxins in the air" [emphasis in original].⁷ Furthermore, using e-cigarettes in enclosed spaces could concentrate the released vapor (and, therefore, the airborne chemicals), which could pose additional health risks to non-users.⁸

Smoke-free laws protect everyone's right to breathe clean air. Given the uncertainties about the harm of e-cigarette vapor, it makes no sense for non-users to be exposed to it. While e-cigarette users are free to choose to take the risk of using these products themselves, the rights of non-smokers not to breathe potentially toxic substances must continue to be protected.

Allowing e-cigarette use will undermine enforcement of smoke-free laws.

Smoke-free laws have been implemented successfully across the country with few problems and near-universal compliance rates.⁹ For example, just one year after implementation of New York City's Clean Indoor Air Act, Health Department inspections found that 97 percent of restaurants and bars were smoke-free.¹⁰ These laws work because the rules are simple and clear and easily understood by business owners, workers, patrons, and enforcement agencies.

Allowing e-cigarettes in workplaces and public places would cause needless confusion and complicate enforcement of smoke-free laws. Not only are some e-cigarettes made to closely resemble conventional cigarettes and be smoked like them; the marketing of these products in television and other advertising promotes their use in a way that mimics smoking conventional cigarettes.

Business owners, employees, and enforcement officers would have to make an extra effort to distinguish between e-cigarettes and actual cigarettes and possibly take time to referee disputes between users and other customers. Having to distinguish e-cigarettes from others will complicate enforcement and may even make smokers of conventional cigarettes think smoking is allowed.

These problems are entirely avoidable by including e-cigarettes in smoke-free laws along with other tobacco products. Experience in smoke-free cities and states shows that customers quickly adjust to smoke-free laws, and even smokers come to support them. Including e-cigarettes in the law means that those wishing to use the products would simply need to step outside, just as cigarette smokers do under the law. And just as cigarette smokers across the country have adjusted to abiding by smoke-free laws, e-cigarette users will adjust as well.

Smoke-free laws are working to improve public health and should not be undermined.

As noted above, a majority of the U.S. population now lives in jurisdictions that prohibit smoking in most workplaces and public places. Smoke-free laws not only protect everyone's right to breathe clean air; they also create an environment in which smokers are more likely to try to quit and succeed in doing so and in which kids are less likely to start smoking. Allowing e-cigarettes in workplaces and public places could reverse this progress.

- By encouraging smokers to use e-cigarettes in places where they cannot smoke, e-cigarette marketing discourages quitting by offering smokers a way to get nicotine when they otherwise cannot.
- Allowing e-cigarette smoking in workplaces and public places will add to the reglamorization of smoking that e-cigarette companies are attempting to achieve through their marketing efforts, which include many of the same tactics and themes that have addicted kids for decades.¹¹

Conclusion on e-cigarettes and smoke-free laws

Despite the dramatic rise in the use of e-cigarettes, there is still very little known about the potential health risks they pose to both users and non-users. The use of e-cigarettes in otherwise smoke-free places raises challenges for enforcement and has the potential to undermine the public health impact of smoke-free laws. Including e-cigarettes in smoke-free laws is the best policy for public health and the best policy to protect everyone's right to breathe clean air.

E-cigarettes as a harm reduction strategy

Some argue that e-cigarettes should not be regulated or minimally regulated because they are less harmful than cigarettes and can, therefore, be used as a replacement product for more harmful conventional cigarettes. However, the science is far from clear on the harms of inhaled or exhaled e-cigarette vapor. Moreover, even if e-cigarettes are less harmful than conventional ones, if they serve to draw more kids into nicotine addiction and potential smoking, discourage rather than help smokers quit by serving as a bridge product for smokers when they can't smoke, and/or lure former smokers back into smoking, they will do more harm than good.

Today, despite many anecdotes about smokers quitting with e-cigarettes, there is little evidence that they are safe and effective cessation products, and no manufacturer has applied to the FDA for such a designation. There is disturbing evidence that youth are experimenting with e-cigarettes in increasing numbers. Given the potential harm and uncertain science on the impact of e-cigarettes, common-sense restrictions are needed to limit their appeal to kids, protect non-users from exhaled vapor, and discourage smokers from simply using them as a bridge product.

Evidence is limited that e-cigarettes help smokers quit.

Promoters of e-cigarettes argue that many smokers are using e-cigarettes to quit smoking conventional cigarettes. However, there is a lack of evidence that e-cigarettes are a safe and effective smoking cessation device. According to the Centers for Disease Control and Prevention (CDC) "There is currently no conclusive scientific evidence that e-cigarettes promote long-term cessation, and e-cigarettes are not included as a recommended smoking cessation method by the U.S. Public Health Service."¹²

In order for e-cigarette manufacturers to make a cessation claim, they must first demonstrate to the FDA that the product is a safe and effective tool for quitting smoking. To date, no e-cigarette product has received such approval from the FDA (and we are not aware that any such applications have been submitted).

While a few studies have shown that e-cigarettes have been helpful in quitting, several others have shown that e-cigarettes DO NOT help smokers quit.

- A 2013 study in the American Journal of Preventive Medicine found that users of e-cigarettes were not more likely to quit smoking than non-users.¹³
- A 2013 study of tobacco cessation Quitline callers found that e-cigarette users were significantly less likely to be abstinent seven months after the Quitline intervention than were participants who had never tried e-cigarettes.¹⁴
- Another 2013 study found that current smokers who tried e-cigarettes did not differ from current smokers who never tried e-cigarettes in their plans to quit smoking or in their quit attempts.¹⁵

Even a "less harmful" e-cigarette could do more harm than good to individual smokers and public health.

Even if e-cigarettes are less harmful that conventional cigarettes, they will do more harm than good if they serve to keep some smokers smoking, draw kids into nicotine addiction and potential use of conventional cigarettes, and lure former smokers back into smoking.

If smokers mistakenly believe that e-cigarettes will help them quit smoking, they may be discouraged from using those interventions that have been proven safe and effective for quitting—such as nicotine replacement therapies (NRT)—and end up continuing to smoke. Even if the use of e-cigarettes results in people smoking fewer conventional cigarettes, if it extends the duration of their conventional cigarette smoking, it will do more harm than good.

• The risk of lung cancer and other smoking-related diseases depends largely on how long a person smokes—not just the number of cigarettes smoked.¹⁶ Therefore, prolonging smoking, even if a person is smoking fewer cigarettes by using e-cigarettes, will continue to put that person's health at greater risk than if he/she had quit smoking entirely.

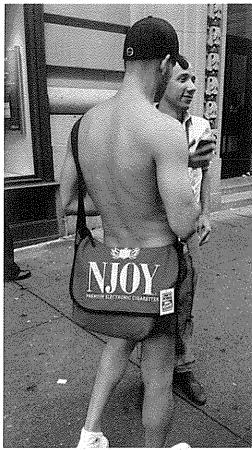
A growing number of kids are using e-cigarettes.

E-cigarettes are not just marketed to adult smokers. The combination of flavorings, "high-tech" image, and social media marketing potentially make these products even more attractive to youth and young adults.¹⁷ Thus, e-cigarettes can serve as yet another path to addiction and potential progression to conventional cigarettes among youth. With the three major cigarette manufacturers (Phillip Morris, Reynolds, and Lorillard) now in the e-cigarette business with their multi-billion dollar marketing budgets and history of marketing to kids, the risk is even greater.

Data recently released by the CDC show that the number of high school and middle school students who have ever tried e-cigarettes doubled between 2011 and 2012, drawing them into potential nicotine addiction and possible progression to smoking conventional cigarettes.

- From 2011 2012, ever use of e-cigarettes among all students in grades 6 12 more than doubled, from 3.3% to 6.8%. Among high school students alone, everuse increased from 4.7% to 10%.¹⁸
- This doubling of e-cigarette experimentation and recent use among middle and high school students translates into an estimated 1.78 million youth in 2012 who had used e-cigarettes.¹⁹
- State data show similar trends. In Florida, the percentage of high school students who had tried an e-cigarette more than doubled between 2011 and 2013, from 6% to 12.1%. 1.8% of middle school and 5.4% of high school students in the state currently use e-cigarettes.²⁰

This is disturbing but not surprising given that the marketing tactics and themes mirror the efforts that have been used by tobacco companies for decades to addict generations of kids to tobacco products. Television advertising, ubiquitous retail displays, sports and music sponsorships, association with celebrities, and the use of flavors are tactics that are all too familiar, as are the themes of masculinity, glamour, sex, and rebellion that are used to market e-cigarettes. Sex



Handing out free samples of NJOY at the New York City Gay Pride Parade, 2013

Retail Placement



Truck stop convenience store, York, Nebraska, April 2013. Courtesy of Counter Tobacco, www.countertobacco.org

Glamour



August 15, 2013 Screenshot of blu e-cigarette YouTube video, featuring Jenny McCarthy

Sports and Music Sponsorships



blu e-cigarette sponsorship of The Governors Ball Music Festival, June 2013, NYC

Recent data shows the majority of youth e-cigarette users are dual-users.

