

SB1220

Measure Title: RELATING TO CHAPTER 245, HAWAII REVISED STATUTES.

Report Title: Tobacco Products; Excise Tax; Hawaii Cancer Research Special Fund

Description: Expands the definition of "tobacco products" to include any product containing nicotine, but not containing tobacco. Imposes an excise tax equal to 80 per cent of the wholesale price of any tobacco product, other than large cigars, sold by a wholesaler or dealer on and after January 1, 2016, whether or not sold at wholesale, or if not sold then at the same rate upon the use by the wholesaler or dealer. Requires any increase in the excise tax rate imposed on cigarettes or little cigars on or after 1/1/2016 to trigger an automatic excise tax increase on other tobacco products on or after 1/1/2016. Requires the additional moneys collected under the excise tax to be deposited to the credit of the Hawaii cancer research special fund.

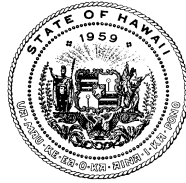
Companion:

Package: None

Current Referral: CPN, WAM

Introducer(s): BAKER, Kidani, Ruderman, Wakai

<u>Sort by Date</u>		Status Text
1/28/2015	S	Introduced.
1/28/2015	S	Passed First Reading.
1/28/2015	S	Referred to HTH/CPN, WAM.
2/2/2015	S	The committee(s) on CPN added the measure to the public hearing scheduled on 02-05-15 9:00AM in conference room 229.
2/2/2015	S	Re-Referred to CPN, WAM.



STATE OF HAWAII
DEPARTMENT OF HEALTH
P. O. Box 3378
Honolulu, HI 96801-3378
doh.testimony@doh.hawaii.gov

Testimony in SUPPORT of SB1220
RELATING TO CHAPTER 245, HAWAII REVISED STATUTES

SENATOR ROSALYN H. BAKER, CHAIR
SENATE COMMITTEE ON COMMERCE AND CONSUMER PROTECTION
Hearing Date: February 5, 2015 Room Number: 229

1 **Fiscal Implications:** None.

2 **Department Testimony:** The Department of Health (DOH) supports SB1220 to increase the excise tax
3 equal to 80% of the wholesale price of any tobacco product, other than large cigars, as an amount that
4 would provide parity with the current tax on cigarettes. The DOH further supports the requirement that
5 any increase in excise tax on cigarettes would trigger an automatic excise tax increase on other tobacco
6 products (OTP); however, would defer to the Department of Taxation on matters of implementation and
7 revenue generation.

8 The National Campaign for Tobacco-Free Kids has recommended an excise tax of 80% of the
9 wholesale value as the amount to achieve parity between the tax on cigarettes and OTPs in Hawaii. The
10 last change in excise tax for OTPs was in 2009. OTPs are currently taxed lower than cigarettes, yet are
11 similarly addictive and dangerous. They present a significant health risk leading to cancer, heart disease,
12 respiratory illnesses, and other serious diseases. Adult and youth smokers are attracted to purchase the
13 less expensive tobacco products, including small cigars, smokeless, loose, or roll-your-own tobacco. This
14 is heightened as a result of Hawaii's high tax on cigarettes. OTPs pose a danger as gateway products
15 that can lead to habitual tobacco use, including smoking and long-term addiction to nicotine.

16 According to the Centers for Disease Control and Prevention, "increasing the price of tobacco
17 products is the single most effective way to prevent initiation among nonsmokers and to reduce
18 consumption."^{1,2} The 2014 CDC Office on Smoking and Health document, "Best Practices for
19 Comprehensive Tobacco Control Programs," reports that smoking and tobacco use are the leading
20 causes of preventable death and disease in Hawaii, claiming 1,200 lives each year and creating \$526
21 million in annual health care costs.

- 1 **Offered Amendments:** No amendments are requested.
- 2 Thank you for the opportunity to testify.

¹ Centers for Disease Control and Prevention. Federal and state cigarette taxes – United States, 1995-2009. *Morbidity and Mortality Weekly Report* 2009; 58(19):524-7.

² U.S. Department of Health and Human Services. *Reducing Tobacco Use. A Report of the Surgeon General*, 2000.

DAVID Y. IGE
GOVERNOR

SHAN TSUTSUI
LT. GOVERNOR



MARIA E. ZIELINSKI
DIRECTOR OF TAXATION

STATE OF HAWAII
DEPARTMENT OF TAXATION
P.O. BOX 259
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To: The Honorable Rosalyn H. Baker, Chair
and Members of the Senate Committee on Commerce and Consumer Protection

Date: Thursday, February 5, 2015
Time: 9:00 A.M.
Place: Conference Room 229, State Capitol

From: Maria E. Zielinski, Director
Department of Taxation

Re: S.B. 1220, Relating to Chapter 245, Hawaii Revised Statutes

The Department of Taxation (Department) provides the following comments on S.B. 1220 for your consideration.

S.B. 1220 amends the Cigarette Tax and Tobacco Tax Law by taxing non-tobacco nicotine-containing products at the same rate as tobacco products other than cigarettes or cigars, and raises the tax from 70% of the wholesale price to 80% of the wholesale price on or after January 1, 2016. The measure also states the rate shall automatically increase in the future at the same rate of any future increases to the tax on cigarettes or little cigars. This measure also specifies that the funds from the tax on tobacco products other than cigarettes and cigars shall be deposited in the Hawaii cancer research special fund.

With respect to both the inclusion of non-tobacco nicotine-containing products in the definition of "tobacco products" and the raising of the rate to 80% of wholesale price effective January 1, 2016, the Department notes it would be able to administer both of these changes.

The Department prefers that any rate change be done by the Legislature at the same time, when and if, the tax on cigarettes and little cigars is increased. This will prevent any confusion or misunderstanding by taxpayers as to the applicable rate on all tobacco subject to this tax.

The Department defers to the Department of Health regarding the effect of taxing such products would have on the State's health and wellness.

Thank you for the opportunity to provide comments.

TAXBILLSERVICE

126 Queen Street, Suite 304

TAX FOUNDATION OF HAWAII

Honolulu, Hawaii 96813 Tel. 536-4587

SUBJECT: TOBACCO, Increase tax; imposition on nicotine

BILL NUMBER: SB 1220; HB 1164 (Identical)

INTRODUCED BY: SB by Baker and 3 Democrats; HB by Takayama

EXECUTIVE SUMMARY: This is a tax increase beginning on 1/1/16, on tobacco products, other than cigarettes and large cigars. The tobacco tax will rise to 80% of the wholesale value, with the revenues to go to the Hawaii cancer research special fund. The measure also proposes to tax nicotine products that do not contain tobacco.

The increased tax on tobacco products is designed to result in less consumption, meaning less tax revenue to the Hawaii cancer research special fund, so lawmakers may want to consider a direct appropriation to this program area.

BRIEF SUMMARY: Amends HRS 245-3 to increase the tax on tobacco products other than cigarettes and large cigars to 80% of the wholesale price sold by the wholesaler or dealer on and after 1/1/16; provided that if the excise tax rate of 16 cents for each cigarette or little cigar increases on or after 1/1/16, the excise tax rate in this paragraph shall automatically increase by the same percentage as the excise tax rate per cigarette or little cigar.

Amends HRS section 245-1 by amending the definition of “tobacco products” to include any product containing nicotine, but not containing tobacco, that is intended for human consumption, whether chewed, smoked, absorbed, dissolved, inhaled, snorted, sniffed, or ingested by any other means, that has not been approved by the United States Food and Drug Administration for tobacco cessation or other medical purposes.

Amends HRS section 245-3(a)(13) to provide that the revenue generated under the rate increase shall be deposited to the credit of the Hawaii cancer research special fund for research and operating expenses and capital expenditures.

EFFECTIVE DATE: January 1, 2015

STAFF COMMENTS: Currently tobacco products, other than cigarettes and large cigars, are taxed at 70% of the wholesale price of the product. Under the bill, beginning on 1/1/16 tobacco products, other than cigarettes and large cigars, would be taxed at 80% of the wholesale value. The measure also amends the definition of tobacco products to include any product containing nicotine that does not contain any tobacco. If this measure were enacted, it would subject smoking cessation devices such as gum, lozenges, patches, nasal spray, as well as e-cigarettes, eggplant, cauliflower, and potatoes as all of these items contain nicotine. If it is the intent of this measure to also tax e-cigarettes under the tobacco tax law, the definition should be revised because not all e-cigarettes contain nicotine.

The proposed measure also provides that the revenues derived from the proposed tax increase on tobacco products shall be deposited into the Hawaii cancer research special fund. Care should be exercised in attempting to generate additional revenues from specific excise taxes like the tobacco tax. First, the tobacco tax is actually designed to deter consumption by making it more expensive. If this actually works, the revenue generated will be less, not more. Next, Hawaii's tax rates on these products are already among the highest in the nation. Not only would another rate increase reaffirm the perception that Hawaii is a tax hell, but it would probably have an effect on the patterns of consumption of taxed product. Such a hike will, no doubt, have an effect on behavioral responses and affect actual consumption of these products and it will probably drive consumers to find other sources for these products that would not incur the tax. Mail order and Internet sales are sources of product that could escape taxation as well as black market purchases made from the military reservations in Hawaii. So instead of seeing growing collections from higher tax rates, lawmakers may just find that collections will drop due to its effect to discourage consumption and send consumers to other markets. As noted above, the higher one pushes the cost of these products, the greater the possibility of actually seeing a decline in consumption as consumers moderate consumption or shift it in ways that would avoid the tax. In fact, as was evidenced in the states of New Jersey and Maryland, lawmakers there counted on an increase in the cigarette tax to help balance their budgets only to learn that collections actually went down below their prior levels. Thus, care should be exercised in targeting these products for specific programs or services.

For this very reason, earmarking the tax for a specific project or program could actually backfire. For example, should cigarette consumption decline, the amount earmarked for the cancer center will also decline. What will the cancer research center then do if the resources are not sufficient to maintain operations? If it is the intent of the legislature to provide adequate revenue to Hawaii cancer research, a direct appropriation would be preferable.

It should be noted that the hikes in the cigarette tax have begun to have an effect on collections not only locally but also nationally. For the first time in the continual drive to raise the tax on cigarettes, collections have fallen below their previous levels. For whatever reason, the rise in rate has jeopardized this source of revenue. If nothing else, lawmakers need to make up their minds whether or not they see this tax as a source of revenue or a means by which to deter consumption.

Digested 2/3/15



To: The Honorable Rosalyn H. Baker, Chair, Committee on Commerce & Consumer Protection
The Honorable Brian T. Taniguchi, Vice Chair, Committee on Commerce & Consumer Protection
Members, Senate Committee on Commerce & Consumer Protection

From: Jessica Yamauchi, Executive Director
Date: February 4, 2015
Hrg: Senate Committee on Commerce and Consumer Protection; Thurs., February 5, 2015 at 9:00 a.m. in Rm 229
Re: **Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes**

Thank you for the opportunity to offer testimony in **strong support of SB 1220**, which raises the taxes on other tobacco products to 80% of the wholesale price to achieve parity between cigarette taxes and other tobacco products (OTPs).

The Coalition for a Tobacco Free Hawaii (Coalition) is a program of the Hawaii Public Health Institute working to reduce tobacco use through education, policy and advocacy. Our program consists of over 100 member organizations and 2,000 advocates that work to create a healthy Hawaii through comprehensive tobacco prevention and control efforts.

Health is Promoted By Increasing the Tax on Tobacco Products Other Than Cigarettes

By increasing the cost of each tobacco product sold and making it comparable to cigarettes, tobacco use by adults and young people will decrease. This will result in a decline in the serious health conditions that arise from use of smokeless tobacco including cancer of the esophagus, pharynx, larynx, stomach, and pancreas, gum disease, and the risk of cardiovascular disease, and a decrease in the diseases caused by smoking roll-your-own tobacco.

Adolescents and young adults are two to three times more sensitive to tobacco price changes than adults—when price increases, less youth will begin to start using smokeless tobacco and other tobacco products, and more will reduce their consumption. Hawaii has seen youth use of smokeless tobacco fluctuate despite our decreasing smoking rates.



A Portion of the Revenues Should Be Earmarked for Tobacco Prevention and Control

In a recent poll conducted by Qmark for the Coalition, Hawaii residents overwhelmingly agree (94%) that it's important for the state to earmark some of the revenue from cigarette and tobacco taxes to fund tobacco prevention and quit smoking programs. When the price of tobacco increases, more seek help to quit. We ask that you earmark a portion of these new funds to tobacco prevention and tobacco dependence treatment services.

The Coalition strongly supports creating parity between OTPs and cigarettes. Thank you for the opportunity to provide testimony in support of this measure.

Thank you for the opportunity to testify on this matter.

A handwritten signature in black ink that reads "Jessica Yamauchi". The signature is written in a cursive, flowing style.

Jessica Yamauchi, M.A.
Executive Director



American Cancer Society
Cancer Action Network
2370 Nu`uanu Avenue
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808.432.9149
www.acscan.org

Senate Committee on Commerce and Consumer Protection
Senator Rosalyn Baker, Chair
Senator Brian Taniguchi, Vice Chair

SB 1220 – RELATING TO CHAPTER 245, HAWAII REVISED STATUTES

Cory Chun, Government Relations Director – Hawaii Pacific
American Cancer Society Cancer Action Network

Thank you for the opportunity to provide testimony in support of SB 1220, which increases the tax on other tobacco products other than large cigars to 80% of the wholesale price, amends the definition of tobacco products, and also includes automatic excise tax increases on other tobacco products in conjunction with an increase in cigarette taxes.

The American Cancer Society Cancer Action Network (ACS CAN) is the nation's leading cancer advocacy organization. ACS CAN works with federal, state, and local government bodies to support evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem.

The purpose of this measure is to ensure parity between the taxes on cigarettes and other tobacco products. In addition, any increase in cigarette taxes will also trigger an automatic increase in the tax on other tobacco products, so that parity continues between the two products.

While some other tobacco products, like smokeless tobacco products including snus, dissolvable strips, sticks and orbs, do not create combustible chemical smoke like cigarettes, they are still harmful to our health. To date, use of smokeless tobacco has been shown to cause:

- Cancer of the mouth, pancreas, and esophagus;
- Precancerous mouth lesions;
- Dental problems including gum recession, dental cavities , and bone loss around the teeth; and
- Nicotine addiction.

Having consistency with the taxes on cigarettes and other tobacco products prevents having one product be significantly less expensive than the other, and discourages the purchase and use of all tobacco products.

Thank you for the opportunity to submit testimony on this matter.

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Fighting for Air

February 4, 2015



To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

Thank you for the opportunity to submit testimony in support of SB 1220. I serve as the Hawai'i director for the American Lung Association of the Mountain Pacific; our mission is to save lives by improving lung health and preventing lung disease. We support increasing the tax on other tobacco products (OTPs) to 80% to create parity between cigarettes and OTPs.

Increasing the tax on OTPs is one of the best ways to keep youth from ever using tobacco and also encourages current users to quit. Establishing tax parity between cigarettes and OTPs works to ensure smokers won't switch from cigarettes to cheaper other tobacco products. As cigarette tax increases, smokers will look towards quitting or they will find cheaper means to continue using tobacco. We must be sure taxes on all tobacco products are equitable so that those who are addicted to nicotine will quit. More smokers quitting, means less cost to our state in tobacco-related medical expenses.

I can be reached at 808-687-5375 or knguyen@ala-hawaii.org, should you have any questions. Thank you for the opportunity to provide testimony in support of this measure.

Kind regards,

A handwritten signature in black ink that reads "Kim Nguyen".

Kim Nguyen, MSW
Executive Director – Hawai'i
American Lung Association of the Mountain Pacific



To: Senator Rosalyn H. Baker, Chair;
Senate Committee on Commerce & Consumer Protection

Hrg: Thursday, February 5, 2015 @ 9:00am, Conference Room 229

Re: **Testimony in STRONG SUPPORT of SB1220 , “Relating to Chapter 245, Hawaii Revised Statutes” with amendment**

By: Valerie Chang, JD, Executive Director
Hawaii COPD Coalition, www.hawaiicopd.org
700 Richards St., Suite 2410, Honolulu, HI 96813
(808)699-9839
copd.hawaii@yahoo.com

I thank you for this opportunity in STRONG SUPPORT of SB1220, which increase the excise tax equal to 80% of the wholesale price of any tobacco product (other than large cigars) as an amount that would provide parity with the current tax on cigarettes. The Hawaii COPD Coalition also strongly supports having any further increase in excise taxes on cigarettes would also trigger an automatic excise on other tobacco products (OTP).

This topic is very important to our organization, as we help those who suffer the awful ravages of long-term exposure to carbon monoxide and tobacco, those with emphysema and chronic bronchitis. All measures that help reduce the number of people who suffer the health consequences of tobacco exposure are very important to the public health of our state.

My name is Valerie Chang. I am Executive Director of the Hawaii COPD Coalition. Our organization provides services and support to Hawaii's people affected by Chronic Obstructive Pulmonary Disease, more commonly known as emphysema and chronic bronchitis. COPD is now the third leading cause of death in the US and second leading cause of disability. Over 46,015 people in Hawaii have already been diagnosed with COPD and it is estimated that at least 46,015 more people may suffer from COPD but remain undiagnosed. Many of these COPD patients were seduced by tobacco when they were very young and unable to quit the addiction for decades, causing irreparable harm. There are over \$55 million in COPD hospital charges in Hawaii each year.

The Centers for Disease Control and Prevention has identified increasing the price of tobacco products as the single most effective way to prevent initiation among nonsmokers and reduce consumption. Along these lines, the Hawaii COPD Coalition sees no reason that large or premium cigars should be exempted from this tobacco tax increase and indeed with the rising numbers of youth experimenting with other tobacco products including cigars, would urge that SB1220 be amended to INCLUDE large and premium cigars in the tax increase.

Tobacco and nicotine products are **still** the leading cause of preventable disease. COPD is estimated to cause one in four deaths in Canada, our neighbors to the north. Let us continue to minimize our exposure in Hawaii by keeping taxes of these products appropriately high. Taxes on all tobacco products must be equitable so that nicotine addicts will quit rather than switching to a less expensive option. More smokers quitting means reduced costs to our state in tobacco-related medical expenses.

Thanks for the opportunity to testify about this issue that is so vital to the health of Hawaii and our nation. This issue is very important to our state and our Hawaii COPD Coalition is very glad that this committee has taken a leadership role in addressing this important matter. Please pass SB 1220, relating to Chapter 245 of the Hawaii Revised Statutes, increasing excise tax equal to 80% of the wholesale price of all tobacco products INCLUDING large and premium cigars, to protect the health of Hawaii's people.

From: mailinglist@capitol.hawaii.gov
To: [CPN Testimony](#)
Cc: mz9995@hotmail.com
Subject: Submitted testimony for SB1220 on Feb 5, 2015 09:00AM
Date: Tuesday, February 03, 2015 2:28:29 PM

SB1220

Submitted on: 2/3/2015

Testimony for CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Michael Zehner	Hawaii Smokers Alliance	Oppose	No

Comments: We should have a full and detailed independent auditing of where the "Cancer Research Center" is spending its' money before this bill is considered. Furthermore, the Legislature helped cause declining tax and settlement revenues by overtaxing tobacco to begin with.

Please note that testimony submitted less than 24 hours prior to the hearing, improperly identified, or directed to the incorrect office, may not be posted online or distributed to the committee prior to the convening of the public hearing.

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February 3, 2015

To: The Honorable Rosalyn H. Baker, Chair
Members, Senate Committee on Commerce and Consumer Protection

From: Cory Smith, VOLCANO Fine Electronic Cigarettes®
CEO and Owner

RE: SB1220 – oppose.

Thank you for the opportunity to submit testimony.

VOLCANO Fine Electronic Cigarettes® is the largest manufacturer and retailer of vapor products and vaping accessories in the State of Hawaii. We currently own and operate 11 locations statewide and employ over 100 full-time workers to support sales of our products not only here in Hawaii, but to all 50 states as well as Japan and the UK. We stand in opposition to SB1220 for the following:

- SB1220 states in its justification that products that contain nicotine have the same risk profile as all other tobacco products and thus should be taxed at the same rate which is an entirely baseless statement not rooted in science. There currently exists a growing body of evidence in support of harm reduction strategies and e-cigarettes that contain nicotine are leading the way in proving as a highly effective tool in helping smokers lower their risk and break their addiction to tobacco and nicotine altogether.
- SB1220 attempts to levy an 80% tax on any product that contains nicotine and yet exempts traditional NRT products that contain nicotine even though electronic cigarettes are being shown to be a much more effective tool for helping people quit smoking.
- The average cost for an industry standard bottle of e-liquid that contains nicotine is \$13 and is already higher than the cost of a pack of cigarettes. When you factor in the average cost of a reusable starter kit, which can range anywhere from \$45 to more than \$300 for a premium device, and the accessories one must regularly purchase to keep their device in normal working order, users are already paying a comparable or higher price than they would be if they were using a traditional tobacco product. Even most one-time use electronic cigarettes are priced comparably to a traditional pack of cigarettes and provide a user a comparable amount of puffs. Yet in many instances, users choose a much lower dose of nicotine than you would ever get from a cigarette and this bill does not make any distinction in that regard.
- Some smokers are already hesitant to try electronic cigarettes due to the high start-up costs



involved. Levying 80% taxes on electronic cigarettes that contain nicotine would only serve to further discourage current smokers from switching to an effective harm reduction tool. Even worse, a dramatic increase in the cost of e-cigarettes may send some current users back to smoking tobacco cigarettes. In order to make cigarettes obsolete, electronic cigarettes and other harm reduction products should be embraced and allowed to fairly compete on the market with traditional tobacco cigarettes.

- SB 1220 would put Hawaii-based electronic cigarette companies at a competitive disadvantage in the national market for vapor products. In Hawaii, many customers of our brick and mortar locations will turn to the Internet if faced with a sudden price increase. Additionally, our wholesale and retail partners on the mainland will undoubtedly scoff at price hikes and will turn to suppliers in the 48 states that do not tax electronic cigarettes. This could force us to either move out of state, taking the jobs and revenue with us, or close the business altogether. This would mean a loss of both jobs and GET tax revenues.
- Over the years that we have been in business in the state, we have provided a product that tens of thousands of customers use every day to greatly reduce their tobacco use or quit smoking altogether. This has improved the lives of smokers and ex-smokers in this state. The removal of secondhand smoke has helped non-smokers as well and has cut down on the amount of butt discard in our community.
- VOLCANO Fine Electronic Cigarettes is currently one of the largest electronic cigarette suppliers in the mainland U.S. We are also the number one FedEx shipper in the State of Hawaii. We bring money into the local economy from the mainland and have provided a much-needed boost to Hawaii by hiring local employees. Throughout the recession we have grown our business and our taxable revenues every year.

It is our belief that this unjustified product classification and tax policy is in the best interest of no one in the state of Hawaii.

Thank you for your time and consideration. If you have any questions, please feel free to contact me or Volcano's representative Celeste Nip at nipfire@me.com.

Sincerely,
Cory Smith
CEO and Owner
VOLCANO Fine Electronic Cigarettes®

1003 Sand Island Access Rd. Suite #1260, Honolulu, HI 96813

Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study

Jamie Brown^{1,2}, Emma Beard¹, Daniel Kotz^{1,3}, Susan Michie^{2,4} & Robert West^{1,4}

Cancer Research UK Health Behaviour Research Centre, University College London, London, UK,¹ Department of Clinical, Educational and Health Psychology, University College London, London, UK,² Department of Family Medicine, CAPHRI School for Public Health and Primary Care, Maastricht University Medical Centre, Maastricht, the Netherlands³ and National Centre for Smoking Cessation and Training, London, UK⁴

ABSTRACT

Background and Aims Electronic cigarettes (e-cigarettes) are rapidly increasing in popularity. Two randomized controlled trials have suggested that e-cigarettes can aid smoking cessation, but there are many factors that could influence their real-world effectiveness. This study aimed to assess, using an established methodology, the effectiveness of e-cigarettes when used to aid smoking cessation compared with nicotine replacement therapy (NRT) bought over-the-counter and with unaided quitting in the general population. **Design and Setting** A large cross-sectional survey of a representative sample of the English population. **Participants** The study included 5863 adults who had smoked within the previous 12 months and made at least one quit attempt during that period with either an e-cigarette only ($n = 464$), NRT bought over-the-counter only ($n = 1922$) or no aid in their most recent quit attempt ($n = 3477$). **Measurements** The primary outcome was self-reported abstinence up to the time of the survey, adjusted for key potential confounders including nicotine dependence. **Findings** E-cigarette users were more likely to report abstinence than either those who used NRT bought over-the-counter [odds ratio (OR) = 2.23, 95% confidence interval (CI) = 1.70–2.93, 20.0 versus 10.1%] or no aid (OR = 1.38, 95% CI = 1.08–1.76, 20.0 versus 15.4%). The adjusted odds of non-smoking in users of e-cigarettes were 1.63 (95% CI = 1.17–2.27) times higher compared with users of NRT bought over-the-counter and 1.61 (95% CI = 1.19–2.18) times higher compared with those using no aid. **Conclusions** Among smokers who have attempted to stop without professional support, those who use e-cigarettes are more likely to report continued abstinence than those who used a licensed NRT product bought over-the-counter or no aid to cessation. This difference persists after adjusting for a range of smoker characteristics such as nicotine dependence.

Keywords Cessation, cross-sectional population survey, e-cigarettes, electronic cigarettes, nicotine replacement therapy, NRT, quitting, smoking.

Correspondence to: Jamie Brown, Health Behaviour Research Centre, Department of Epidemiology and Public Health, University College London, 1-19 Torrington Place, London WC1E 6BT, UK. E-mail: jamie.brown@ucl.ac.uk

Submitted 27 February 2014; initial review completed 8 April 2014; final version accepted 12 May 2014

INTRODUCTION

Smoking is one of the leading risk factors for premature death and disability and is estimated to kill 6 million people world-wide each year [1]. The mortality and morbidity associated with cigarette smoking arises primarily from the inhalation of toxins other than nicotine contained within the smoke. Electronic cigarettes (e-cigarettes) provide nicotine via a vapour that is drawn into the mouth, upper airways and possibly lungs [2, 3].

These devices use a battery-powered heating element activated by suction or manually to heat a nicotine solution and transform it into vapour. By providing a vapour containing nicotine without tobacco combustion, e-cigarettes appear able to reduce craving and withdrawal associated with abstinence in smokers [2,4,5], while toxicity testing suggests that they are much safer to the user than ordinary cigarettes [3].

E-cigarettes are increasing rapidly in popularity: prevalence of ever-use among smokers in the United

States appears to have increased from approximately 2% in 2010 to more than 30% in 2012, and the rate of increase appears to be similar in the United Kingdom [6–9]. Although there are concerns about their wider public health impact relating to the renormalization of smoking and promotion of smoking in young people, crucially two randomized controlled trials have suggested that e-cigarettes may aid smoking cessation [10,11]. However, there are many factors that influence real-world effectiveness, including the brand of e-cigarette, the way they are used and who chooses to use them [12]. Therefore, it is a challenge to establish probable contribution to public health through randomized efficacy trials alone. Moreover, this kind of evidence will take many years to emerge, and in the meantime the products are developing rapidly and countries require evidence on effectiveness to inform decisions on how to regulate them [13–19]. As a result, there is an urgent need to be able to make an informed judgement on the real-world effectiveness of currently popular brands as chosen by the millions of smokers across the world who are using them in an attempt to stop smoking [6–9].