- The recent CDC study also found that 76% of middle and high school students who had used an e-cigarette in the past 30 days had also smoked conventional cigarettes in the same time period.²¹
- As with the national data, the Florida data also show concurrent use of ecigarettes and conventional ones. Among Florida High school students who had smoked e-cigarettes in the past month, 64% had also smoked conventional cigarettes during that time period.²²

E-cigarette marketing urges smokers to use e-cigarettes at times and in places where they cannot smoke conventional cigarettes. This type of marketing encourages this dual use of electronic and conventional cigarettes, thus promoting continued smoking. One study found that more than 80% of e-cigarette users pointed to use in smoke-free zones as a reason for using the product.²³



Magazine ads for blu e-cigarettes, 2011 and 2012. Source: Trinkets & Trash, www.trinketsandtrash.org

Innovative cessation interventions are needed but must be based in science.

With tobacco use still killing more than 430,000 Americans every year, we need new and innovative ways to help smokers quit in order to save lives and health care dollars. These interventions must be based in science, however. If products are promoted to reduce smoking when their real effect is to discourage quitting and encourage initiation, we will continue to pay the price in lives lost and health care costs.

If, as some claim, there is evidence for e-cigarettes in terms of helping smokers quit, the companies should demonstrate that to the FDA so the products can be promoted as such.

¹ U.S. Food and Drug Administration (FDA), <u>http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm</u> ² FDA, *Summary of results: Laboratory analysis of electronic cigarettes conducted by FDA*, July 22, 2009, accessed April 5, 2012 from <u>http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm</u>.

³ Product packaging for at least three e-cigarettes (NJOY, MarkTen, and Mistic) include warnings that state nicotine is "very toxic by inhalation."

⁴ Goniewicz, et al., "Levels of selected carcinogens and toxicants in vapour from electronic cigarettes," *Tobacco Control*, March 6, 2013, doi:10.1136/tobaccocontrol-2012-050859. Williams, M., et al., "Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette CArtomizer Fluid and Aerosol," *PlosOne*, 8(3), March 2013. See also Williams, M., "Electronic Cigarette Liquids and Vapors: Is It Harmless Water Vapor," presented October 3, 2013 at TRDRP Electronic Cigarette Webinar, <u>http://www.trdrp.org/docs/Williams%20e-cig%20vapor%20this%20time%20slides%202013.pdf</u>.

⁵ Goniewicz, et al., "Levels of selected carcinogens and toxicants in vapour from electronic cigarettes," *Tobacco Control*, March 6, 2013, doi:10.1136/tobaccocontrol-2012-050859. Williams, M., et al., "Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette CArtomizer Fluid and Aerosol," *PlosOne*, 8(3), March 2013. See also FDA, "Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke:

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Schripp, T, et al., "Does e-cigarette consumption cause passive vaping?" Indoor Air, 23:25-31, 2013.

⁷ Glantz. S. "e-cigarettes release toxic chemicals indoors, should be included in clean indoor air laws and policies," September 19, 2012, http://www.tobacco.ucsf.edu/e-cigarettes-release-toxic-chemicals-indoors-should-be-includedclean-indoor-air-laws-and-policies.

The Department of Transportation's notice of proposed rulemaking to prohibit the use of e-cigarettes in airplanes along with cigarettes stated, "We are unaware of sufficient studies on the health impact on third parties from these vapors to conclude that they would not negatively impact the air quality within the aircraft and/or increase the risk of adverse health effects on passengers and crewmembers." [Department of Transportation, "Notice of Proposed Rulemaking on Smoking of Electronic Cigarettes on Aircraft," Docket No. DOT-OST-2011-0044, Federal Register 76(179):57008-57012, September 15, 2011.1

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¹⁴ Vickerman, K., et al. "Use of Electronic Cigarettes Among State Tobacco Cessation Quitline Callers," *Nicotine* & Tobacco Research, 2013, doi: 10,1093/ntr/ntt061

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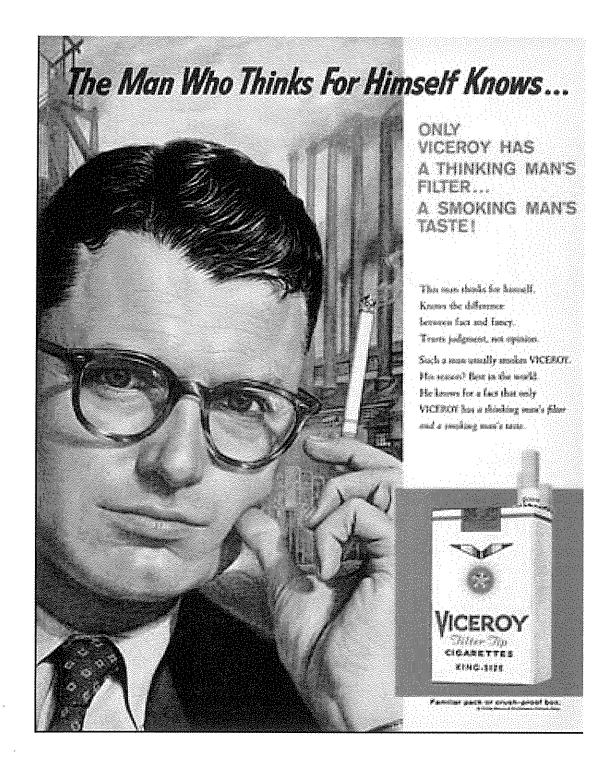
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This man thinks for himself. Knows the difference between fact and fancy. Trusts judgment, not opinion.

Such a man usually smokes VICEROY. His reason? Best in the world. He knows for a fact that only VICEROY has a thinking man's filter and a smoking man's taste.

BAD FLASHBACK -- Reminiscent of Lorillard's ads for True cigarettes in the 1970s.

WHY QUIT? SWITCH TO BLU

bies is the second charge for southers working a charge light light book your insection to smake when and where your work without light is small also is everything you enjoy about smalling and realizing the Habedy likes a gainer, so make the switch today.

Visit blucigs com

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PREMIUM EXECTEDNIC COGRESSIES Be only instrumentation of the second state of the seco Considering all I'd heard, I decided to either quit or smoke True.

I smoke True.

The low tar, low nicotine cigarette. Think about it.

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DEAR SMOKING BAN,

blu ELECTRONIC CIGARETTE

Take back your freedom to smoke anywhere with blu electronic cigarettes. blu produces no smoke and no ash, only vapor, making it the smarter alternative to regular cigarettes. It's the most satisfying way to tell the smoking bans to kiss off. Okay, maybe the second-most satisfying way.

New blu Smart Pack

bİu

only.

blucigs.com

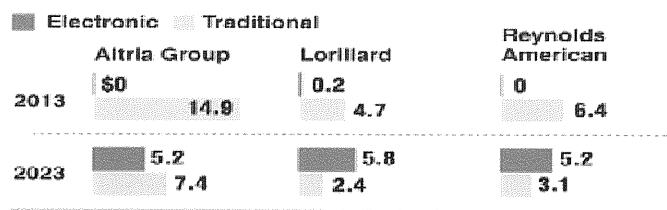
CALIFORNIA PROPOSITION 65 Worning: This product contains nicotine, a chemical known to the state of California to cause birth delects or other reproductive horm.

About e-cigarettes

Revenue from electronic cigarettes for the top U.S. cigarette manufacturers is projected to near or surpass revenue from traditional cigarettes by 2023.

Growing e-cigarette market

Actual and projected revenue, in billions



How e-cigarettes work

Light Simulates cigarette glow, indicates when device is ready for use and works as battery indicator Electronic components Include control circuits, pneumatic airflow sensor Vaporizer Atomizes the nicotine smoking liquid in the liquid container

Nicotine liquid container



Nicotine levels compared

Electronic

Traditioal

One e-cigarette	Equivalent	6-7 cigarettes
· • • • • • • • • • • • • • • • • • • •	Puffs per cigarette	16
6-24 mg.	Nicotine level	0.6-2.4 mg.
E-cigarette with 24 mg of nicotine 0.16 mg/putt	Nicotine per puff	Cigarette with 1.8 mg of nicotine 0.16 mg/puff

Written testimony of Lucy Popova, Ph.D. Postdoctoral Fellow, Department of Medicine University of California San Francisco

Before the New York City Council Committee on Health

December 4, 2013

Thank you for the opportunity to address T2013-7248. I am a scientist who has been doing research on new and alternative tobacco products, including electronic cigarettes.

Electronic cigarettes (e-cigarettes) are a new product on the US market, but we already have scientific data pertinent to the decision on the proposed bill. I will present scientific evidence backing up two main points:

- 1) E-cigarettes are not effective smoking cessation devices.
- 2) E-cigarettes "vapor" (including "secondhand vapor") contains harmful chemicals.

The second point is the main reason why the New York City Council members should vote for this bill.

E-cigarettes are not effective smoking cessation devices.

Currently, there is no scientific evidence that e-cigarettes (as they are used in real life populations) help smokers quit. In contrast, studies show that e-cigarettes might make it harder for smokers to quit.

In our study with a nationally representative sample of 1,836 U.S. adult smokers (Popova, 2013) (attached), we found that smokers who used e-cigarettes were less likely to be successful quitters than those who never tried e-cigarettes. Two other studies examined smokers' quitting attempts over time and found that smokers who used e-cigarettes did not have a higher quitting rate (Adkison et al., 2013) or had an even lower quitting rate than smokers who did not use e-cigarettes (Vickerman, Carpenter, Altman, Nash, & Zbikowski, 2013).