Several studies have attempted to examine the relationship between the use of e-cigarettes and smoking status in the real world by surveying regular e-cigarette users [20–27]. These studies—including one using a longitudinal design [27]—have found that users consistently report that e-cigarettes helped them to quit or reduce their smoking. However, because the samples were self-selected, the results have to be interpreted with caution. In more general samples the evidence is less positive. One national study of callers to a quitline, which assessed the cross-sectional association of e-cigarette use and current smoking status at a routine follow-up evaluation of the quitline service, found that e-cigarette users compared with never users were less likely to be abstinent [28]. In a longitudinal study of a general population sample, e-cigarette users at baseline were no more likely to have quit permanently at a 12-month follow-up despite having reduced their cigarette consumption [29]. However, neither of these studies adjusted for important potential confounding variables and both evaluated the association between quitting and the use of e-cigarettes for any purpose, not specifically as an aid to quitting. It is crucial to distinguish between the issue of whether use of e-cigarettes in a quit attempt improves the chances of success of that attempt from the issue of whether the use of e-cigarettes, for whatever purpose, such as aiding smoking reduction or recreation, promotes or suppresses attempts to stop. In determining the overall effect on public health both considerations are important, but they require different methodologies to address them.

An ongoing national surveillance programme (the Smoking Toolkit Study) has been tracking the use of

e-cigarettes as a reported aid to cessation among the general population in England since July 2009 [30]. This programme has established a method of assessing real-world effectiveness of aids to cessation by comparing the success rates of smokers trying to quit with different methods and adjusting statistically for a wide range of factors that could bias the results, such as nicotine dependence [31]. The method has been able to detect effects of behavioural support and prescription medications to aid cessation and found a higher rate of success when using varenicline than prescription nicotine replacement therapy (NRT) [32,33], supporting findings from randomized controlled trials and clinical observation studies [34–37]. This method cannot achieve the same level of internal validity as a randomized controlled trial, but clearly has greater external validity, so both are important in determining the potential public health contribution of devices hypothesized to aid cessation, such as e-cigarettes.

Given that smokers already have access to licensed NRT products, it is important to know whether e-cigarettes are more effective in aiding quitting. This comparison is particularly important for two reasons. First, buying a licensed NRT product from a shop, with no professional support, is the most common way of using it in England, and secondly, previous research has found that this usage was not associated with greater success rates than quitting unaided in the real-world [33]. It is therefore important to know whether e-cigarettes can increase abstinence compared to NRT bought over-the-counter.

The current study addressed the question of how effective e-cigarettes are compared with NRT bought over-the-counter and unaided quitting in the general population of smokers who are attempting to stop.

METHODS

Study design

The design was cross-sectional household surveys of representative samples of the population of adults in England conducted monthly between July 2009 and February 2014. To examine the comparative real-world effectiveness of e-cigarettes, the study compared the self-reported abstinence rates of smokers in the general population trying to stop who used e-cigarettes only (i.e. without also using face-to-face behavioural support or any medically licensed pharmacological cessation aid) with those who used NRT bought over-the-counter only or who made an unaided attempt, while adjusting for a wide range of key potential confounders. The surveys are part of the ongoing Smoking Toolkit Study, which is designed to provide information about smoking

prevalence and behaviour in England [30]. Each month a new sample of approximately 1800 adults aged ≥ 16 years are selected using a form of random location sampling, and complete a face-to-face computer-assisted survey with a trained interviewer. The full methods have been described in detail and shown to result in a sample that is nationally representative in its socio-demographic composition and proportion of smokers [30]. Approval was granted by the ethics committee of University College London, UK.

Study population

For the current study, we used aggregated data from respondents to the survey in the period from July 2009 (the first wave to track use of e-cigarettes to aid cessation) to February 2014 (the latest wave of the survey for which data were available), who smoked either cigarettes (including hand-rolled) or any other tobacco product (e.g. pipe or cigar) daily or occasionally at the time of the survey or during the preceding 12 months. We included those who had made at least one quit attempt in the preceding 12 months, assessed by asking: 'How many serious attempts to stop smoking have you made in the last 12 months? By serious attempt I mean you decided that you would try to make sure you never smoked again. Please include any attempt that you are currently making and please include any successful attempt made within the last year'. We included respondents who used either e-cigarettes or NRT bought over-the-counter during their most recent quit attempt, and an unaided group defined as those who had not used any of the following: e-cigarettes; NRT bought over-the-counter; a prescription stop-smoking medication; or face-to-face behavioural support. We excluded those who used either e-cigarettes or NRT bought over-the-counter in combination with one another, a prescription stop-smoking medication or face-to-face behavioural support.

Measurement of effect: quitting method

The use of different quitting methods were assessed for the most recent attempt by asking: 'Which, if any, of the following did you try to help you stop smoking during the most recent serious quit attempt?' and included: (i) e-cigarettes; (ii) NRT bought over-the-counter; (iii) no aid (i.e. had not used any of e-cigarettes, NRT bought over-the-counter, a prescription stop-smoking medication or face-to-face behavioural support).

Measurement of outcome: self-reported non-smoking

Our primary outcome was self-reported non-smoking up to the time of the survey. Respondents were asked: 'How long did your most recent serious quit attempt last before

you went back to smoking?'. Those responding 'I am still not smoking' were defined as non-smokers. Previous research has shown that self-reported abstinence in surveys of this kind is not subject to the kind of biases observed in clinical trials where there is social pressure to claim abstinence [38].

Measurement of potential confounders

We measured variables potentially associated with the different quitting methods and that may also have an effect on the outcome. These potential confounders were chosen a priori. The most important factor was nicotine dependence, for which we used two questions. First, time spent with urges to smoke was assessed by asking all respondents: 'How much of the time have you felt the urge to smoke in the past 24 hours? Not at all (coded 0), a little of the time (i), some of the time (ii), a lot of the time (iii), almost all of the time (iv), all of the time (v)'. Secondly, strength of urges to smoke was measured by asking: 'In general, how strong have the urges to smoke been? Slight (i), moderate (ii), strong (iii), very strong (iv), extremely strong (v)'. This question was coded '0' for smokers who responded 'not at all' to the previous question. In this population these two ratings have been found to be a better measure of dependence (i.e. more closely associated with relapse following a quit attempt) than other measures [32,33,39]. The demographic characteristics assessed were age, sex and social grade (dichotomized into two categories: ABC1, which includes managerial, professional and intermediate occupations; and C2DE, which includes small employers and own-account workers, lower supervisory and technical occupations, and semi-routine and routine occupations, never workers and long-term unemployed). We also assessed the number of quit attempts in the last year prior to the most recent attempt, time since the most recent quit attempt was initiated (either more or less than 6 months ago), whether smokers had tried to quit abruptly or gradually and the year of the survey.

Analysis

Bivariate associations between the use of different quitting methods and potentially confounding socio-demographic and smoking history variables were assessed with χ^2 tests and one-way analyses of variance (ANOVA)s for categorical and continuous variables, respectively. Significant omnibus results were investigated further by *post-hoc* Sidak-adjusted χ^2 tests and *t*-tests.

Our measure of dependence (strength of urges to smoke) assumed that the score relative to other smokers would remain the same from pre- to post-quitting [32,33]. If a method of quitting reduced the strength of

urges to smoke more than another method, this would tend to underestimate the effectiveness of that intervention because the smokers using this method would appear to be less dependent. To test for this bias, we used an analysis of covariance (ANCOVA) to examine whether the difference in strength of urges to smoke in smokers versus non-smokers depended upon the method of quitting, adjusting for the time since the quit attempt started.

In the analysis of the associations between quitting method and abstinence, we used a logistic regression model in which we regressed the outcome measure (self-reported non-smoking compared with smoking) on the effect measure (use of e-cigarettes compared with either NRT bought over-the-counter or no aid). The primary analysis was an adjusted model that included the potential confounders listed above and two interaction terms: (i) between time since last quit attempt and time spent with urges, and (ii) between time since last quit attempt and strength of urges to smoke. These interaction terms were used to reflect the fact that urges to smoke following a quit attempt are influenced by whether an individual is currently abstinent and the duration of abstinence [32,33]. In addition to the model from the primary analysis ('fully adjusted model'; model 4), we constructed a simple model including only the effect measure ('unadjusted model'; model 1), a model that included the effect measure, year of the survey and all potential confounders except for the two measures of tobacco dependence, and a model that included all variables from the previous model and the two measures of tobacco dependence but without their interaction terms ('partially adjusted models'; models 2 and 3, respectively) to assess the extent of confounding by dependence. As *post-hoc* sensitivity analyses, the models were re-examined using different potential confounders from the ones specified a priori and reported in previous publications using the same methodology [32,33]. First, the time since the initiation of the quit attempt was included using the following six categories: 'in the last week'; 'more than a week and up to a month'; 'more than 1 month and up to 2 months'; 'more than 2 months and up to 3 months'; 'more than 3 months and up to 6 months'; and 'more than 6 months and up to a year'. Secondly, an additional index of dependence—the heaviness of smoking index (HSI) [40]—was included. The HSI was assessed by asking current smokers to estimate current cigarettes per day and time to first cigarette (the two items comprising HSI) and by asking non-smokers to recall these behaviours prior to their quit attempt. Finally, in *post-hoc* subgroup analyses all models were repeated (i) among those reporting smoking one or more than one cigarette per day (CPD) to determine whether inclusion of very light smokers might have had an influence on the results; (ii) among those completing the survey between 2012–14

once e-cigarette usage had become prevalent; and (iii) in the two subsamples of respondents who had started their most recent quit attempt less or more than 6 months ago, in order to assess the interplay between long-term effectiveness and the occurrence of differential recall bias. All analyses were performed with complete cases.

RESULTS

A total of 6134 respondents reported a most recent quit attempt in the last 12 months that was either unaided ($n = 3477$) or supported by NRT bought over-the-counter ($n = 2095$), e-cigarettes ($n = 489$) or both ($n = 73$). Those using both were excluded as were those using a prescription stop-smoking medication or face-to-face behavioural support in combination with either NRT bought over-the-counter ($n = 173$) or e-cigarettes ($n = 25$). Thus, the study population consisted of 5863 smokers who had made an attempt to quit in the previous year, of whom 7.9% (464) had used e-cigarettes, 32.8% (1922) had used NRT bought over-the-counter and 59.3% (3477) had used no aid to cessation. Quitting method did not differ by sex or the number of quit attempts in the past year but was associated with age, social grade, time since the quit attempt started, CPD, smoking less than one CPD, the measures of dependence (time with and strength of urges and HSI) and whether the attempt had begun abruptly (see Table 1). The *post-hoc* comparisons showed that those who used either e-cigarettes or no aid were younger than those using NRT over-the-counter, and that those who used NRT over-the-counter or no aid were more likely to hold a lower social grade than those using e-cigarettes. As would be expected, given the recent advent of e-cigarettes, the quit attempts of e-cigarette users were less likely to have begun more than 6 months previously than those using NRT over-the-counter or no aid. Those using NRT bought over-the-counter smoked more cigarettes and scored higher than either of the other two groups on all measures of dependence. E-cigarette users smoked more cigarettes, and were more dependent by the strength of urges measure and HSI than those using no aid. Finally, those using no aid were more likely to have smoked less than one CPD and stopped abruptly than the other two groups.

Strengths of urges to smoke were higher in smokers than in non-smokers (see Table 2). However, the mean differences in strength of urges between smokers and non-smokers were similar across method of quitting: the interaction between smoking status (smokers versus non-smokers) and method of quitting in an ANCOVA of the strength of urges adjusted for the time since quit attempt started was not significant ($F_{(2, 5856)} = 1.50, P = 0.22$).

Non-smoking was reported among 20.0% (93 of 464) of those using e-cigarettes, 10.1% (194 of 1922) using

Table 1 Associations between characteristics of the sample and use of different quitting methods.

	<i>E-cigarettes</i> (<i>n</i> = 464)	<i>NRT over-the-counter</i> [§] (<i>n</i> = 1922)	<i>No aid</i> (<i>n</i> = 3477)	<i>P</i>
Mean (SD) age	39.0 (15.6) ^a	41.2 (15.3) ^{ab}	37.5 (16.2) ^b	***
% (<i>n</i>) Female	47.2 (219)	51.1 (982)	48.9 (1699)	NS
% Social grade C2DE	59.3 (275) ^{cd}	65.9 (1266) ^c	65.5 (2277) ^d	*
Mean (SD) cigarettes per day [¶]	12.6 (8.0) ^{ef}	13.8 (8.5) ^{eg}	10.9 (8.1) ^{fg}	***
% (<i>n</i>) < 1 cigarettes per day [¶]	0.7 (3) ^h	0.8 (15) ⁱ	2.8 (94) ^{hi}	***
% (<i>n</i>) Time since quit attempt started >26 weeks	23.7 (110) ^{jk}	36.4 (700) ^j	36.5 (1269) ^k	***
Mean (SD) quit attempts in the past year	1.6 (0.9)	1.6 (0.9)	1.5 (0.9)	NS
Mean (SD) time spent with urges to smoke (0–5)	1.9 (1.3) ^l	2.2 (1.3) ^{lm}	1.8 (1.3) ^m	***
Mean (SD) strength of urges to smoke (0–5)	2.0 (1.2) ^{no}	2.2 (1.1) ^{np}	1.8 (1.1) ^{op}	***
Mean (SD) heaviness of smoking index [†]	2.0 (1.5) ^{qr}	2.3 (1.5) ^{qs}	1.6 (1.5) ^{rs}	***
% (<i>n</i>) Abrupt attempt (no gradual cutting down first)	50.4 (234) ^t	52.5 (1010) ^u	59.0 (2051) ^{tu}	***

Different pairs of superscript letters indicate a significant difference ($P < 0.05$) between two groups after Sidak adjustment for multiple comparisons. * $P < 0.05$; *** $P < 0.001$; NS = not statistically significant ($P \geq 0.05$). §A subgroup of those using nicotine replacement therapy (NRT) over-the-counter provided information about the form of NRT ($n = 975$): 60.0% (585) used a patch, 21.0% (205) gum, 14.9% (145) an inhalator, 6.2% (60) lozenges, 1.2% (12) microtabs and 1.0% (10) nasal spray. NB: response options were not mutually exclusive and 11.1% (108) reported using more than one form. ¶Data were missing for 156 respondents (e-cigarettes: 22; NRT over-the-counter: 34; no aid: 100). †Data were missing for 172 respondents (e-cigarettes: 23; NRT over-the-counter: 36; no aid: 113). SD = standard deviation.

Table 2 Differences between smokers and non-smokers in strength of urges to smoke by method of quitting.

<i>Method of quitting</i>	<i>n</i>	<i>Mean (SD) strength of urges to smoke in smokers</i>	<i>n</i>	<i>Mean (SD) strength of urges to smoke in non-smokers</i>	<i>Mean difference (95% CI) in strength of urges to smoke</i>
E-cigarettes	371	2.3 (1.1)	93	0.8 (1.1)	1.4 (1.2–1.7)
NRT over-the-counter	1728	2.3 (1.0)	194	1.2 (1.3)	1.2 (1.0–1.3)
No aid	2942	2.0 (1.0)	535	0.7 (1.1)	1.3 (1.2–1.4)

NB: the mean differences are calculated from exact rather than the rounded figures presented in columns 3 and 5 of this table. The mean difference in strength of urges to smoke was not different across the methods of quitting ($F_{(2, 5856)} = 1.50$, $P = 0.22$ for the interaction term between smoking status and method of quitting adjusted for the time since the quit attempt started). SD = standard deviation; CI = confidence interval; NRT = nicotine replacement therapy.

NRT over-the-counter and 15.4% (535 of 3477) using no aid. The unadjusted analyses indicated that e-cigarette users were more likely to be abstinent than either those using NRT bought over-the-counter [odds ratio (OR) = 2.23, 95% confidence interval (CI) = 1.70–2.93] or those who used no aid (OR = 1.38, 95% CI = 1.08–1.76; see model 1, Table 3). The primary analyses revealed that the fully adjusted odds of non-smoking in users of e-cigarettes were 1.63 (95% CI = 1.17–2.27) times higher compared with users of NRT bought over-the-counter and 1.61 (95% CI = 1.19–2.18) times higher compared with those using no aid (see model 4, Table 3). The relative magnitudes of the ORs from the fully adjusted model with the other three unadjusted and partially adjusted models illustrate the confounding effects of dependence (see Table 3).

In *post-hoc* sensitivity analyses, the associations between quitting method and non-smoking were re-examined using models including different potential confounders. In a model including the more fine-grained assessment of time since the initiation of the quit attempt

than the measure presented in Table 1, the adjusted odds of non-smoking in users of e-cigarettes were 1.58 (95% CI = 1.13–2.21) times higher compared with users of NRT bought over-the-counter and 1.55 (95% CI = 1.14–2.11) times higher compared with those using no aid. In another model that included another measure of dependence (HSI; missing data 3%, $n = 172$), the adjusted odds of non-smoking in users of e-cigarettes were 1.63 (95% CI = 1.15–2.32) times higher compared with users of NRT bought over-the-counter and 1.43 (95% CI = 1.03–1.98) times higher compared with those using no aid.

In *post-hoc* subgroup analyses, very light smokers were shown to have little influence on the pattern of results: in repeated analyses among those 5595 smokers reporting smoking one or more than one CPD the adjusted odds of non-smoking in users of e-cigarettes were higher compared with users of NRT bought over-the-counter (OR = 1.59, 95% CI = 1.13–2.26) and compared with those using no aid (OR = 1.63, 95% CI = 1.18–2.24). Similarly, the exclusion of respondents

Table 3 Associations between quitting method and abstinence.

	(1) <i>e-Cigarettes</i>	(2) NRT <i>over-the-counter</i>	(3) <i>No aid</i>	(1) versus (2)		(1) versus (3)	
				Model 1: OR (95% CI)	Model 2: OR (95% CI)	Model 1: OR (95% CI)	Model 2: OR (95% CI)
Full sample (<i>n</i> = 5863)							
% (<i>n</i>) Self-reported non-smoking	20.0 (93/464)	10.1 (194/1922)	15.4 (535/3477)	2.23 (1.70–2.93)***	1.88 (1.40–2.52)***	1.38 (1.08–1.76)*	1.21 (0.92–1.58)
				1.63 (1.17–2.28)**	1.63 (1.17–2.27)**	1.62 (1.19–2.19)**	1.61 (1.19–2.18)**
Subsample: quit attempt started ≤26 weeks (<i>n</i> = 3784)							
% (<i>n</i>) Self-reported non-smoking	20.3 (72/354)	11.0 (135/1222)	14.6 (323/2208)	2.06 (1.50–2.82)***	1.80 (1.27–2.55)***	1.49 (1.12–1.98)**	1.39 (1.01–1.90)*
				1.56 (1.06–2.29)*	–	1.88 (1.32–2.68)***	–
Subsample: quit attempt started >26 weeks (<i>n</i> = 2079)							
% (<i>n</i>) Self-reported non-smoking	19.1 (21/110)	8.4 (59/700)	16.7 (212/1269)	2.56 (1.49–4.42)***	1.98 (1.11–3.53)**	1.18 (0.72–1.94)	0.91 (0.54–1.55)
				1.64 (0.83–3.24)	–	1.10 (0.59–2.06)	–

Model 1 = unadjusted; model 2 = adjusted for age, sex, social grade, time since quit attempt started, quit attempts in the past year, abrupt versus gradual quitting and year of the survey; model 3 = adjusted for the variables from model 2 and time spent with urges to smoke and strength of urges to smoke; model 4 = adjusted for the variables from model 3 and the interaction terms time since last quit attempt started × time spent with urges and time since last quit attempt started × strength of urges to smoke. NB: for the two subsample analyses, model 4 is redundant, as there is no variation in the time since quit attempt. * $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$. OR = odds ratio; CI = confidence interval; NRT = nicotine replacement therapy.

during a time when e-cigarette usage was relatively rare (2009–11) had little effect on the results: among those 2306 smokers responding between 2012–14 the adjusted odds of non-smoking in users of e-cigarettes were higher compared with users of NRT bought over-the-counter (OR = 1.59, 95% CI = 1.05–2.42) and those using no aid (OR = 1.46, 95% CI = 1.04–2.05). In a final subgroup analysis the models were re-examined among those who started their quit attempt more or less than 6 months ago: there was only evidence among those who began their attempts less than 6 months ago of higher odds of non-smoking in users of e-cigarettes compared with users of NRT bought over-the-counter or those using no aid in the fully adjusted models (see Table 3).

DISCUSSION

Respondents who reported having used an e-cigarette in their most recent quit attempt were more likely to report still not smoking than those who used NRT bought over-the-counter or nothing. This difference remained after adjusting for time since the quit attempt started, year of the survey, age, gender, social grade, abrupt versus gradual quitting, prior quit attempts in the same year and a measure of nicotine dependence.

The unadjusted results have value in that they demonstrate self-reported abstinence is associated with quit-

ting method among those who use these methods to aid cessation in real-world conditions. However, this was not a randomized controlled trial and there were differences in the characteristics of those using different methods. For example, more dependent smokers tended to be more likely to use treatment, and smokers from lower social grades were less likely to use e-cigarettes. Although the adjustments go beyond what is typically undertaken in these types of real-world studies [28,29,41–44], it was not possible to assess all factors that may have been associated with the self-selection of treatment and we cannot rule out the possibility that an unmeasured confounding factor is responsible for the finding. For example, motivation to quit is likely to have been associated positively with the use of treatment. However, previous population studies have found that the strength of this motivation is not associated with success of quit attempts once started, so it is unlikely to explain our findings [45]. There are other variables which are typically related to abstinence that may also be related to the selection of treatment; for example, those using e-cigarettes may have been less likely to share their house with other smokers, had better mental health or greater social capital of a kind not measured by social grade. These possibilities mean the associations reported here must be interpreted with caution. Nevertheless, the data provide some evidence in forming a judgement as to whether the advent of e-cigarettes in the UK market is likely to be having a

positive or negative impact on public health, in a way that a randomized controlled trial is unable to do.

The finding that smokers who had used an e-cigarette in their most recent quit attempt were more likely to report abstinence than those who used NRT bought over-the-counter, and that the latter did not appear to give better results than not using any aid [33], contributes to the debate about how far medicine regulation can go in ensuring that products used for smoking cessation are or continue to be effective in the real world [14–17]. Randomized controlled trials are clearly important in identifying potential efficacy, but real-world effectiveness will depend upon a number of other contextual variables. The current study, together with previous randomized trials, suggests that e-cigarettes may prove to be both an efficacious and effective aid to smoking cessation [10,11]. In so far that this is true, e-cigarettes may substantially improve public health because of their widespread appeal [6–9] and the huge health gains associated with stopping smoking [46]. This has to be offset against any detrimental effects that may emerge, as the long-term effects on health have not yet been established. However, the existing evidence suggests the associated harm may be minimal: the products contain low levels of carcinogens and toxicants [3] and no serious adverse event has yet been reported in any of the numerous experimental studies. Regardless, the harm will certainly be less than smoking, and thus of greater importance is the possible long-term effect of e-cigarettes on cigarette smoking prevalence beyond helping some smokers to quit. For example, it has been suggested that e-cigarettes might re-normalize smoking, promote experimentation among young people who otherwise may not have tried smoking or lead to dual use together with traditional cigarettes, and thereby deter some smokers from stopping [47]. The current data do not address these issues. However, the rise in e-cigarette prevalence in England since 2010 has coincided with continued reduction in smoking prevalence [48].

If e-cigarette use is proving more effective than NRT bought over-the-counter, a number of factors may contribute to this [49]. A greater similarity between using e-cigarettes and smoking ordinary cigarettes in terms of the sensory experience could be one factor. Greater novelty is another. It is also possible that users of e-cigarettes use their products more frequently or for a longer period than those using NRT without professional support. These are all issues that need to be examined in future research.

This study was not designed to assess the comparative effectiveness of e-cigarettes and NRT or other medications obtained on prescription or behavioural support. The evidence still favours the combination of behavioural support and prescription medication as providing the

greatest chance of success [33,34,37], which is currently offered free at the point of access by the NHS stop smoking services in the United Kingdom.

A major strength of the current study is the use of a large, representative sample of the English population. Additionally, the study benefits from having begun to track the use of e-cigarettes as an aid to cessation at a time when e-cigarettes were only an emerging research issue. The importance of adjusting for nicotine dependence in real-world studies of smoking cessation is illustrated by the difference in the ORs between the models with and without this adjustment. The optimal method of adjusting for dependence would be to assess this in all participants prior to their quit attempt. However, in a wholly cross-sectional study, we believe the particular method used to adjust for dependence, established in two previous studies, is valid [32,33]. One of the most commonly used alternative measures of dependence—HIS—relies upon the number of cigarettes smoked and time to first cigarette of the day [40]. When smokers relapse they tend to do so with reduced consumption, which can lead to a false estimation of prior dependence in cross-sectional studies. This potential confound was avoided in the primary analysis by using a validated measure involving ratings of current urges to smoke and statistical adjustment of the urges for the time since the quit attempt was initiated [39]. The value of strength of urges as a measure of dependence in cross-sectional research would be limited if different methods of stopping were linked differentially to lower or higher levels of urges in abstinent compared with relapsed smokers. For example, a method of stopping that led to a relatively higher reduction in urges could underestimate the effectiveness of that method by making it seem that those using it were less dependent. However, we have not previously found evidence in this population data set that urges to smoke in smokers versus quitters differs as a function of method [33], and it was true again in this study. Regardless, the pattern of results remained the same in both a sensitivity analysis that also included HSI and in a subgroup analysis that excluded very light smokers. It is unlikely, therefore, that differential dependence between the users of different treatments has led to a substantial over- or underestimation of the relative effectiveness of e-cigarettes in the current study. Nevertheless, future studies may be able to draw stronger inferences by including a broader array of dependence measures or assessing dependence prior to a quit attempt.

The study had several limitations. First, abstinence was not verified biochemically. In randomized trials, this would represent a serious limitation because smokers receiving an active treatment often feel social pressure to report abstinence. However, in population surveys the

social pressure and the related rate of misreporting is low and it is generally considered acceptable to rely upon self-reported data [38]. A related issue is the assessment of abstinence by asking respondents whether they were 'still not smoking'. This definition classified as abstinent those who had one or more lapses but resumed not smoking. This limitation would be serious if the rate of lapsing was associated with method of quitting, and should be assessed in future studies. By contrast, advantages of this measure were the assessment of prolonged abstinence, as advocated in the Russell Standard, and a clear relationship to the quit attempt in question. An alternative approach, with a view to survival analysis, may have been to assess the length of abstinence since quit date among all respondents, including those who had relapsed by the time of the survey. However, this assessment would have added noise and potential bias with smokers needing to recall the time of relapse and having different interpretations of their return to smoking (i.e. first lapse, daily but reduced smoking, or smoking at pre-quit level). The strength of our approach is that smokers only needed to know whether they were currently still not smoking.

Secondly, there was a reliance upon recall data. The assessment of the most recent quit attempt involved recall of the previous 12 months and introduced scope for bias. The bias associated with recall of failed quit attempts would be expected to reduce the apparent effectiveness of reported aids to cessation because quit attempts using such aids would be more salient than those that were unaided [31]. Therefore, recall bias should militate against finding a benefit of e-cigarettes compared with no aid to cessation. Consistent with this explanation, the effect size for e-cigarettes compared with no aid appeared lower in smokers who started their quit attempt more than 6 months ago than in smokers who started their quit attempt less than 6 months ago. Although the power to detect the associations in these subgroups was limited, the explanation that the lack of effect in the more distant attempts was related to differential recall bias is also supported by the absolute rate of non-smoking being higher in those making unaided attempts more than 6 compared with less than 6 months ago. Alternatively, the finding may reflect a reduced long-term effectiveness of e-cigarettes. Future longitudinal studies of e-cigarettes as aids to cessation in the general population may differentiate these explanations and would represent a valuable improvement upon the current study.