1

How can the results of these large representative studies be reconciled with the many individual anecdotes of smokers saying that e-cigarettes helped them quit smoking? What it means is that for every successful quitter testifying at this hearing there is at least one smoker out there who was inhibited from quitting because of e-cigarettes.

Furthermore, even if e-cigarettes are shown to be effective smoking cessation aids, that is not a sufficient reason to allow their use in places where smoking of regular cigarettes is prohibited. Allowing their use in those places will expose innocent bystanders to harmful chemicals contained in "secondhand vapor."

E-cigarettes "secondhand vapor" contains harmful chemicals.

Studies found that "secondhand vapor" from e-cigarettes contain a number of **harmful chemicals**, such as:

- Formaldehyde
- Acetaldehyde
- Isoprene
- Acetic acid
- 2-butanodione
- Acetone
- Proponal (Schripp, Markewitz, Uhde, & Salthammer, 2013)

In addition, e-cigarette emissions contain **fine and ultra-fine particles** (also called nanoparticles) (Schripp et al., 2013; Williams, Villarreal, Bozhilov, Lin, & Talbot, 2013; Zhang, Sumner, & Chen, 2013). The problem with these ultrafine particles is that they are deposited in the furthers reaches of the lung and can then penetrate into bloodstream and affect other organs, including the central nervous system (Elder et al., 2006). Thus, fine and ultrafine particles can contribute to pulmonary and inflammatory problems and increase the risk of cardiovascular and respiratory disease and death (Brook et al., 2010; Pope et al., 2009).

Finally, **"secondhand vapor" contains nicotine**. A study found that "passive vapers" breathing e-cigarette emissions have detectable levels of nicotine in their blood, similar to the levels of nicotine after breathing in second-hand smoke (Flouris et al., 2013).

When innocent bystanders (including children and pregnant women) are near someone who is using an e-cigarette, they inhale "secondhand vapor" and all the harmful chemicals it contains.

Summary

Scientific studies do not show that e-cigarettes help smokers quit smoking; some evidence suggests that they make it harder to quit. But even if e-cigarettes were effective cessation devices, their use in areas where smoking is prohibited should not be allowed because e-cigarette emissions or "secondhand vapor" are not "harmless water vapor," but contain recognized carcinogens and toxins, nanoparticles, and nicotine. We do not have data yet on the long-term effects of breathing in "secondhand vapor," but do we want to wait and allow it knowing what we already know about what it contains? The answer is no. New York has cleaned up the indoor air. There is no reason to allow it to be re-filled with nicotine and other toxic chemicals.

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4

Alternative Tobacco Product Use and Smoking Cessation: A National Study

Lucy Popova, PhD, and Pamela M. Ling, MD, MPH

Smoking rates in the United States have been driven down by health concerns, increasing regulations, higher prices, and changing social norms. Cigarette companies have recognized that smokeless tobacco may be a way to retain profits and customers,¹ and since 2006, the promotion of novel and alternative tobacco products has escalated. However, traditional smokeless tobacco products, such as loose leaf chewing tobacco and moist snuff (Figure 1), continue to dominate the smokeless market.8 Although the market share of loose leaf chewing tobacco is decreasing,8 moist snuff has the largest share of the US market (75% in 2009),⁹ and its use has steadily increased since the 1980s.8

In addition, since about 2006, various alternative tobacco products, such as snus, dissolvables, and electronic cigarettes (e-cigarettes), have been promoted in the United States (Figure 1). Although snus has been used in Sweden since the early 19th century,¹⁰ in 2006, the major US cigarette manufacturers acquired smokeless tobacco companies and began selling snus bearing cigarette brand names (e.g., Marlboro Snus, Camel Snus).¹¹ E-cigarettes were first marketed in China in 2004¹² but have been aggressively promoted on the Internet in the United States since 2007.13 In addition, between 2009 and 2011, dissolvable tobacco products with cigarette brand names (e.g., Camel Orbs, Sticks, and Strips; Marlboro Sticks) were introduced in the United States.14

Surveillance data on novel tobacco products are limited, but the rates of use of novel smokeless tobacco products and e-cigarettes appear to be growing. A recent study that used data from the 2009 ConsumerStyles survey reported that 5.4% of US adults tried snus in their lifetime, and 1.8% used snus in the past month.¹⁵ In addition, the percentage of Americans trying e-cigarettes increased from 0.6% in 2009 to 2.7% in 2010, with 1.2% of adults reporting current use.¹⁶ Objectives. We investigated the frequency of alternative tobacco product use (loose leaf, moist snuff, snus, dissolvables, electronic cigarettes [e-cigarettes]) among smokers and the association with quit attempts and intentions.

Methods. A nationally representative probability-based cross-sectional survey of 1836 current or recently former adult smokers was completed in November 2011. Multivariate logistic regressions evaluated associations between alternative tobacco product use and smoking cessation behaviors.

Results. Of the smokers, 38% had tried an alternative tobacco product, most frequently e-cigarettes. Alternative tobacco product use was associated with having made a quit attempt, and those intending to quit were significantly more likely to have tried and to currently use the products than were smokers with no intentions to quit. Use was not associated with successful quit attempts. Interest in future use of alternative tobacco products was low, except for e-cigarettes.

Conclusions. Alternative tobacco products are attractive to smokers who want to quit smoking, but these data did not indicate that alternative tobacco products promote cessation. Unsubstantiated overt and implied claims that alternative tobacco products aid smoking cessation should be prohibited. (*Am J Public Health.* 2013;103:923–930. doi:10.2105/AJPH.2012.301070)

Some claim that the health risks posed by smokeless tobacco use are significantly lower than the health risks caused by cigarette smoking, and promoting smokeless tobacco has been proposed as a method of harm reduction.17.18 However, smokeless tobacco is addictive, and its use has been associated with an increased risk of oral, esophageal, and pancreatic cancer¹⁹; myocardial infarction and stroke²⁰; oral disease²¹; and reproductive problems.²² In addition, smokeless tobacco can serve as a gateway for smoking initiation among youths.23 Although studies have not examined this prospectively over extended periods, dual use of alternative tobacco products and cigarettes may make it more difficult to quit tobacco use.²⁴

The newer tobacco product marketing includes messages that these smokeless tobacco products may facilitate reduction or cessation of cigarette use (Figure 2) or that they should be used in smoke-free environments, such as smoke-free bars, workplaces, or airplanes.¹¹ This messaging may encourage dual use of smokeless tobacco and cigarettes among smokers, which raises significant health concerns. Dual use is associated with several negative health outcomes, such as increased rates of cardiovascular disease²⁵⁻²⁷ and pancreatic and esophageal cancers^{21,28} and greater risk of inflammatory bowel disease.²⁹

Although some companies make anecdotal claims that smokeless tobacco can be used to aid smoking cessation and some researchers put forth correlational evidence from Scandinavian countries,³⁰ 2 controlled clinical trials found no long-term benefit of using smokeless tobacco (such as snus) to aid in smoking cessation.^{31,32} Also, no long-term controlled clinical trials have established the efficacy of e-cigarettes for smoking cessation, and these products are not approved for this purpose.

We have examined rates of trial and current use of alternative tobacco products (including traditional smokeless tobacco, novel smokeless tobacco products, and e-cigarettes) among a nationally representative US sample of current and former smokers and the association between alternative tobacco product use and smoking cessation intentions and behavior.

Pro	oduct	Description	Common Brands	Use		
Loose leaf chewing tobacco		Air cured tobacco usually treated with sugar and licorice. ²	Red Man, Levi Garrett	Requires spitting.		
Moist snuff		Ground tobacco with a high moisture and salt content. ³ Some moist snuff is sold in porous pouches (e.g., Skoal Bandits).	Copenhagen, Skoal, Grizzly	Requires spitting.		
Snus		Finely ground oral tobacco packaged in small porous pouches ⁴ ; placed between gum and lip. "Snus" name refers to a traditional Swedish product, which is produced with a different manufacturing process (including pasteurization and storage in refrigeration) that reduces tobacco-specific nitrosamines linked to oral cancer. ⁵⁶	Camel Marlboro	Tobacco- laden saliva is swallowed.		
Dissolvable tobacco		Dissolvable pellets, strips, or sticks either made fully from tobacco or consisting of wooden dowels coated with tobacco. Designed to be held and dissolved in the mouth for between 3 (strips) and 30 (sticks minutes.	Camel	Tobacco- laden saliva is swaliowed.		
Electronic cigarettes		A device comprising a battery, a heater, and a cartridge filled with a solution of nicotine, propylene glycol, and other chemicals. This solution is vaporized by the heater and inhaled. ⁷	blu, V2, Smokestik	Vapor is inhaled.		

cription of alternative tobacco products.

METHODS

A nationally representative probabilitybased sample of 1836 current or recently former smokers completed an online crosssectional survey in November 2011. Because e-cigarettes and novel smokeless tobacco products such as dissolvables were introduced to the market fairly recently, and because relapse rates for former smokers who were abstinent for more than 2 years are low,³³ we excluded former smokers who had quit more than 2 years before the study. Participants were part of a panel maintained by the research company Knowledge Networks, which randomly enlists participants through probabilitybased sampling using address-based sampling methods, and compensates them for taking surveys either with incentive points redeemable for cash or with hardware and free access to the Internet. Thus, the probability panel covered both online and offline populations in the United States, in contrast to Internet convenience panels. All participants were members of the Knowledge Networks panel, and all completed the surveys online and in English.