Thirdly, NRT over-the-counter and e-cigarettes both represent heterogeneous categories. In particular, there is considerable variability in nicotine vaporization between different types of e-cigarette [50, 51]. Similarly, the simple definition of using one or the other aid to support an attempt is likely to have masked variability in how heavily, frequently and how long either NRT over-the-counter or

e-cigarettes were used by different smokers [12, 52–54]. It is also possible that there were differences between the groups in their experience of unanticipated side effects. It is precisely because of all these factors—type/brand of NRT over-the-counter or e-cigarette, intensity and frequency of usage and experience of unanticipated side effects—that it is important to examine real-world effectiveness. However, it also means that we cannot make more exact statements about relative effectiveness of different products and ways in which they may be used. Given this huge variability it may be many years before one could accumulate enough real-world data to address these questions. Finally, the prevalence of e-cigarettes has been increasing in England over the study period and this may affect real-world effectiveness. Although the evidence does not yet suggest an 'early adopters' effect—the current results persisted after adjusting for the year of survey and in a subgroup analysis limiting the data to a period when e-cigarette usage had become prevalent—these findings will need to be revisited to establish whether or not the apparent advantage of e-cigarettes is sustained.

In conclusion, among smokers trying to stop without any professional support, those who use e-cigarettes are more likely to report abstinence than those who use a licensed NRT product bought over-the-counter or no aid to cessation. This difference persists after adjusting for a range of smoker characteristics such as nicotine dependence.

Declaration of interests

All authors have completed the Unified Competing Interest form at http://www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: JB's post is funded by a fellowship from the UK Society for the Study of Addiction; R.W. is funded by Cancer Research UK; Cancer Research UK, the Department of Health and Pfizer funded data collection for this study (including a Pfizer investigator initiated award), and that at the outset data collection for the Smoking Toolkit Study was also supported by GlaxoSmithKline and Johnson and Johnson; J.B., D.K. and E.B. have all received unrestricted research grants from Pfizer; R.W. undertakes research and consultancy and receives fees for speaking from companies that develop and manufacture smoking cessation medications (Pfizer, J&J, McNeil, GSK, Nabi, Novartis and Sanofi-Aventis); there are no other financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years, particularly electronic cigarette companies, and there are no other relationships or activities that could appear to have influenced the submitted work. Funding was provided for the conduct of this research and preparation of the manuscript. The funders had no

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Transparency declaration

J.B. affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

STROBE statement

All authors declare that study hypotheses arose before any inspection of the data and that all STROBE recommendations were followed.

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Original Article

Electronic cigarettes as a harm reduction strategy for tobacco control: A step forward or a repeat of past mistakes?

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Abstract The issue of harm reduction has long been controversial in the public health practice of tobacco control. Health advocates have been reluctant to endorse a harm reduction approach out of fear that tobacco companies cannot be trusted to produce and market products that will reduce the risks associated with tobacco use. Recently, companies independent of the tobacco industry introduced electronic cigarettes, devices that deliver vaporized nicotine without combusting tobacco. We review the existing evidence on the safety and efficacy of electronic cigarettes. We then revisit the tobacco harm reduction debate, with a focus on these novel products. We conclude that electronic cigarettes show tremendous promise in the fight against tobacco-related morbidity and mortality. By dramatically expanding the potential for harm reduction strategies to achieve substantial health gains, they may fundamentally alter the tobacco harm reduction debate.

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Keywords: electronic cigarette; harm reduction; nicotine regulation; tobacco control

Introduction

Harm reduction is a framework for public health policy that focuses on reducing the harmful consequences of recreational drug use without necessarily reducing or eliminating the use itself.¹ Whereas harm reduction policies have been widely adopted

for illicit drug use (for example, needle exchange programs²) and alcohol use (for example, designated driver programs³), they have not found wide support in tobacco control. Many within the tobacco control community have embraced nicotine replacement therapy (NRT) and other pharmaceutical products, but these products are designed as cessation strategies rather than recreational alternatives. Recently, however, a new product that does not fit neatly into any previous category has entered the nicotine market: the electronic cigarette. Electronic cigarettes do not contain tobacco, but they are recreational nicotine devices and the user closely mimics the act of smoking. Thus, they are neither tobacco products nor cessation devices. The novel potential of electronic cigarettes warrants revisiting the harm reduction debate as it applies to these products.

In this article, we first explain what electronic cigarettes are and why they are difficult to categorize. Second, we examine the available evidence concerning the safety and efficacy of electronic cigarettes. Then, we review the most common arguments made against harm reduction in the tobacco control literature, followed by an analysis of each of these arguments in light of the recent emergence of electronic cigarettes. Finally, we identify conclusions from this analysis and their implications for the public health practice of tobacco control.

What are Electronic Cigarettes and Why are They Novel?

Electronic cigarettes are hand-held devices that deliver nicotine to the user through the battery-powered vaporization of a nicotine/propylene-glycol solution. The act of ‘smoking’ an electronic cigarette is called ‘vaping’ and it mimics smoking; but, there is no combustion and the user inhales vapor, not smoke. Although the nicotine is derived from tobacco, electronic cigarettes contain no tobacco. Theoretically, we would expect *vaping* to be less harmful than smoking as it delivers nicotine without the thousands of known and unknown toxicants in tobacco smoke. Moreover, a product that mimics the act of smoking, in addition to delivering nicotine, can address both pharmacologic and behavioral components of cigarette addiction. Electronic cigarettes are not manufactured or distributed by the tobacco industry or by the



pharmaceutical industry. Hundreds of small distributors market them over the internet and in shopping mall kiosks. They have been on the market in the United States for more than 3 years and have become increasingly popular.

Review of Evidence Regarding the Safety of Electronic Cigarettes

As ~5300 of the estimated 10000–100000 chemicals in cigarette smoke have ever been identified,⁴ we already have more comprehensive knowledge of the chemical constituents of electronic cigarettes than tobacco ones. We were able to identify 16 studies^{5–17} that have characterized, quite extensively, the components contained in electronic cigarette liquid and vapor using gas chromatography mass spectrometry (GC-MS) (Table 1). These studies demonstrate that the primary components of electronic cigarette cartridges are propylene glycol (PG), glycerin, and nicotine. Of the other chemicals identified, the FDA has focused on potential health hazards associated with two: tobacco-specific nitrosamines (TSNAs) and diethylene glycol (DEG).⁵

TSNAs have been detected in two studies at trace levels.^{5,6} The maximum level of total TSNAs reported was 8.2 ng/g.⁶ This compares with a similar level of 8.0 ng in a nicotine patch, and it is orders of magnitude lower than TSNA levels in regular cigarettes.¹⁸ Table 2 shows that electronic cigarettes contain only 0.07–0.2 per cent of the TSNAs present in cigarettes, a 500-fold to 1400-fold reduction in concentration. The presence of DEG in one of the 18 cartridges studied by the US Food and Drug Administration (FDA) is worrisome, yet none of the other 15 studies found any DEG. The use of a non-pharmaceutical grade of PG may explain this contamination.

Other than TSNAs and DEG, few, if any, chemicals at levels detected in electronic cigarettes raise serious health concerns. Although the existing research does not warrant a conclusion that electronic cigarettes are safe in absolute terms and further clinical studies are needed to comprehensively assess the safety of electronic cigarettes, a preponderance of the available evidence shows them to be much safer than tobacco cigarettes and comparable in toxicity to conventional nicotine replacement products.

Table 1: Laboratory studies of the components in and safety of electronic cigarettes⁵⁻¹⁷

<i>Study</i>	<i>Brand tested</i>	<i>Main findings</i>
Evaluation of e-cigarettes (FDA laboratory report) ⁵	NJOY, Smoking Everywhere	'Very low levels' of tobacco-specific nitrosamines (TSNAs) were detected in 5 of 10 cartridges tested. Diethylene glycol (DEG) was detected about 0.1% in 1 of 18 cartridges tested.
Safety Report on the Ruyan e-Cigarette Cartridge and Inhaled Aerosol ⁶	Ruyan	Trace levels of TSNAs were detected in the cartridge liquid. The average level of TSNAs was 3.9 ng/cartridge, with a maximum level of 8.2 ng/cartridge. Polyaromatic hydrocarbon carcinogens found in cigarette smoke were not detectable in cartridge liquid. No heavy metals detected. Exhaled carbon monoxide levels did not increase in smokers after use of the e-cigarette. The study concluded that e-cigarettes are very safe relative to cigarettes and safe in absolute terms on all measurements applied.
Ruyan E-cigarette Bench-top Tests ⁷	Ruyan	None of the 50 priority-listed cigarette smoke toxicants were detected. Toxic emissions score for e-cigarette was 0, compared to 100-134 for regular cigarettes.
Characterization of Liquid 'Smoke Juice' for Electronic Cigarettes ⁸	Liberty Stix	No compounds detected via gas chromatography mass spectrometry (GC-MS) of electronic cigarette cartridges or vapors other than propylene glycol (99.1% in vapor), glycerin (0.46%), and nicotine (0.44%).
Analysis of Components from Gamucci Electronic Cigarette Cartridges, Tobacco Flavour Regular Smoking Liquid ⁹	Gamucci	GC-MS detected propylene glycol (77.5%), glycerin (14.0%), nicotine (8.5%), and cyclotene hydrate (0.08%) in e-cigarette liquid. Levels of cyclotene hydrate were not believed to be of concern.
Analysis of Components from Gamucci Electronic Cigarette Cartridges, Tobacco Flavour Light Smoking Liquid ⁹	Gamucci	GC-MS detected propylene glycol (80.4%), glycerin (14.4%), and nicotine (5.3%) in e-cigarette liquid. No other compounds detected.

Analysis of Components from Gamucci Electronic Cigarette Cartridges, Ultra Light Smoking Liquid ⁹	Gamucci	GC-MS detected propylene glycol (85.5%), glycerin (11.2%), and nicotine (3.3%) in e-cigarette liquid. No other compounds detected.
Analysis of Components from Gamucci Electronic Cigarette Cartridges, Tobacco Flavour Zero, Smoking Liquid ⁹	Gamucci	GC-MS detected propylene glycol (84.3%), glycerin (7.6%), 1,3-bis(3-phenoxyphenoxy)Benzene (7.0%), 3-Isopropoxy-1,1,1,7,7,7-hexamethyl-3,5,5-tris(trimethylsiloxy)tetrasiloxane (0.77%), and α , β , γ -tris[(trimethylsilyloxy)Benzeneacetic acid (0.39%) in e-cigarette liquid. No other compounds were detected. 1,3-bis(3-phenoxyphenoxy) Benzene is non-hazardous. The other two chemicals have an unknown safety profile, but are present at nominally low levels.
NJOY e-Cigarette Health Risk Assessment ¹⁰	NJOY	The vapor constituents detected were propylene glycol, glycerin, nicotine, acetaldehyde, 1-methoxy-2-propanol, 1-hydroxy-2-propanone, acetic acid, 1-menthone, 2,3-butanediol, menthol, carvone, maple lactone, benzyl alcohol, 2-methyl-2-pentanoic acid, ethyl maltol, ethyl cinnamate, myosamine, benzoic acid, 2,3-bipyridine, cotinine, hexadecanoic acid, and 1'1-oxybis-2-propanol. No TSNAs, polyaromatic hydrocarbons, or other tobacco smoke toxicants were detected. On the basis of the amounts of these components present and an examination of the risk profile of these compounds, the report concludes that the only significant side effect expected would be minor throat irritation resulting from the acetaldehyde.
Characterization of Regal Cartridges for Electronic Cigarettes ¹¹	inLife	No DEG was detected in the cartridge liquid or vapors.
Characterization of Regal Cartridges for Electronic Cigarettes – Phase II ¹²	inLife	No TSNAs were detected in the e-cigarette liquid (limit of detection was 20 ppm).



Table 1 continued

<i>Study</i>	<i>Brand tested</i>	<i>Main findings</i>
Analysis of Components from “e-Juice XX High 36 mg/ml rated Nicotine Solution”: ref S55434 ¹³	e-Juice	GC-MS detected propylene glycol (51.2%), 1,3-bis(3-phenoxy phenoxy)Benzene (20.2%), glycerin (15.0%), nicotine (10.0%), vanillin (1.2%), ethanol (0.5%), and 3-cyclohexene-1-menthol, α , α , α .4-trimethyl (0.4%). No other compounds detected. 1,3-bis(3-phenoxyphenoxy)Benzene is non-hazardous. Vanillin and 3-cyclohexene-1-menthol, α , α , α .4-trimethyl have unknown safety profiles.
Analysis of Chemical Components from High, Med & Low Nicotine Cartridges ¹⁴	The Electronic Cigarette Company (UK)	The compounds detected by GC-MS were propylene glycol, water, nicotine, ethanol, nitrogen, and triacetin. Triacetin is not known to be hazardous. No other compounds were detected.
Chemical Composition of “Instead” Electronic Cigarette Smoke Juice and Vapor ¹⁵	Instead	No DEG was detected in e-cigarette liquid or vapor for the two products tested.
Gas Chromatography Mass Spectrometry (GC-MS) Analysis Report ¹⁶	Not specified	GC-MS detected propylene glycol, glycerin, nicotine, caffeine, tetra-ethylene glycol, pyridine, methyl pyrrolyl, pyridine, methyl pyrrolidiny, butyl-amine, and hexadecanoic acid in the e-cigarette liquid.
Super Smoker Expert Report ¹⁷	Super Smoker	GC-MS detected propylene glycol, glycerin, nicotine, ethanol, acetone ethyl acetate, acetals, isobutyraldehyde, essential oils, and 2-methyl butanal in the e-cigarette liquid. No other compounds were detected.



Table 2: Maximum tobacco-specific nitrosamine levels^a in various cigarettes and nicotine-delivery products (ng/g, except for nicotine gum and patch that are ng/patch or ng/gum piece)⁶

Product	NNN	NNK	NAT	NAB	Total
Nicorette gum (4 mg) ¹⁸	2.00	ND	ND	ND	2.00
NicoDerm CQ patch (4 mg) ¹⁸	ND	8.00	ND	ND	8.00
Electronic cigarettes⁶	3.87	1.46	2.16	0.69	8.18
Swedish snus ¹⁸	980	180	790	60	2010
Winston (full) ¹⁸	2200	580	560	25	3365
Newport (full) ¹⁸	1100	830	1900	55	3885
Marlboro (ultra-light) ¹⁸	2900	750	1100	58	4808
Camel (full) ¹⁸	2500	900	1700	91	5191
Marlboro (full) ¹⁸	2900	960	2300	100	6260
Skoal (long cut straight) ¹⁸	4500	470	4100	220	9290

^aThe concentrations here represent nanograms (ng) of toxin detected in 1 ruyan 16-mg multi-dose cartridge (which contains approximately 1 gm of e-liquid). They are compared to the amount of toxin contained in approximately one tobacco cigarette (approximately 1 gm of tobacco) or one unit of nicotine replacement product.

Abbreviations: NNN=4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone; NNK=N'-nitrosonor-nicotine; NAT=N'-nitrosoanatabine; NAB=N'-nitrosoanabasine.

ND=Not detected.

Review of Evidence about the Effectiveness of Electronic Cigarettes in Smoking Cessation

No studies have measured directly the effectiveness of electronic cigarettes in helping smokers cease smoking. Two published studies have examined the effectiveness of the product by measuring their effect on cravings and other short-term indicators. We summarize them briefly in Table 3.^{19,20} Bullen *et al*¹⁹ demonstrated that electronic cigarettes deliver nicotine effectively, more rapidly than a nicotine inhaler. In this study, electronic cigarette use significantly reduced craving, a similar effect to what was observed with a nicotine inhaler. Nicotine delivery and reduction in cigarette craving was much less than with a regular cigarette. Eissenberg²⁰ found that 10 puffs on one brand of electronic cigarettes delivered a small amount of nicotine, again far less than a tobacco cigarette, whereas another brand delivered little to none. The first brand was able to significantly reduce cigarette craving.

Taken together, this evidence suggests that electronic cigarettes are capable of reducing cigarette craving, but that the effect is not due exclusively to nicotine. Bullen *et al* observe that 'the reduction in

Table 3: Studies of the effectiveness of electronic cigarettes in reducing cigarette craving and other nicotine withdrawal symptoms^{19,20}

<i>Study</i>	<i>Brand tested</i>	<i>Summary of findings</i>
Effect of an E-Cigarette on Cravings and Withdrawal, Acceptability and Nicotine Delivery: Randomized Cross-Over Trial ¹⁹	Ruyan	The 16 mg electronic cigarette delivered nicotine more rapidly than a nicotine inhaler, but less rapidly than cigarettes. Electronic cigarette use significantly reduced craving, but less than cigarettes. The reduction of craving was similar to that observed with the nicotine inhaler. The electronic cigarettes produced fewer minor side effects than the nicotine inhaler.
Electronic Nicotine Delivery Devices: Ineffective Nicotine Delivery and Craving Suppression after Acute Administration ²⁰	NJOY and Crown Seven	After 10 puffs on an electronic cigarette, one of the two brands tested significantly reduced the craving for a cigarette. Nicotine delivery was found to be minimal.

desire to smoke in the first 10 min[utes] of [electronic cigarette] use appears to be independent of nicotine absorption’ (p. 100).¹⁹ The sizable craving reduction achieved by the ‘placebo’ – a nicotine-free electronic cigarette – demonstrates the ability of physical stimuli to suppress cravings independently.¹⁹ Many studies have established the ability of *denicotinized* cigarettes to provide craving relief.^{21,22} Barrett²¹ found that denicotinized cigarettes reduce cravings more than a *nicotinized* inhaler, supporting Buchhalter *et al*’s²² conclusion that although some withdrawal symptoms can be treated effectively with NRT, others, such as intense cravings, respond better to smoking-related stimuli.

Although more research is needed before we will know how effective electronic cigarettes are at achieving smoking abstinence, there is now sufficient evidence to conclude that these products are at least capable of suppressing the urge to smoke. There is also reason to believe that they offer an advantage over traditional nicotine delivery devices ‘[t]o the extent that non-nicotine, smoking-related stimuli alone can suppress tobacco abstinence symptoms indefinitely’ (p. 556).²²



The Most Common Arguments against Harm Reduction

Our review of the existing literature identified five primary arguments against harm reduction as a tobacco control strategy. These arguments explain why, in the past, harm reduction has not been accepted as a tobacco control strategy.

Promotion of safer alternatives will inhibit smoking cessation/prevention efforts

The core fear is that smokers who might otherwise have quit smoking altogether will instead become addicted to another harmful product. In addition, a product that reduces harm to the individual may attract new, nonsmoking users, and thus undermine efforts to prevent tobacco use.²³

Skepticism about the role of combusted products in harm reduction

The argument here, based on numerous related concerns, is that the combustion of tobacco produces inherently dangerous exposures and thus the search for a 'safer' cigarette is futile. It is impossible to assess the risks of a new product using machine measured delivery of smoke constituents, because there is no good way to simulate actual smoking behavior.²³ We cannot, moreover, easily infer human risk from chemical measurements because no reliable toxicity indices exist.²⁴ A widespread school of thought in tobacco control holds that the very nature of tobacco combustion precludes safer cigarettes, and therefore attempts to develop them should be abandoned.²⁵

Alternatives promoted as safer may prove more dangerous, or they may be equally dangerous, leading to false or unsupported claims and to the misleading of the public

Experience with potentially reduced exposure products in the past has revealed that products promoted by the tobacco industry as potentially safer have ended up either not being safer or resulted in increased toxicant exposures.²³ In particular, a broad consensus within the public health community holds that 'light' cigarettes

misled consumers into thinking that they were being exposed to lower levels of toxic chemicals.²⁶ Smokers ended up compensating for the reduced nicotine in ‘lights’ by smoking with greater frequency and intensity, resulting in higher exposures than originally reported.²³

NRT has not been effective, meaning that harm reduction equals harm maintenance

Pierce²⁷ argued that using NRT for tobacco harm reduction is, in fact, harm maintenance because NRT is so ineffective that it essentially ensures that Big Tobacco (the large tobacco industry companies) will not lose its customers. Smokers simply do not like products that merely deliver nicotine, and therefore ‘we should not assume that smokers would be willing and able to substitute a nicotine maintenance product for their cigarette smoking’ (p. S54).

Big Tobacco cannot be trusted to develop and market a safer tobacco alternative

The final argument is that the tobacco companies, based on their history of lies and deception, simply cannot be trusted to develop and market a safer tobacco alternative.²⁸ Fairchild and Colgrove²⁸ make a related point, that ‘prioritizing the reduction of harm, however great or minimal, may necessitate some level of cooperation with the tobacco industry and will *certainly prove lucrative for it*’ (our emphasis added, p. 201) Thus, tobacco harm reduction will necessarily benefit the tobacco industry regardless of what else might be achieved.

Analysis of Arguments in Light of the Emergence of Electronic Cigarettes

With the emergence of electronic cigarettes, the harm reduction debate in tobacco control has changed. We now address the five major arguments against harm reduction in light of the emergence of electronic cigarettes.



Promotion of safer alternatives will inhibit smoking cessation/prevention efforts

In contrast to reduced risk cigarettes or smokeless tobacco products, electronic cigarettes are not tobacco products. Thus, switching to electronic cigarettes is not an alternative to smoking cessation, but rather a form of smoking cessation akin to long-term use of NRT. Moreover, because 'low absolute abstinence rates suggest that nicotine alone may not be sufficient to suppress ... abstinence symptoms effectively' (p. 551),²² higher abstinence rates are likely to obtain from a product that better addresses these symptoms. Crucially, electronic cigarettes could entice smokers who were not otherwise inclined, to attempt to quit. Although the use of electronic cigarettes by nonsmokers is a theoretical concern, there is no existing evidence that youths or nonsmokers are using the product. Regulations can address the sale and marketing of these products to minors.

Skepticism about the role of combusted products in harm reduction

Electronic cigarettes, such as NRT, are not tobacco products and no combustion takes place.

Alternatives promoted as safer may actually be equally or more dangerous

Thus far, none of the more than 10000 chemicals present in tobacco smoke,⁴ including over 40 known carcinogens, has been shown to be present in the cartridges or vapor of electronic cigarettes in anything greater than trace quantities. No one has reported adverse effects, although this product has been on the market for more than 3 years. Still, the FDA struck a more ominous tone in its July 2009 press release, warning of the presence of carcinogens at 'detectable' levels.²⁹ Yet it failed to mention that the levels of these carcinogens was similar to that in NRT products (Table 2). Whereas electronic cigarettes cannot be considered safe, as there is no threshold for carcinogenesis, they are undoubtedly safer than tobacco cigarettes.

NRT is unappealing and ineffective

Pharmaceutical products for dispensing nicotine are unappealing ‘by design’ (p. S123)³⁰ to avoid ‘abuse-liability’.³⁰ Electronic cigarettes, on the other hand, were designed with the express purpose of replicating the act of smoking, without using tobacco.³¹ An investment newsletter reports that demand thus far has been explosive.³² Intense consumer interest in electronic cigarettes has already spawned a vibrant online community of ‘vapers’ who compare and contrast the performance of various brands and models according to their durability, battery life, thickness of vapor, and other criteria.³³ No non-tobacco nicotine product has heretofore elicited such dedication among its users, suggesting the rare promise of the electronic cigarette as a smoking cessation tool.

Big Tobacco cannot be trusted

Electronic cigarettes are not tobacco products and not produced by tobacco companies. They were invented in Beijing by a Chinese pharmacist Hon Lik, whose employer, Golden Dragon Holdings, ‘was so inspired that it changed its name to Ruyan (meaning “like smoke”) and started selling abroad’.³¹ Rather than being helpful to cigarette makers, electronic cigarettes compete directly against them.³² Thus David Sweanor, adjunct law professor specializing in tobacco control issues at the University of Ottawa, says they are ‘exactly what the tobacco companies have been afraid of all these years’.³¹

Conclusion

Tobacco cigarettes are the leading cause of disease in the United States, which is why the ‘primary goal of tobacco control is to reduce mortality and morbidity associated with tobacco use’ (p. 326).²³ Electronic cigarettes are designed to mitigate tobacco-related disease by reducing cigarette consumption and smoking rates. The evidence reviewed in this article suggests that electronic cigarettes are a much safer alternative to tobacco cigarettes. They are likely to improve upon the efficacy of traditional pharmacotherapy for smoking cessation.

In light of this evidence, it is unfortunate that in the United States, the American Cancer Society, American Lung Association, American



Heart Association, Campaign for Tobacco-Free Kids, Action on Smoking and Health, American Legacy Foundation, American Academy of Pediatrics, and the Association for the Treatment of Tobacco Use and Dependence have all issued statements supporting FDA efforts to take them off the US market.³⁴ In the United States, the courts will ultimately determine whether the FDA has the legal authority to do this, but we question the ethical and health policy merits of this approach.

Do products with established user bases warrant a different regulatory approach than entirely new products? This would seem to follow from consistent application of the principal of nonmaleficence – ‘do no harm.’ Products yet to enter the market have only *potential* beneficiaries, people who can only speculate about what the precise therapeutic effects of the product will be for them. In contrast, products already on the market have users who may already be deriving benefits. By definition, enacting a ban will harm current users, unless the evidence suggests that the harms outweigh the benefits *for those already using the product*. The burden of proof is on the regulatory agency to demonstrate that the product is unreasonably dangerous for its intended use.

How does this principle apply to electronic cigarettes? For the many vapers who report using them in place of cigarettes,³³ the benefits of the product are readily observable, already established. Simply demonstrating that electronic cigarettes are ‘not safe’ may not be sufficient grounds to ban them. Unless the evidence suggests that vaping does not yield the anticipated *reduction* in harm to the user, enacting an electronic cigarette prohibition will do harm to hundreds of thousands of vapers already using electronic cigarettes in place of tobacco ones – a clear violation of nonmaleficence.

The essential rationale for the FDA’s pre-market approval process – to keep dangerous products out of the marketplace – may not easily extend to new nicotine products because a range of extraordinarily deadly nicotine products is already grandfathered into the market. This has led to an awkward nicotine regulatory structure where dirty tobacco products face few barriers to market entry whereas cleaner products are subject to oft onerous hurdles. The FDA contends that they can and should regulate electronic cigarettes as ‘drug-device combinations’ that are required to meet stringent Federal Food Drug and Cosmetic Act (FDCA) safety standards. The FDA reasons that

electronic cigarettes do not qualify for the usual exemption from FDCA standards afforded to most other recreational nicotine products because ‘much less is known about the safety of E-Cigarettes’ and ‘it may be possible for E-Cigarettes ... to satisfy the FDCA’s safety, effectiveness, and labeling requirements and obtain FDA approval’ (p. 26).³⁵ Ironically, the only nicotine products exempted from FDCA safety requirements are those that are too obviously harmful to have any chance of meeting these requirements. Litigation presently before the US Court of Appeals for the District of Columbia may ultimately determine whether the FDA can legally regulate electronic cigarettes as drug-device combinations.³⁶ Regardless of the court’s decision, we believe a better regulatory approach would not actively discourage producers of harm reduction products.

Fairchild and Colgrove²⁸ conclude that ‘the later history of tobacco industry deception and manipulation was an important factor contributing to the erosion of public health support for harm reduction’(p. 201). With entrenched skepticism toward harm reduction now manifested as deep cynicism about electronic cigarettes – a distinct product that actually *does* reduce risk and threatens cigarette makers – the tobacco industry is ironically benefiting from its own past duplicity. The push to ban electronic cigarettes may repeat the mistakes of the past in the name of avoiding them. Regulatory policy for electronic cigarettes and other novel nicotine products must be guided by an accurate understanding of how they compare to tobacco cigarettes and NRT in terms of reducing toxic exposures and helping individual smokers quit.