Of the 7776 sampled adult (older than 18 years) smokers (smoked 100 cigarettes in their lifetime) invited to participate, 4525 (58%) completed the screening, and 1836 (41%) qualified for participation based on the selection criteria: either currently smoking or having quit no longer than 2 years ago. All 1836 of the qualified participants completed the survey.

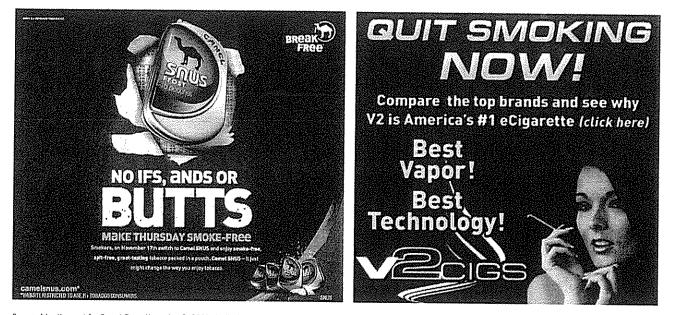
Measures

We measured ever and current use of alternative tobacco products for each of 5 alternative tobacco products in this study: loose leaf and moist snuff, which are "traditional smokeless tobacco products"; snus and dissolvables, which are "novel smokeless tobacco products"; and e-cigarettes. In this article, we use "alternative tobacco products" to refer to all or any of the 5 products and "smokeless tobacco" to refer to both traditional (loose leaf, moist snuff) and novel smokeless (snus, dissolvable) products. Participants viewed pictures of each of the 5 alternative tobacco products and reported whether they had ever used each product (ever use) or had used it at least once in the past 30 days (current use).

Participants also reported how open they were to trying each of the 4 products (snus, moist snuff, e-cigarette, and dissolvable tobacco) in the future on a 9-point Likert scale ranging from "not at all open" to "extremely open." In addition, they reported willingness to use or switch to a smokeless tobacco product (1) in a situation when they could not smoke, (2) to reduce health risk, (3) to cut down on number of cigarettes smoked, and (4) to quit smoking on a 9-point Likert scale ranging from "definitely would not" to "definitely would."

Participants reported having made a quit attempt of at least 1 day in the past year. We compared responses among "successful quitters" (participants who were not currently smoking and had quit smoking within the past 2 years), "unsuccessful quitters" (people who made a quit attempt in the past but were currently smoking), and those who never tried to quit smoking. Everyone but successful quitters were asked whether they intended to quit in the next month, in the next 6 months, in the future but not in the next 6 months, or never. All participants also reported whether they ever tried to quit smoking by switching to

RESEARCH AND PRACTICE



Source. Advertisement for Camel Snus. November 7, 2011. Available at: http://www.trinketsandtrash.org/detail.php?artifactid=7037&page=1. Accessed April 3, 2012; Top Electronic Cigarettes Web site. Available at: http://topelectroniccigarettes.com/reviews/332-v2-e-cigarettes-review-break-the-addiction-to-gain-better-health-and-lifestyle. Accessed April 3, 2012

FIGURE 2-Advertisements for Camel Snus and electronic cigarettes promoting the use of alternative tobacco products for smoking cessation.

chewing tobacco, snuff, or snus, with answers being "Yes"; "I considered it, but never tried it"; and "No, I have never even considered it."

Statistical Analysis

We weighted percentages to the national population to adjust for any survey nonresponse, noncoverage, or undersampling or oversampling resulting from the study-specific sample design. We compared demographic groups by calculating weighted unadjusted odds ratios (ORs; $\alpha = 0.05$) via univariate logistic regression. We used multivariate logistic regression to examine associations between use of alternative tobacco products and quitting status and intentions. Separate regressions were run for the following dependent variables: ever use of each individual product, ever use of any of the alternative products, and current use of any of the alternative products. For each of these regressions, we analyzed (1) smoking status (successful quitters, unsuccessful quitters, and those who never tried to quit) as an independent categorical variable while we controlled for demographics (age, gender, race/ethnicity, income, and education) and (2) different quit intentions (intends to quit in the next month, in the next 6 months, in the future but not in the next 6 months, or never) as an

independent categorical variable while we controlled for demographics. The relation between having made a quit attempt, quitting intentions, and interest in e-cigarettes was assessed with analyses of variance (ANOVAs) because e-cigarettes were the only product for which the rates of use differed by history of quit attempts. We also used ANOVAs to assess the relations between past use of each of the alternative tobacco products (moist snuff, snus, and e-cigarettes) and interest in their future use.

RESULTS

The sample was almost equally split between men and women, the mean age was 42 years, and most participants were non-Hispanic White; the distribution of participants by income, education, and US region was diverse (Table 1). The majority (59.9%) tried quitting smoking in the past but went back to smoking; about a quarter of the sample were successful quitters (23.3%), and 16.8% had never tried quitting (Table 2). Of those still smoking, only 10.9% never expected to quit, and 60.7% reported intentions to quit in the future but not in the next 6 months (Table 2). Among current smokers, 70.1% were daily smokers, 23.7% were nondaily smokers, and 6.2% reported not smoking in the past 30 days. Among those who successfully quit smoking, 19.6% had been abstinent for less than 1 month, 33.0% had been abstinent between 1 and 6 months, 20.0% had been abstinent between 6 and 12 months, and 27.4% had quit smoking between 1 and 2 years ago.

Prevalence of Use of Alternative Tobacco Products

Overall, 38% of smokers had tried an alternative tobacco product (Table 1). E-cigarettes had been tried most frequently; 20.1% of the respondents had ever used them, and 7.6% of all respondents reported past month use. Dissolvable tobacco products had been tried least frequently (2.9%).

The following differences in demographic characteristics of alternative tobacco users were statistically significant at the P<.05 level. Men used traditional smokeless tobacco products and snus significantly more frequently than did women; women used e-cigarettes more frequently than did men. Across all types of alternative tobacco products (except dissolvable tobacco), younger people were more likely to have ever used them compared with people older than 60 years. Non-Hispanic Black smokers were less likely than White

	Loose Leaf Chewing Tobacco (Ever)		М	Moist Snuff (Ever)		Snus (Ever)		Dissolvable Tobacco (Ever)		Electronic Cigarettes (Ever)		Any Alternative Tobacco Product Use (Ever)		Any Alternative Tobacco Product Use (Past 30 Days)	
	No. (%)	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% Ci)
Gender															
Men	939 (51.1)	20.6	3.26* (2.42, 4.38)	24.6	5.17* (3.77, 7.07)	19.0	3.04* (2.25, 4.11)	2.2	0.62 (0.36, 1.09)	18.3	0.79* (0.63, 0.99)	46.9	2.18* (1.79, 2.64)	16.0	1.53* (1.17, 2.01)
Women (Ref)	898 (48.9)	7.4	1.00	5.9	1.00	7.2	1.00	3.5	1.00	22.1	1.00	28.8	1.00	11.0	1.00
Age, y							*								
18-29	483 (26.3)	18.6	2.74* (1.62, 4.63)	20.7	2.75* (1.67, 4.53)	22.4	3.98* (2.31, 6.88)	4,3	2.27 (0.82, 6.26)	31.5	2.32* (1.57, 3.42)	52.8	2.72* (1.95, 3.78)	19.4	1.42 (0.93, 2.17)
30-44	526 (28.7)	16.2	2.33* (1.37, 3.94)	16.9	2.15* (1.30, 3.55)	12.7	2.00* (1.14, 3.52)	2.1	1.04 (0.35, 3.11)	15.4	0.92 (0.61, 1.39)	38.2	1.51* (1.09, 2.09)	10.8	0.71 (0.45, 1.12)
45-59	585 (31.8)	11.3	1.54 (0.90, 2.64)	12.8	1.55 (0.93, 2.57)	8.9	1.35 (0.76, 2.40)	2.9	1.47 (0.52, 4.15)	16.4	0.99 (0.66, 1.48)	29.2	1.00 (0.72, 1.39)	10.9	0.73 (0.47, 1.13)
≥ 60 (Rel)	242 (13.2)	7.8	1.00	8.7	1.00	6.6	1.00	2.1	1.00	16.5	1.00	29.2	1.00	14.5	1.00
Race															
White, non-Hispanic (Ref)	1241 (57.6)	15.1	1.00	16.9	1.00	16.3	1.00	2.7	1.00	20.5	1.00	40.9	1.00	14.1	1.00
Black, non-Hispanic	242 (13.2)	8.7	0.53* (0.33, 0.86)	8.7	0.46* (0.29, 0.74)	7.4	0.42* (0.26, 0.70)	5.8	2.29* (1.22, 4.32)	20.2	0.99 (0.70, 1.39)	24.5	0.47* (0.35, 0.65)	12.0	0.82 (0.54, 1.25)
Hispanic	243 (13.2)	11.1	0.70 (0.46, 1.07)	13.6	0.78 (0.53, 1.16)	5.3	0.29* (0.16, 0.52)	1.6	0.55 (0.18, 1.63)	16.9	0.77 (0.54, 1.12)	37.4	0.87 (0.65, 1.15)	11.5	0.79 (0.51, 1.20)
American Indian or Alaska Native	33 (1.8)	12.1	0.85 (0.31, 2.38)	9.1	0.44 (0.13, 1.54)	3.0	0.18 (0.03, 1.20)	0.0	0 (0, 0)	12.1	0.59 (0.21, 1.63)	26.5	0.50 (0.23, 1.10)	15.2	1.04 (0.39, 2.76)
Asian	17 (0.9)	29.4	2.19 (0.74, 6.45)	23.5	1.46 (0.46, 4.62)	0.0	0 (0, 0)	0.0	0 (0, 0)	41.2	2.76* (1.03, 7.39)	70.5	3.34* (1.17, 9.57)	23.5	1.80 (0.57, 5.71)
Native Hawaiian/Pacific Islander	11 (0.6)	9.1	0.39 (0.03, 4.55)	0.0	0 (0, 0)	0.0	0 (0, 0)	0.0	0 (0, 0)	9.1	0.27 (0.02, 3.14)	9.1	0.10 (0.01, 1.17)	9.1	0.42 (0.04, 4.94)
≥2 races, non-Hispanic	25 (1.4)	16.0	1.13 (0.39, 3.26)	16.0	1.06 (0.37, 2.97)	11.5	0.57 (0.15, 2.12)	4.0	1.72 (0.26, 11.62)	24.0	1.24 (0.49, 3.12)	40.0	1.00 (0.45, 2.23)	4.0	0.28 (0.04, 1.89)
Other, non-Hispanic	25 (1.4)	40.0	3.59* (1.60, 8.10)	40.0	3.16* (1.40, 7.10)	26.9	1.83 (0.75, 4.48)	0.0	0 (0, 0)	26.9	1.37 (0.56, 3.35)	40.0	0.93 (0.42, 2.08)	26.9	2.15 (0.88, 5.29)
Education											,				(,=-,
< high school	205 (11.2)	17.5	0.89 (0.56, 1.41)	18.5	0.97 (0.62, 1.53)	18.5	1.69* (1.03, 2.77)	3.9	4.39* (1.10, 17.56)	16.1	0.85 (0.53, 1.36)	38.0	0.74 (0.51, 1.06)	21.0	2.41 (1.46, 4.00)*
High school	769 (41.9)	9.1	0.42* (0.29, 0.61)	11.8	0.57* (0.40, 0.82)	10.5	0.87 (0.57, 1.32)	3.1	3.49 (0.99, 12.29)		1.10 (0.78, 1.54)	32.6	0.58* (0.44, 0.77)	11.6	1.19 (0.77, 1.84)
Some college	561 (30.6)	17.1	0.86 (0.60, 1.23)	17.5	0.89 (0.62, 1.28)	15.7	1.37 (0.90, 2.08)	3.2	3.64* (1.01, 13.09)	22.6	1.28 (0.90, 1.82)	41.4	0.85 (0.64, 1.13)	15.5	1.67* (1.07, 2.59)
≥ bachelor's degree (Ref)	301 (16.4)	19.3	1.00	19.2	1.00	12.0	1.00	1.0	1.00	18.6	1.00	45.5	1.00	10.0	1.00
Annual income, \$1000															
< 15	483 (26.3)	17.2	1.13 (0.80, 1.61)	16.4	0.84 (0.60, 1.18)	15.3	1.32 (0.90, 1.92)	3.9	2.18 (0.95, 4.98)	20.1	0.99 (0.72, 1.36)	37.5	0.92 (0.71, 1.20)	16.5	1.43 (0.99, 2.08)
15-24.9	236 (12.9)	16.1	1.05 (0.68, 1.61)	20.3	1.10 (0.74, 1.63)	18.6	1.66* (1.07, 2.56)	3.0	1.58 (0.57, 4.39)	19.0	0.91 (0.61, 1.36)	48.5	1.45* (1.06, 2.0)	17.8	1.56* (1.00, 2.41)
25-39.9	377 (20.5)	10.6	0.65* (0.43, 0.99)	7.4	0.35* (0.22, 0.54)	9.3	0.74 (0.47, 1.15)	1.9	0.94 (0.34, 2.64)	20.4	1.00 (0.71, 1.41)	31.6	0.71* (0.53, 0.95)	11.7	0.95 (0.62, 1.45)
40-59.9	300 (16.3)	10.3	0.62* (0.40, 0.98)	15.0	0.76 (0.51, 1.12)	12.3	1.03 (0.66, 1.62)	3.7	2.07 (0.84, 5.14)	20.7	1.02 (0.71, 1.47)	36.7	0.89 (0.66, 1.21)	9.7	0.76 (0.47, 1.22)
≥ 60 (Ref)	440 (24.0)	15.5	1.00	18.9	1.00	12.0	1.00	1.8	1.00	20.2	1.00	39.3	1.00	12.3	1.00
Region															
Northeast	305 (16.6)	9.8	0.55* (0.34, 0.87)	15.7	1.10 (0.72, 1.68)	10.2	0.68 (0.43, 1.09)	4.6	6.11* (1.71, 21.76)	22.2	1.15 (0.79, 1.67)	36.6	0.71* (0.52, 0.97)	12.4	0.96 (0.61, 1.52)
Midwest	419 (22.8)	12.2	0.70 (0.47, 1.04)	16.9	1.21 (0.82, 1.77)	20.7	1.56+ (1.07, 2.27)	4.1	5.42* (1.56, 18.92)	20.3	1.03 (0.72, 1.46)	36.5	0.71* (0.53, 0.95)	13.4	1.04 (0.69, 1.58)
South	744 (40.5)	15.9	0.95 (0.68, 1.34)	15.1	1.05 (0.74, 1.49)	9.8	0.65* (0.45, 0.95)	2.4	3.11 (0.90, 10.80)	19.4	0.97 (0.71, 1.33)	36.2	0.70* (0.54, 0.90)	14.5	1.15 (0.80, 1.67)
West (Ref)	368 (20.0)	16.6	1.00	14.4	1.00	14.4	1.00	0.8	1.00	19.8	1.00	44.7	1.00	12.8	1.00
Overall	1836 (100.0)	14.1		15.5		13.2		2.9		20.1		38.0		13.6	

Note. CI = confidence interval; OR = odds ratio. Percentages may not add to 100% because of rounding.

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		Loose Leaf Chewing Tobacco (Ever)		Mo	oist Snuff (Ever)		Snus (Ever)		Dissolvable Tobacco (Ever)	Electronic Cigarettes (Ever)		Dissolvables, Moist Snuff, or Electronic Cigarettes (Ever)	
	No. (%)	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% Cl)
Quit status													
Successful quitters	427 (23.3)	16.6	1.50 (0.95, 2.36)	15.9	0.97 (0.63, 1.50)	12.6	1.15 (0.71, 1.86)	2.1	0.92 (0.35, 2.42)	17.6	1.09 (0.72, 1.65)	34.9	1.50* (1.06, 2.12)
Unsuccessful quitters	1100 (59.9)	13.6	1.14 (0.77, 1.71)	14.9	0.89 (0.62, 1.29)	13.7	1.31 (0.87, 1.97)	3.2	1.27 (0.58, 2.78)	22.5	1.78* (1.25, 2.53)	36.4	1.78* (1.32, 2.39)
Never tried to quit (Ref)	309 (16.8)	12.3	1.00	17.2	1.00	12.3	1.00	2.6	1.00	15.2	1.00	26.9	1.00
Quit intentions (among current													
smokers, n = 1409)													
Will quit in the next month	98 (6.9)	9.2	0.76 (0.31, 1.83)	11.2	0.79 (0.35, 1.77)	6.1	0.62 (0.23, 1.75)	1.0	0.26 (0.02, 3.14)	12.2	0.55 (0.26, 1.18)	24.5	0.76 (0.42, 1.39)
Will quit in the next 6 mo	297 (21.1)	10.4	0.83 (0.44, 1.57)	17.8	1.16 (0.65, 2.06)	19.5	2.26* (1.22, 4.21)	1.7	0.68 (0.18, 2.58)	24.2	1.30 (0.78, 2.18)	42.1	1.61* (1.03, 2.50)
May quit in the future but not	845 (60.0)	15.2	1.40 (0.81, 2.42)	15,0	1.00 (0.60, 1.67)	12.8	1.34 (0.76, 2.38)	3.8	1.47 (0.50, 4.26)	21.7	1.18 (0.74, 1.87)	33.8	1.19 (0.80, 1.77)
in the next 6 mo													,
Never expect to quit (Ref)	151 (10.7)	13.2	1.00	17.2	1.00	11.9	1.00	2.6	1.00	18.4	1.00	31.1	1.00

TABLE 2-Use of Alternative Tobacco Products by Quit Attempts and Intentions to Quit Smoking Among 1836 US Current and Recent Smokers, November 2011

Note. CI = confidence interval; OR - odds ratio. Results of multiple logistic regression that controlled for age, gender, education, income, and race *P < .05.

smokers to use e-cigarettes and to have tried smokers to use all types of alternative products any alternative product in the past (Table 1). Asian smokers were more likely than White except e-cigarettes and dissolvable tobacco.