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Editorial

Tobacco harm reduction: How rational public policy could transform a pandemic

Abstract

Nicotine, at the dosage levels smokers seek, is a relatively innocuous drug commonly delivered by a highly harmful device, cigarette smoke. An intensifying pandemic of disease caused or exacerbated by smoking demands more effective policy responses than the current one: demanding that nicotine users abstain. A pragmatic response to the smoking problem is blocked by moralistic campaigns masquerading as public health, by divisions within the community of opponents to present policy, and by the public-health professions antipathy to any tobacco-control endeavours other than smoking cessation. Yet, numerous alternative systems for nicotine delivery exist, many of them far safer than smoking. A pragmatic, public-health approach to tobacco control would recognize a continuum of risk and encourage nicotine users to move themselves down the risk spectrum by choosing safer alternatives to smoking – without demanding abstinence.

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Introduction

In efforts aimed at reducing the risk of death, injury or disease from any behaviour there are four broad areas of possible intervention. These include efforts to prevent the behaviour ever taking place, efforts aimed at ending the behaviour, efforts aimed at preventing the activity from harming third parties and efforts aimed at reducing the risks of those who engage in the behaviour. The interaction of these four pillars of public health intervention can be seen in everything from pharmaceutical policy, the rules of sport, automobile regulation, workplace safety standards and food processing and preparation regimes.

Interestingly, when dealing with issues of sexual behaviour and the use of licit and illicit drugs there is often strong opposition to efforts aimed at the reduction of risks among those who will engage in the behaviour in question. This schism appears to be the result of a persistent tension between a rational, scientific program and a behavioural, moralistic approach (Brandt, 1987, p. 182).

The conflict over means traces to a fundamental disagreement about aims: Is the purpose of an intervention to make people healthier or safer? Or is it to create better moral souls, to make people less “bad”? The availability of ‘risk reduction’ among accepted interventions can be seen as a

key distinguishing feature between scientific public health interventions whose aims are pragmatic, and moralistic ones, whose aims are impossible to measure.

If the goal of public policy interventions on tobacco is to achieve the greatest possible reduction in deaths, injury and disease, then it is necessarily pragmatic. Therefore, it is necessary for policy makers to seriously consider the role of risk reduction for continuing users of tobacco/nicotine products. This does not mean that risk reduction strategies must replace other strategies any more than protection of third parties needs to replace cessation strategies. An ideal public health approach rationally combines the various possible interventions in pursuit of the greatest achievable reduction in deaths, injuries and disease.

The case for applying harm reduction strategies to public health interventions on tobacco

It is estimated that cigarette smoking resulted in the deaths of roughly 100 million people in the last century, and that at current trends in consumption will kill 10 times that many this century (Peto & Lopez, 2001). Roughly half of long-term smokers will die as a direct result of diseases caused by their smoking, and half of those deaths will occur during

middle age. In terms of drug related deaths cigarettes dwarf the toll from other drugs.

The primary reason for smoking cigarettes is to obtain nicotine. The cigarette is an effective – but almost uniquely hazardous – delivery device for the drug, nicotine. As with the use of other drugs the pursuit of nicotine can be attributed to a combination of recreation, addiction and self-medication. The extent of each of these motivations will vary over time and between smokers just as the reasons behind the pursuit of alcohol or caffeine will vary between consumers and change over time.

We stress that nicotine is the primary cause of tobacco consumption. But it is not the nicotine that causes the harm: the inhalation of tobacco smoke is responsible for the pandemic of cancers, heart disease, respiratory diseases and other deadly results of tobacco consumption. Nicotine itself is comparatively benign. A fatal dose of nicotine would require roughly 60 mg for an average person, but, as with a fatal dose of caffeine, such a quantity is far more than is sought or attained by consumers (Fagerstrom, 2005). Were the world's 1.3 billion cigarette smokers acquiring their nicotine from clean delivery systems rather than through repeated inhalation of smoke, nicotine use would likely not rank much higher than caffeine use as a public health priority.

Given the projected death rates associated with smoking and the fact that these deaths can largely be explained by the recognition that 'it's the smoke, stupid', harm reduction interventions are essential. The case for harm reduction is made all the stronger when one considers that there already are various alternatives to cigarettes that are markedly less toxic and clearly acceptable to large numbers of consumers (See Table 1).

In Sweden a smokeless tobacco product known as 'snus' has come to dominate the tobacco market, with sales rising as cigarette sales have fallen. Many former smokers have switched to snus, far more males use snus than smoke, and snus sales amongst females – which had long lagged male usage – is now evidently growing rapidly. As a result Sweden has the lowest level of tobacco related disease in males among OECD countries, and has reported male smoking prevalence that has now hit single digit percentages in parts of the country.

Table 1
Examples of western world smoke-free alternatives to cigarettes

Transdermal nicotine patch (of various strengths and regimens)
Nicotine chewing gum (range of flavours and 2 strengths)
Nicotine inhaler ['puffers']
Nicotine nasal spray
Medicinal nicotine lozenges (range of flavours and 3 strengths, including sublingual)
Ultra-low nitrosamine tobacco lozenges [Ariva, Stonewall]
Swedish snus
Hard tobacco [Oliver Twist]
Moist snuff [Skoal, Copenhagen]
Spit-free tobacco pouches
Chewing tobacco

Norway and the United States have also in recent years seen a rapid increase in sales of smokeless tobacco products, and these sales trends are ascribed at least in part to growing awareness that non-combustible products are massively less hazardous than smoking (Morgan Stanley Research North America, 2006). Many countries also now have experience with medicinal nicotine (gum, patches, lozenges and 'inhalers') meeting the needs of smokers not just for short-term cessation efforts but for longer term use as a replacement for smoking.

Smokeless tobacco products do cause disease – but at very low rates compared to cigarettes. The disease risk of smokeless tobacco can be made lower still through changes in manufacturing techniques that reduce toxins such as tobacco-specific nitrosamines. It has been estimated that modern smokeless tobacco products are least 90%, and perhaps closer to 99%, less deadly than smoking cigarettes (Levy et al., 2004; RCP, 2002). While there is popular recognition that 'smokeless tobacco causes oral cancer' few recognize that the risk of oral cancer from the sort of high nitrosamine smokeless products that used to be on Western markets (and upon which the oral cancer risk was based) was actually considerably lower than the risk of the disease from smoking. Nor is there widespread recognition that low nitrosamine products such as Swedish snus do not appear to cause oral cancer at all.

Medicinal nicotine products appear to be significantly less hazardous even than smokeless tobacco. These products have been subjected to rigorous evaluation by drug regulatory authorities in many countries and been in use for decades. The major risk of such products is not inherent dangers, but the fact that they are not used at a sufficient dosage for a sufficient length of time and so result in users reverting to cigarette smoking. In part this underutilization of medicinal nicotine can be attributed to government regulations that restrict the nature and availability of such products out of an expressed concern that there is a potential for 'abuse'. This cautious approach to medicinal nicotine, combined with assorted attacks on tobacco and nicotine that demonize nicotine and fail to distinguish inter-product risks helps to explain why a vast number of smokers incorrectly believe that nicotine itself causes cancer.

Current cigarettes and cigarette-like products are at the high end of a continuum of risk. Moving down the continuum, but still very likely to be high risk are alternative 'cigarette' designs that primarily heat rather than burn tobacco. These products are undoubtedly more hazardous than non-combustion-based delivery, but very likely less hazardous than smoking. Even tinkering with the toxicity levels of cigarettes, through such things as lowering nitrosamine levels in the tobacco leaf, has potential to reduce mortality. Non-combustion products, and particularly low nitrosamine smokeless tobacco and medicinal nicotine products are at the least hazardous end of this risk continuum.

The relative safety of smokeless tobacco and other smoke-free systems for delivering nicotine demolishes the claim that

abstinence-only approaches to tobacco are rational public-health campaigns. This is not to say that all smokers would or should necessarily switch to snus or current forms of medicinal nicotine. But it does mean that cigarettes need not be seen as the only way consumers can obtain their nicotine. This also means that it need not be that the only alternative to continued cigarette smoking must be complete cessation of nicotine in any form.

Alternative nicotine delivery devices will still entail risks. But as nothing in life is devoid of risks it is nonsensical to dismiss an alternative to a tremendously harmful activity by claiming the alternative is not absolutely 'safe', or to claim that the pursuit of a less hazardous alternative implies that the alternative is "virtually harmless" (Gray & Henningfield, 2006).

As more alternatives to conventional cigarettes are considered it is clear that there is a wide range of possibilities on the continuum of risk. The variation of risk among interchangeable products creates a strong basis for regulatory intervention aimed at shaping the market. It should also be the basis for accurate communications to consumers. The fact that alternative products can meet the needs of some significant number of those who would likely otherwise smoke cigarettes also raises key issues about just what sort of products might be available, what sort of information consumers can be given about relative risks and what sort of policy environment could achieve maximum public health benefits through the greatest transition of smokers to less toxic alternatives.

The critical issue in looking at consumer safety, and one that makes tobacco/nicotine an ideal area for harm reduction interventions, is that smokers are capable of moving down the risk continuum when offered alternative products and accurate information on relative risks. A pragmatic goal would be to move current smokers as far down the continuum of risk as possible, without depriving consumers of all choice. The consumer who rejects (or cannot achieve) abstinence but will use a product that reduces risk by 90% should not be prevented from making that preferred choice. Indeed, it is exactly the forced choice between smoking and abstinence that reinforces the current dominance of cigarettes.

Fitting harm reduction into existing public health interventions on tobacco

Comparing tobacco control interventions with efforts that have historically been directed at reducing the toll associated with other potentially dangerous consumer products reveals how tobacco and the harms of smoking it, are positioned in the consumer culture. With products such as food, pharmaceuticals, automobiles, electrical goods, toys, sports equipment and caffeine products, reform movements embraced risk reduction. Though this often came after a fight between pragmatists and 'absolutists' (Young, 1989), the transition was not nearly as drawn out or heated as

is currently the case on tobacco/nicotine. More than 40 years after the U.S. Surgeon General's Report on the Health Consequences of Smoking opened the protracted public-health campaign to stamp out smoking-related disease, no public-health approach to tobacco has emerged that can fully counteract smoking-promoted morbidity and mortality. While many tobacco-control interventions have reduced smoking rates and prevented millions of deaths, that success is limited: Even today, policy makers refuse to deal directly with the nature of nicotine itself by giving viable alternative delivery systems to smokers. The result is that millions of tobacco users, unable to quit, are not encouraged – or simply not told – that they might be safer by moving down the "risk continuum" to an alternative nicotine-delivery system.

Current debates within tobacco control circles more closely resemble those found on issues such as alcohol, illicit drugs and sexual practices rather than the dangers of consumer items. In regard to substance use and sex, the pragmatism that marks the typical harm-reduction approach to product safety collides with moralistic approaches to human behaviour. The conflicts over drug use, especially in the context of deadly viral infections potentially spread through drug delivery systems (i.e., needle and syringe), are well known. In many countries, battles still rage over what to tell people – especially adolescents – about sex and in particular whether to encourage them to use condoms or simply to abstain from sex outside of marriage. While tobacco use has not yet elicited the same emotional intensity as have concerns about addiction and teen sex, the failure to establish a rational and evidence-based public-health approach to tobacco use can be traced to similar sorts of pragmatism–moralism debates.

And the situation with tobacco might be even more complicated than the debate over illicit drug use. One of the challenges facing tobacco control efforts is that the advocates pushing for social change include both public health pragmatists who are genuinely concerned about reducing tobacco-associated illness and death caused by smoking and moral absolutists whose concern is with the bad habit of substance (nicotine) use. They find common ground on elimination of smoking and doing battle with the tobacco companies. But, as seen in the history of the Pure Food movement in the United States in the 1800s it might be impossible to get absolutists to endorse risk reduction interventions. Those with an abstinence-only view on nicotine (or tobacco) might never change their view regardless of the science, as their views are possibly not actually based on scientific principles any more than the Christian Right's opposition to condoms is primarily based on science.

Can advocates of change in existing policies work together without undermining each other? If so, how? We see two ways in which efforts to reduce tobacco harms are unusual, even in the context of public-health approaches to use of other substances such as heroin or alcohol.

For one, the nature of the marketplace and the increasingly rapid dissemination of information of interest to consumers will undoubtedly see an acceleration of market changes that

will likely marginalize those tobacco control advocates who adhere to an abstinence-only orientation (Meier & Shelley, 2006). That still leaves those who simply do not yet recognize that risk reduction is, along with prevention, cessation and protection of third parties, one of the four pillars of public health interventions.

The other is that, thus far, tobacco harm reduction has not been backed by the liberal public health establishment. In other contexts, the liberationist and social-justice sentiments of the public-health profession worked in favour of promoting harm-reduction interventions for sex-related harms (condoms) and drug-injection-related harms (syringe exchange), rather than insist that people cease engaging in activities that are potentially risky but impossible to eradicate. To a pragmatist – that is, to the public-health professional – the reason for a behaviour is less important than the fact that the behaviour is going to continue. The public-health profession supported the harm-reduction stance on sex and illicit-drug use even before the safety of those interventions had been established. With tobacco, by contrast, the public-health profession has yet to support tobacco HR despite the strong, consistent, and increasingly extensive evidence that many alternative nicotine delivery systems would be safer than smoking.

An understanding of the public-health profession's position is important, because its voice would sound loud in the policy debate were it to renounce its support of cessation-only approaches. We see two ingredients to the public-health establishment's reluctance to embrace the concept of a continuum of risk and advocate non-cessation approaches for nicotine users.