tried any alternative tobacco product. and less likely in the South, and smokers in the were more likely to have been tried in the western United States were most likely to have northeastern and midwestern United States come group (Table 1). Novel tobacco products lower income compared with the highest insmokeless tobacco products, as were some with education were more likely to have tried novel In general, smokers with lower levels of

Use of Snus,

Use of Snus,

Dissolvables,

Moist Snuff, or

Electronic Cigarettes

(Past 30 Days)

OR (95% CI)

0.68 (0.40, 1.15)

1.32 (0.87, 1.99)

1.62 (0.67, 3.92)

2.48* (1.24, 4.95)

1.71 (0.89, 3.27)

1.00

%

7.3

13.8

10.7

11.2

17.5

13.0

7.9 1.00

ing \$60 000. 3.25) than were smokers with income exceed were more likely to have used e-cigarettes in the past 30 days (OR = 1.95; 95% CI = 1.17, Smokers with income less than \$15 000 also than were smokers with a bachelor's degree. 30 days, OR = 2.09; 95% CI = 1.13, 3.86) of e-cigarettes (used e-cigarettes in the past tion were more likely to be current users ever users, smokers with some college educainterval [CI] = 1.11, 13.80 although unlike have used snus (OR = 3.92; 95% confidence native tobacco products (data not reported in education were significantly more likely to Table 1). Smokers with less than a high-school in the demographics of current users of alter-We observed similar patterns to ever users

Use of Smokeless Tobacco and Quitting

may affect cessation (Figure 2)-specifically, alternatives to smoking,¹ with messages that ucts that have been promoted to smokers as we focused on those alternative tobacco prod alternative tobacco product use and cessation When analyzing the association between

(n = 1169), 8.9% said that they tried to quit people who made quit attempts in the past year bacco, and 9.9% of them considered it. Among quit smoking by switching to smokeless topast (n = 632), 21.0% said that they tried to never considered it. Among those who tried that they tried to quit smoking by switching to by switching to smokeless tobacco. any of the 4 alternative tobacco products in the 5.8% considered it but never tried, and most chewing tobacco, snuff, or snus; an additional snus, dissolvables, e-cigarettes, and moist snuff Overall, 7.8% of the respondents reported Among

former smokers (n = 427), 7.4% reported that they tried to quit smoking by switching to chewing tobacco, snuff, or snus, and an additional 4.6% considered but never tried this option for quitting.

Past use of any of the 4 alternative tobacco products differed significantly by quit attempt. history: compared with those who never tried to quit, unsuccessful quitters and successful quitters were more likely to have tried alternative tobacco products in the past (Table 2). Unsuccessful quitters also were significantly more likely than those who never tried to quit to have tried e-cigarettes. Smokers who were planning on quitting in the next 6 months were the most likely to have tried snus, to have tried any of the 4 alternative tobacco products, and to have used these products in the past 30 days, compared with those who never expect to quit (see Table 2 for ORs).

Because e-cigarettes were the only product for which the rates of use differed by history of quit attempts, we examined separately the relation between being open to using e-cigarettes and different quit histories. Unsuccessful quitters were significantly more open to using e-cigarettes in the future than were those who never tried quitting, who were more open than successful quitters (mean openness to e-cigarettes = 4.0, 3.1, and 2.3, respectively, on a 9-point scale; F_{2,1725} = 56.72; P<.001). In addition, those who intended to quit within the next month, within the next 6 months, or in the future had higher interest in e-cigarettes than did those who did not ever plan on quitting (mean = 4.6, 4.1, and 3.9, respectively, vs $mean = 2.7; F_{3.1311} = 10.8; P < .001).$

Interest in Using Smokeless Tobacco in the Future

In general, most participants were not at all open to trying snus, moist snuff, or dissolvable tobacco in the future (on a 9-point scale, the mean score for interest in snus = 1.5 [SD = 1.4], the mean score for interest in moist snuff = 1.4 [SD = 1.4], and the mean score for interest in dissolvables = 1.3 [SD = 1.2]), with 86% to 89% of respondents choosing the "not at all open" option (rating 1 on the 1–9 scale). By contrast, participants were more open to trying e-cigarettes (mean = 3.5; SD = 2.9), and many fewer (47%) said they were "not at all open." However, questions that listed specific reasons

for using or trying smokeless tobacco products elicited higher levels of interest: only 49% reported that they "definitely would not try" smokeless tobacco (either traditional or novel products) in a situation when they could not smoke (mean = 3.19; SD = 2.7), and only about 37% definitely would not try smokeless tobacco to reduce health risk (mean = 4.22; SD = 3.0), to cut down on number of cigarettes (mean = 4.22; SD = 3.0), or to quit smoking (mean = 4.29; SD = 3.1). Thus, although overall interest in smokeless tobacco was still low. smokers were more open to trying the product if the questions were framed as though the product helped reduce health risks or helped one to quit smoking.

Prior use of a particular alternative tobacco product was positively associated with interest in using that product in the future. Those who used moist snuff in the past were significantly more open to trying moist snuff in the future (mean used = 3.0 vs mean not used = $1.1; F_{1,1713} = 485.3; P < .001$); smokers who tried snus were more open to using snus in the future (mean used = 2.9 vs mean not used = $1.3; F_{1,1713} = 322.9; P < .001$), and those who tried e-cigarettes were more interested in using them again than were those who did not try them before (mean used = 5.4 vs mean not used = 3.0; $F_{1,1726} = 209.3; P < .001$).

DISCUSSION

Many US adult smokers sampled (38.0%) have tried an alternative tobacco product in the past, and 13.6% used one in the past 30 days. In addition, about 12% of smokers in our sample were current dual users (smoked cigarettes and used some other tobacco product) in the past 30 days. Men and younger people were most likely to have used any alternative tobacco products in the past (except dissolvables), and women and people of Asian descent were more likely to have tried e-cigarettes, although the sample size of Asian participants was small and may not be representative.

Among various alternative tobacco products, e-cigarettes were tried most frequently, and participants were most open to using them in the future. The 20.1% of smokers who tried e-cigarettes in our study is comparable to the 19.2% previously reported by Regan et al.,¹⁶ and the small increase we observed may be a result of the growing popularity of e-cigarettes. Rates of use of loose leaf tobacco, moist snuff, and snus were about equal to one another, with 13% to 15% of smokers reporting having used one of those products. Our observation that interest in and trial of e-cigarettes is higher than that for all smokeless tobacco products is consistent with qualitative studies showing that smokers regard e-cigarettes as more appealing than smokeless tobacco.³⁴

Recently, some have endorsed smokeless tobacco as a means to reduce harm caused by smoking.17,18 It is argued that for those who cannot and will not quit smoking (e.g., "inveterate"18 smokers), it is better to switch to smokeless tobacco than to continue smoking.35 However, our data showed that smokers who were not interested in quitting also were not interested in using alternative tobacco products. By contrast, smokers planning to quit in the next 6 months or unsuccessful quitters were the most interested in using alternative tobacco products. No data indicate that smokeless products aid cessation, and some studies suggest that dual users (smokers who also use smokeless tobacco) are less likely to quit using tobacco than are those who solely use either cigarettes or smokeless tobacco.36 In addition, dual users try to quit more often than do those who only smoke cigarettes but have less success. 37 By encouraging smokers to use smokeless tobacco, rather than achieving abstinence from all tobacco products or complete switching to smokeless tobacco, dual use of cigarettes and smokeless tobacco may result.

We observed that 51% of smokers expressed at least some interest in using smokeless tobacco in an environment where they could not smoke. Yet use of smokeless tobacco products in smoke-free environments may not be beneficial to public health. The introduction of clean indoor air laws in work and public places is connected to reductions in smoking rates.³⁸ Encouraging smokeless tobacco use in smoke-free workplaces might attenuate this effect on cessation (similar to when a smoking room is allowed in a smokefree workplace),³⁸ which may have significant and detrimental health consequences.

Limitations

This study had several limitations. Because this was a cross-sectional study, we could not

RESEARCH AND PRACTICE

determine whether use of alternative tobacco products resulted in cessation attempts or whether those who were trying to quit—for whatever reason—were using alternative tobacco products. We also could not determine whether use of these products is intended to facilitate quitting and whether use leads to successful quitting. Prospective longitudinal studies should examine whether smokers who use smokeless tobacco are actually more successful at quitting.

Although Knowledge Networks provided a probability-based prerecruited Internetbased panel, this approach still might have nonresponse bias, and people who were recruited to the panel (even though selected based on a probability sample) still might be different from those who refused. However, Knowledge Networks's methods of recruiting participants, such as contacting those chosen to be on the panel repeatedly (up to 14 times in 90 days) and maintaining extensive refusal conversion efforts, minimize these differences. By offering panel participation in exchange for free Internet access, the Knowledge Networks panel avoids many of the biases of other Internet panels, which tend to reflect the higher socioeconomic status and educational status of those with easy Internet access.

All tobacco product use in this study was self-reported by respondents and thus subject to recall or reporting bias. Our use of images of the alternative tobacco products on the survey was intended to improve recall of product use. Biochemical measures could validate the self-reported data in this study, but no validated biomarkers exist for use of the novel tobacco products, and studies have questioned the value of biochemical markers in population-based low-intensity trials.³⁹

Our study was limited to current and former smokers, so we were not able to address awareness of and interest in alternative tobacco products among nonsmokers. However, nonsmokers also have reported use of alternative tobacco products.¹⁶ Similar to previous research,⁴⁰ we found that younger adults (aged 18–29 years) were the most likely of all age groups to have tried all types of smokeless tobacco products and to be dual users. This could be the result of the heavy marketing of smokeless tobacco to younger people.^{41,42} Youth initiation of tobacco use is harmful to health; even if individual products are safer than cigarettes, the products contain the addictive substance nicotine and may lead to continued tobacco use.^{23,43} Interest in and use of alternative tobacco products should be measured in youth surveillance studies, and longitudinal studies should examine the natural history of use of alternative tobacco products.

Conclusions

Although the perceptions of smokeless tobacco products were generally negative, smokers expressed more interest when presented with specific reasons for their use, such as in situations when they cannot smoke or when they are presented as products that help them quit or cut down on smoking. These are exactly the messages used to promote novel smokeless products (Figure 2). For example, Carnel Snus advertisements urge smokers to use snus in smoke-free environments to "Boldly go anywhere" and proclaim snus to be "bar-friendly." Snus also has been promoted as an alternative to smoking cessation in the Camel Snus "Smoke-Free Resolution" campaign, which encouraged smokers to switch to Camel Snus around the New Year, a time when many make a resolution to quit smoking.44 This study suggests that these promotional messages may increase smokers' interest in and trial of alternative tobacco products.

Smokers (and particularly those who tried unsuccessfully to quit) are especially interested in using e-cigarettes. Those trying to quit smoking and younger smokers were most interested in alternative tobacco products, but use of these products was not associated with having made a successful quit attempt. This result calls into question whether these products aid cessation (as some claim) and whether the pattern of use is consistent with harm reduction (when one would expect use by inveterate smokers, not those interested in quitting). Prospective longitudinal studies tracking the effects of use of alternative tobacco products on cigarette use and quit attempts are warranted to inform regulation of the marketing and promotion of these products. Explicit or implied claims that alternative tobacco products are smoking cessation aids should be prohibited in the absence of a body of scientific evidence showing such an effect. 🔳

About the Authors

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Contributors

L. Popova led the writing of the article. P.M. Ling conceptualized and supervised the study. Both authors contributed to the development of the survey instrument; the analysis and interpretation of the data; and the review, revision, and approval of the final article.

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Human Participant Protection

The study was approved by the Committee on Human Research of the University of California, San Francisco.

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TESTIMONY IN SUPPORT OF LOCAL LAW TO AMEND THE ADMINISTRATIVE CODE OF THE CITY OF NEW YORK, IN RELATION TO THE REGULATION OF ELECTRONIC CIGARETTES.

By: Claire Millman

President, Alliance For Smokefree Air (516) 433 8278

I am Claire Millman, President of the Alliance For Smokefree Air. I made the initial appeal for, and subsequent strengthening of, all smoking bans in Suffolk, Nassau, New York City and New York State and have been actively involved in this prominent health issue for 40 years.

New York City, commendably in the forefront of protecting public health, is a prime example of the fact that where stringent smoking bans have been enacted the emergence of nonsmoking as the norm in our environment has resulted in a marked decrease in the percentage of smokers and, logically, a marked decrease in smoking and second hand smoking related diseases.

It is, therefore, with great alarm that we now see the rapidly growing use and popularity of ecigarettes, and we strongly urge that they be prohibited in public places and workplaces with the passage of this bill into law.

The imminent alert, underscored by major newspaper coverage, such as Newsday's Sept. 6 front page: "MORE TEENS SMOKING E-CIGS, Numbers Doubled In A Year, CDC Says, And Many Move On To Smoking Tobacco", with its Top Story: "TEEN E-CIG ALERT: Twice as many young people trying them, CDC says, Experts worry they could start smoking resurgence", and its subsequent editorial on Sept. 10, urging quick action to extend regulations of tobacco products to include e-cigs, must be heeded immediately.

E-cigs emissions <u>are</u> putting detectable levels of several significant carcinogens and toxins into the air. Elevated levels of acetic acid, acetone, isoprene, formaldehyde and acetaldehyde are chemicals that no one should have to breathe. The British Medical Association and the World Health Organization warn of the dangers; Medical News Today cites a report from Greek researchers that e-cigarettes increased breathing difficulty in both smokers and nonsmokers.

The enticement of the youth to the e-cigarettes, with flavors like cherry, strawberry and cookies and cream milk shake is nothing new to those of us who remember the tobacco documents revealed years ago: "It's a well known fact that teen agers like sweet products. Honey might be considered." (Brown and Williamson memo, 1972.) CDC director, Dr. Thomas Friedan, states the fear that many teens starting with e-cigs may be "condemned to struggling with a lifelong addiction and conventional cigarettes".

The banning of e-cigarettes will, in addition to protecting the public, educate the public re the known hazards and clear up misconceptions, as exemplified by the quote in the New York Times article, Nov. 27, by a bartender in Brooklyn who was smoking an e-cigarette and stated: "I'm very much against smoking but with these there's no smoke" ---- the article continues, "To emphasize her point, she smoked it next to a pregnant woman who said she was not bothered."

Please maintain New York City's leadership action on behalf of the health and welfare of our people and quickly pass this bill into law.

Thank you

From: The West Family [mailto:bigorangefamily@gmail.com] **Sent:** Wednesday, December 04, 2013 1:21 PM **Subject:** please submit for record Today's Hearing on Health re:e-cig ban proposition

I am disabled am unable to attend today's hearing.

I had smoked for 20 years. I didn't even consider quitting until my husband purchased one. I quit within 12 weeks. I lost weight---am no longer having issues with diabetes.

I still have my e-cig, but now I have liquid that has ZERO milligrams of nicotine in it. I challenge those who want to protect children under the age of voting of serving in the military to set an 18 yr and older only age for e-cigs.

Does my zero mg. e-cig harm people in the mall? No more than walking past the candle shops, and I see no one complaining about breathing that air.

Children should no be allowed to use e-cigs. Nicotine can be dangerous to people who are not of legal age to decide what to do with their own body. (another issue..I know.)

Why do I have my e-cig still today? Sometimes as an ex-smoker I crave as cigarette-but I have my choice now to use my e-cig.

What will happen if you take away e-cigs from those of us who just use vapor to curb any cravings? Your decision will likely be responsible for the result.

Once again, I do NOT think children to use these, because kids are often NOT responsible. If a person can vote or die for our country, then the decision about using e-cigs should remain theirs until there are years of research to show otherwise.

Please add to the record, as I am disabled an unable to attend. This is the only way for me to submit for the record.

Sincerely,

Holly West

TO: Health Committee, New York City Council

FROM: Miguel Martin, Logic Technology Development, LLC

DATE: December 4, 2013

Re: Written Testimony in Response to Proposed Regulation of Electronic Cigarettes

Logic Technology Development, LLC markets and intends its products to be sold to adult smokers of legal smoking age and older. Our sales and marketing practices demonstrate this - not only in its current voluntary manner, but also in our support of regulations that would make these practices law. Logic believes electronic cigarettes may offer an additional alternative to traditional combustion based cigarettes. We encourage all elected officials and regulatory agencies to conduct the research necessary to understand the differences between these inherently different products. Logic supports regulation commensurate with harm and, as you will see from our submission, Logic voluntarily limits its marketing and sales activity to be consistent with our stated position of marketing and selling our products to adult smokers of legal smoking age. Logic supports age restrictions in a manner similar to cigarettes.

The vast majority of our marketing efforts have been in retail locations, capable of age verification, and through radio advertising during time slots having a 21+ age audience of greater than 70%. This standard of 70% or greater age percentage is the industry standard for alcohol products. We are in the process of voluntarily adding the following language to our radio commercials: "Logic products contain nicotine, an addictive substance. Logic products are intended for sale to adult smokers of legal smoking age."

Logic has not aired any television commercials and <u>would support a ban of the usage of</u> <u>television to market electronic cigarettes</u>. As stated previously, we currently utilize radio, but we air our commercials on stations and during time periods where 70% of the audience is 21 years of age or older. This threshold was selected since it is the industry standard for alcohol products that are a 21+ age product.

To enhance our ability to ensure that we are communicating with adult smokers of legal smoking age, Logic has made significant investments in age verification technology through hiring an industry leading age verification company, Aristotle. This company and its' technology is currently used by many of the nation's largest tobacco companies.

Logic uses print almost exclusively to communicate to trade partners in industry magazines with an adult audience. We have ceased all broad print media applications such as general readership newspapers or magazines.

Logic has taken significant steps to ensure that our trade partners and consumers understand that our products are intended for consumers 18+. We have communicated consistently to our trade partners that our products are for sale to adult consumers 18+. As mentioned previously we are adding industry leading on-line verification tools to ensure that our products are sold to adult smokers of legal smoking age. Our company has consistently turned down marketing opportunities in mediums where it conflicted with our stated responsibility position.

Logic currently manufactures only menthol as a product with characterizing flavors. Logic supports the ban of products that have characterizing flavors with the exception of Menthol, which is a historical cigarette flavor. The removal of menthol as an acceptable flavor for electronic cigarettes ensures that a limited percentage of adult cigarette smokers will try and potentially use electronic cigarettes.

Logic intends its' products to be sold on-line, as in retail stores, to adult smokers of legal smoking age. As previously mentioned Logic is implementing significant enhancements to it's proprietary website. Logic has communicated to all business partners our policy. However, given the difficulty of policing these transactions and to be consistent with our stated intent of sales to adults of legal smoking age - Logic supports the ban of on-line sales.

Logic has limited agreements with retailers to merchandise and sell our products. These retailers currently sell cigarettes and per our stated position, packaging and POS our products are to be sold to adult consumers of legal smoking age. Given the nature of the distribution network, we are not in a position to provide a complete list of all retailers that sell our product.

Logic believes that as long as the product is non self-service or one that requires clerk assistance, they should be allowed to be on the counter. Forcing electronic cigarettes to be placed behind the counter ensures that cigarette and traditional tobacco companies uniquely benefit due to the fact that they have an almost monopolistic hold on those fixtures. Logic supports regulating non-self service for electronic cigarettes.

As stated throughout this submission, Logic's intent and practice is to sell and market our products to adult smokers. Logic has voluntarily restricted its lawful right to market its products in a variety of currently used industry practices and has made significant investments to improve its responsibility system. We have also detailed our support for the ban of many current sales and marketing practices. Logic supports the following regulations: the enactment of age restrictions for electronic cigarettes in a manner similar to cigarettes, the ban of on-line e-cigarette sales, the ban of the use of television in marketing electronic cigarettes, non-self service merchandising of electronic cigarettes. In closing, adult smokers clearly have demonstrated an interest in alternatives to traditional combustion based cigarettes. We hope that you are also looking at how government funded research can be accelerated so that the US smoking population can make a more informed decision about the differences between traditional cigarettes and alternatives such as electronic cigarettes. Thank you for your consideration.

Miguel Martin President, Logic Electronic Cigarettes



New York Association of Convenience Stores 130 Washington Avenue, Suite 300, Albany NY 12210

TELEPHONE: (800) 33-NYACS or (518) 432-1400

FAX: (518) 432-7400

Testimony of James S. Calvin, President New York Association of Convenience Stores Public Hearing on a Local Law Relating to Electronic Cigarettes Before the Committee on Health, New York City Council December 3, 2013, City Hall, New York NY

The New York Association of Convenience Stores is a statewide organization representing 8,000 neighborhood mini-marts, bodegas and convenience stores, the majority of which are licensed by the State of New York to sell legal tobacco products to adult customers.

NYACS defends neither smokers nor smoking, and neither electronic cigarette use nor users. Our concern is the impact of this legislation on the continued ability of our members to responsibly sell e-cigarettes, a growing product category that contributes to the viability of our businesses.

In our view, this legislation is driven purely by conjecture, would leap-frog the regulation of electronic cigarettes that the FDA is currently developing, would ignore the realities of how youths access tobacco-related products, and would inhibit retail commerce. We respectfully oppose its passage.

Let the FDA regulate e-cigarettes. That's what it's there for.

The U.S. Food and Drug Administration previously announced that it intends to regulate ecigarettes in some manner, and is conducting the necessary research and following the necessary regulatory procedures. But rather than allowing the FDA to proceed in an orderly fashion, certain local governments seem prone to rushing to judgment about tobacco products and trade practices, arbitrarily enacting bans or restrictions that may or may not conform to what the FDA ultimately deems appropriate.

The public health community spent years campaigning for landmark federal legislation authorizing the FDA to regulate tobacco. Ever since this crowning achievement was attained, New York localities have done nothing but try to elbow the FDA out of the way, as further evidenced by this proposed local law. We urge the Council to let the FDA do its job.

The New York City Council was a midwife to the birth of e-cigarettes.

New York was among the first cities in the nation to forbid smoking in bars, restaurants, places of employment, and other public settings. It did so because many New Yorkers found second-hand smoke annoying and because public health advocates insisted that inhaling second-hand smoke could kill people.

Private industry responded by inventing a product smokers could use in such places *without* exposing others to second-hand smoke. Now the City Council is considering banning the use of *that* product? Is water vapor from an e-cigarette being used in a public park any more harmful than the steam rising from a manhole in a street beside the park?

When did 'visual similarity' become a basis for legislative action?

The sponsors lament that the use of e-cigarettes "is visually similar to the smoking of cigarettes" and "has already been observed in locations where smoking is prohibited, creating concern and confusion."

A police officer sitting in a coffee shop is "visually similar" to a public servant goofing off on the job, even though he or she is actually taking an authorized work break. Should the City ban cops from coffee shops so as to avoid "creating concern and confusion" on the part of onlookers?

As for confusion:

- Isn't it confusing that tobacco is so dangerous to kids that a store owner who sells it to a minor gets fined and/or loses their tobacco and lottery licenses, but it's not dangerous enough to have a mechanism for taking cigarettes away from a teenager standing on the street across from the store smoking a cigarette he got from Mommy's pocketbook?

- Isn't it confusing that New York City law says stores can accept a college ID to verify the age of a tobacco purchaser, but New York State law says they cannot? And that the Council just passed a law setting the legal purchase age at 21 for some tobacco products but 18 for others, while making the ID cutoff age 25 for some tobacco products and 30 for others?

Without a possession law, the expressed concerns about underage consumption ring <u>hollow</u>.

For decades, you have warned the city's youth that it is illegal for them to buy tobacco products, but you haven't made it illegal for them to *use* tobacco products or e-cigarettes obtained through other means.

Research by the Centers for Disease Control consistently shows that the majority of teenage smokers obtain their cigarettes not from stores, where the purchase age is enforced, but from older relatives and acquaintances.

At what point will the City begin holding underage smokers themselves accountable for their actions? Why not make it a civil violation for minors to possess tobacco products and e-cigarettes, and sentence violators to a smoking cessation class?

This legislation will compound the loss of retail business caused by the two tobacco laws signed into law last month.

Based on interaction with thousands of e-cigarette users, our retail members report that customers buy cigarettes as a step toward quitting regular cigarettes and/or because they want to be able to use them where cigarette smoking is prohibited.

However, if they can no longer use e-cigarettes in parks, restaurants, or even their own private vehicle under this legislation, many will stop buying them and return to regular cigarettes. But because of the excessive taxation of regular cigarettes, and the wide available of cheaper contraband cigarettes out on the street, they won't be buying them in our stores. All of which will defeat the City's public health policy objectives, cost our stores legitimate sales, and reduce City and State sales tax revenue.

This will compound the adverse effects of the 21 purchase age and other tobacco retailing restrictions recently enacted by the City Council, which are certain to chase more smokers away from our licensed stores and into the arms of bootleggers offering untaxed, unregulated cigarettes.

This proposal was sprung upon the industry by the City Council.

We received a phone call and email the day before Thanksgiving that this public hearing would be held in one week. The introduction had not even been assigned a number. We object to the short notice, and assert that a restriction of this magnitude requires more deliberate analysis and more input from the regulated community.

Conclusion

For the foregoing reasons, NYACS opposes passage of this proposed legislation.

Thank you for the opportunity to comment.

For the Record American Academy of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN*

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December 3, 2013

Dear Chairperson Arroyo and Members of the City Council Health Committee,

We are sorry that we cannot be there in person today. But we are pleased to offer you our written testimony in support of LS5074.

The New York State Academy of Pediatrics, District II, representing more than 4,000 pediatricians in every health care delivery setting, fully supports the imposition of all existing tobacco control laws and regulations on e-cigarettes in New York City. Therefore we enthusiastically support LS 5074.

E-cigarettes are an unknown. There is no data on their safety. But there is ample data that they are being used in large numbers by children and teens. Over the last year the percentage of young people reporting e-cigarette use has increased by almost 20%. E-cigarettes are now an easy way for young people to begin smoking. There are no current barriers to access. At this time a 10 year old can buy ecigarettes. The e-cigarette is beyond the control of public health entities. Retail outlets have no legal basis to deny anyone access to e-cigarettes. Kids can now buy a candy bar and e-cigarettes without limit.

And e-cigarettes are clearly being marketed to young people with flavors like chocolate delight, strawberry and sweet vanilla. They are also being marketed as "safe", although there is no evidence that they are indeed safe. We don't know yet. But the evidence is clear that e-cigarettes are an easy and uncontrolled avenue to taking young people onto the main highway of tobacco use and abuse. This avenue must be blocked.

Tobacco use represents the largest percentage of illness and death caused by lifestyle choices that can be modified in New York City. Any public policy that interferes with, or creates barriers between young people and tobacco is a public policy we support. Tobacco kills people. It has no redeeming value in any sphere of human endeavor. All efforts should be made to keep young people from starting smoking. All efforts should be made to help young people and all people stop smoking. E-cigarettes are by their very existence are antithetical to all of our mutual efforts over the last decade to reduce access to and the negative consequences of tobacco use.

We encourage the New York City Council to impose all the existing and future tobacco control laws and regulations on e-cigarettes.

For more information please contact: Elie Ward, MSW Director of Policy and Advocacy NYS AAP eward@aap.net

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	Date: (PLEASE PRINT) Name: CRO-FTEACHITENBERC
	Address: <u>38 ST. MANKS PLACE +32</u> I represent: <u>NUSEIF</u>
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	Name: ULTO BUCKNER Address: 48 Marcon St- Brook UM, My 11216
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