First, the public-health establishment, at least in the U.S. where much of the policy fight is centred, is inclined to be distrustful of big business in general and Big Tobacco in particular. Two of the foundations of public health, occupational hygiene and worker safety, were built on direct opposition to industry; another, environmental monitoring and maintenance, has depended on advocacy to overcome industry standards that tolerated pollution. And the collusion of private business with government regulators that has produced serious public-health disasters – the Triangle fire in New York, the Bhopal disaster in India, mad cow disease in the U.K. – increases the profession's antipathy.

Second, the tobacco industry has played into the hands of its critics by its attempts to suppress information on the harms of smoking and cover up evidence of its own awareness, from early on, that it was making an intrinsically hazardous product.

The paradoxical, and lamentable, outcome of the public-health profession's anti-industry stance is that government and non-profit public-health agencies will generally not fund the research that would define the continuum of risk for nicotine delivery devices, and thereby allow for rational and evidence-based decision making on behalf of the public's health. Instead, in the U.S. (whose research budget dwarfs other countries'), virtually the only substantive research

on alternative delivery systems now being carried out is funded by industry: research on smokeless tobacco products is financed by the tobacco companies, and research on nicotine replacement is financed by the pharmaceutical industry. To public-health advocates whose *idée fixe* is that industry is singularly self-interested, venal, and treacherous, these funding streams serve to discredit the researchers who are doing what would, otherwise, be the essential work of determining how best to serve the public's health. The consequent situation is this tautology: the only nicotine- or tobacco-related research that is recognized as valid is research funded by the government or non-profits; the government and non-profits will fund only research on smoking cessation; only smoking cessation is a valid public-health intervention.

Using policy levers to reduce the risk of tobacco/nicotine use

The potential for tobacco harm reduction interventions is clarified by examining how risk reduction strategies have been applied elsewhere. The long battles to establish regulations pertaining to the manufacturing of food products or to replace 'snake oil' with science-based pharmaceutical products offer examples of how advances in science and a proliferation of alternative products can combine with changing corporate vested interests and political pressure to fundamentally 'morph' a market. The fundamental change with respect to pure foods and pharmaceuticals did not come with legislation per se (e.g., the U.S.'s Food and Drug Act of 1906), but from two broader cultural phenomena: the growth and professionalization of the craft of medicine, and changes in the social contract that demanded more public responsibility from private manufacturers (with concomitantly expanded compliance by the courts). In America, the medical trade advocated for greater regulation of products having to do with health so that it might dominate the market in health-risk avoidance. The movement for purer foods developed in tandem with awareness of nutritional public health, positioning food regulation across both the medical and consumer arenas. Thus, the role of both the health-care industry and the public-health agencies was essential to the development of policies that reduced food- and prescription-drug-associated harms.

The example of food and pharmaceuticals might be promising for nicotine regulation, since nicotine remains a legal drug and tobacco is a consumer product with recognized appeal. But it also highlights the importance of swaying the medical and public-health professions to embrace harm reduction for nicotine users. And, the need to implement tobacco regulation in ways that will cohere with evidence-based public-health strategies.

There are many regulatory strategies that could be reasonably expected to reduce the present levels of tobacco related morbidity and mortality. A key step would be measures that would put the most hazardous products at the greatest market-

place disadvantage. As Sweden has long done in dealing with cigarettes versus snus and many other countries have done in dealing with leaded versus unleaded petrol, differential taxation could dramatically change the market. Combustion-based products could be taxed so as to be, for example, at least twice as expensive as non-combustion alternatives. Cigarettes could also be subjected to more rigorous marketing restrictions and package health labelling. In addition, manufacturing standards could require reductions in known toxins without allowing these changes to be used in promotional efforts by the companies in question. Such efforts would simultaneously promote prevention, cessation, and protection of third parties as well as achieving viable harm reduction for continuing nicotine users.

Conclusion

We can reduce tobacco related death and disease far more rapidly than we can reasonably expect to reduce nicotine use by focusing on the fact that people smoke for the nicotine but die from the smoke. Applying harm reduction principles to public health policies on tobacco/nicotine is more than simply a rational and humane policy. It is more than a pragmatic response to a market that is, anyway, already in the process of undergoing significant changes. It has the potential to lead to one of the greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century.

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David Sweanor
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palcabes@hunter.cuny.edu (P. Alcabes)

4 October 2006

From: [HTHTestimony](#)
To: [CPN Testimony](#)
Subject: FW: Submitted testimony for SB1220 on Feb 5, 2015 09:00AM
Date: Tuesday, February 03, 2015 12:13:08 PM

From: mailinglist@capitol.hawaii.gov [<mailto:mailinglist@capitol.hawaii.gov>]
Sent: Monday, February 02, 2015 3:48 PM
To: HTHTestimony
Cc: vinkim@gmail.com
Subject: Submitted testimony for SB1220 on Feb 5, 2015 09:00AM

SB1220

Submitted on: 2/2/2015

Testimony for HTH/CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Vin Kim Vape Hawaii		Comments Only	No

Comments: Allowing the tax to go through would increase the price of vaping and deter individuals who want to quit smoking from even trying out vaping, which is definitely a lot healthier than smoking traditional tobacco.

Please note that testimony submitted less than 24 hours prior to the hearing, improperly identified, or directed to the incorrect office, may not be posted online or distributed to the committee prior to the convening of the public hearing.

Do not reply to this email. This inbox is not monitored. For assistance please email webmaster@capitol.hawaii.gov

In regards to SB1220

I am the Director of Operations for PC Gamerz, we are a eSports center and Vape lounge located in Aiea. We have hundreds of customers that visit our store on a weekly basis. That vape at our store, many of them used to smoke cigarettes. Many of switched from cigarettes to vaping.

The increase of 80% tax on whole sale is outrageous. And would make most eliquid bottles go from \$18 retail for a 30ml bottle to \$32 retail.

Most of our customers can use a 30ml bottle over the course of 4-7 days. And many of them have multiple bottles on hand to change the flavor they are using.

I personally carry 3-5 bottles of eliquid on me. To change the flavor depending on my mood.

One of the main issues with this excessive bill is it would force people to buy 0mg nicotine eliquid. That would not be taxed. Then they would purchase FDA approved nicotine ONLINE and then add their own nicotine to their bottles. This is not only unsafe, but could have future problems.

Nicotine does not cause cancer. <http://www.nysmokefree.com/Subpage.aspx?P=40&P1=4030>

The Tar, 4000+ checmicals and smoke created from combustion is what causes cancer from smoking cigarettes.

Nicotine is addictive, yes. The reason Big tobacco add all the other chemicals to cigarettes is to increase the addictive nature of them. Ecigarettes do not have those added chemicals and a new study has shown that ecigarettes are far less addictive than cigarettes and LESS than nicotine gum.

<http://acsh.org/2015/01/new-study-shows-addictive-potency-e-cigs-far-less-cigarettes-less-nicotine-gum/>

E-Cigarettes when used correctly have 90%~ less chemicals in them.

What really should be done is an AUDIT on the Cancer research fund to see where the money is going.

By increasing the tax to this level, it would force many shops to close and all of their employee's would be out of jobs.

This increase would also create a black market for eliquid, that you would not be able to enforce or control. People can make their own eliquid in their homes in unsafe and unsanitary environments. Get their nicotine online and make them with no regards for others.

Currently Many company's are making eliquid in Food grade or ISO certified labs. With stainless steel equipment, clean rooms and Hepa filtering.

They have quality control, and testing done on their products. They have labels describing ingredients and child safe caps and bottles.

Please consider this when making a decision to add a SIN tax to something that is not even considered SIN.

Thank you

Devin Wolery
Director of Operations
PC Gamerz, Inc.

From: [Alvin Wong](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 11:21:09 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

Thank you for the opportunity to submit testimony in support of SB 1220. I support increasing the tax on other tobacco products (OTPs) to 80% to create parity between cigarettes and OTPs.

Increasing the tax on OTPs will decrease use, ultimately saving lives. Serious health conditions like cancer, gum disease, and cardiovascular disease caused by snuff and chew will be reduced, saving lives and money to the state. Youth are more sensitive to prices than adults. Increasing the tax on OTPs is an additional disincentive for youth to use tobacco products.

As cigarette tax increases, smokers will look towards quitting or they will find cheaper means to continue using tobacco. We must be sure taxes on all tobacco products are equitable so that those who are addicted to nicotine will quit. More smokers quitting, means less cost to our state in tobacco-related medical expenses.

Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Alvin Wong

Alvin Wong
1163 Hooli Circle
1163 Hooli Circle
Pearl City, HI 96782

From: [Barbara Nosaka](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 11:57:39 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Barbara Nosaka
2216 Hoonanea Street
Honolulu, HI 96822

From: [Beau Lani Barker](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Wednesday, February 04, 2015 9:58:21 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Beau Lani Barker
2370 Nuuanu Ave
Honolulu, HI 96817

From: [Bryan Mih](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 10:44:22 PM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo,
Bryan Mih, MD MPH FAAP
Pediatrician

Bryan Mih
1944 Naniu Pl
Honolulu, HI 96822

From: [Bryan Talisayan](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 10:49:14 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Bryan Talisayan
2403 Pacific Heights Road
Honolulu, HI 96813

From: [Cheryl Reeser](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 9:46:55 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Cheryl Reeser
51-E Kealaloa Ave
Makawao, HI 96768

From: [Dan Domizio](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 9:34:45 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Dan Domizio
15-2662 Pahoia Village rd
Suite 306, PMB 8741
Pahoia, HI 96778

From: [Forrest Batz](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 11:09:40 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

Aloha Senate Committee on Commerce and Consumer Protection,

Thank you for the opportunity to submit testimony in support of SB 1220. I support increasing the tax on other tobacco products (OTPs) to 80% to create parity between cigarettes and OTPs.

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Forrest Batz
34 Rainbow Drive
Keaau, HI 96749

From: [Harald Ebeling](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 12:46:27 PM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Harald Ebeling
2851 Lawa Pl
Honolulu, HI 96822

February 4, 2015

TESTIMONY IN FAVOR OF SB1220

Senator Roz Baker
Chair, Hawaii Senate Committee Commerce & Consumer Protection
415 South Beretania Street
Honolulu, Hawaii

Dear Senator and Committee Members,

I am writing in support of this bill, which will bring in more revenue to ‘tobacco tax’ money which in turn helps to support the UH Cancer Center.

As a regent with UH, I especially appreciate this bill. However, please note that I am testifying as an individual.

Thank you for your favorable consideration.

Sincerely,

Helen Nielsen

oluolu@maui.net

1942 Main Street, Ste. 104, Wailuku, HI 96793

808-283-1038

From: [Holly Dupont](#)
To: [CPN Testimony](#)
Date: Wednesday, February 04, 2015 1:51:33 PM

SB1220 – Relating to Chapter 245, Hawaii Revised Statutes

I support SB 1220 to increase the tax on other tobacco products. Many people think that only tobacco products that are smoked are dangerous, but smokeless tobacco products are just as dangerous to health and is linked to the onset of many types of cancers and other serious health issues. Currently these products are not taxed at the same level as cigarettes, and we should treat all tobacco products the same.

Holly N. Ho-Chee-DuPont
Cancer Patient Navigator
Hilo Medical Center/Hawaii Pacific Oncology Center
1285 Waianuenue Avenue
Hilo, Hawaii 96720
(808) 932-3717
(808) 961-9526, Fax



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I am submitting personal testimony on SB1220 based on my research with adolescents in Hawaii, which was supported by grants from the National Institutes of Health. The comments presented here are my personal testimony and do not necessarily reflect the views of the National Institutes of Health or the University of Hawaii Cancer Center.

The hearing notice states that SB1220 expands the definition of “tobacco products” to include any product containing nicotine but not containing tobacco.

I support this legislation because our research indicates that use of electronic smoking devices (hereafter, e-cigarettes), which typically contain nicotine, is quite prevalent among adolescents in Hawaii. Our recent publication in the medical journal Pediatrics reported that 29% of 9th and 10th grade students in six Hawaii high schools have used e-cigarettes at least once and 18% use them regularly. This rate of e-cigarette use by adolescents in Hawaii is considerably higher than what is found in current studies of adolescents in other areas of the US. Moreover, our study showed that 12% of the sample used both e-cigarettes and cigarettes.

These findings indicate that e-cigarettes are regarded as acceptable to use by adolescents and our data showed that 67% of this sample of adolescents regarded e-cigarettes as healthier than cigarettes. However, using e-cigarettes in most instances exposes adolescents to nicotine, which is a highly addictive substance, and the view expressed by e-cigarette advocates that using e-cigarettes poses no health risk is becoming increasingly untenable. In fact, the director of the California Department of Public Health (Ron Chapman, MD, MPH) was sufficiently concerned by the current evidence that he recently issued a report to the state about e-cigarettes titled “E-Cigarettes: A Community Health Threat.” The two leading cancer research societies, the American Association for Cancer Research and the American Society of Clinical Oncology, also have recently issued calls for regulation of e-cigarettes.

I think that further research is needed to gain more clarity about the consequences of e-cigarette use among adolescents. However, because of the clear evidence that e-cigarettes are increasingly regarded by adolescents as acceptable to use and readily available, I think action is needed now to prevent e-cigarette use by adolescents. This can be done by actions previously shown to be successful for reducing cigarette smoking among adolescents, including meaningful taxation and consistent restrictions on using in public places. SB1220 would help to achieve this goal.

I support SB1220 for these reasons.

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

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As cigarette tax increases, smokers will look towards quitting or they will find cheaper means to continue using tobacco. We must be sure taxes on all tobacco products are equitable so that those who are addicted to nicotine will quit. More smokers quitting, means less cost to our state in tobacco-related medical expenses.

Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Beau Lani Barker
2370 Nuuanu Ave
Honolulu, HI 96817

From: [Jennifer Griffith](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Wednesday, February 04, 2015 8:16:15 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Jennifer Griffith
PO Box 399
Honomu, HI 96728

From: [JoAnn Tsark](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 4:34:17 PM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

JoAnn Tsark
1669 B Palolo Ave
Honolulu, HI 96816

From: [Janelle Kubo](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 11:22:32 PM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Janelle Kubo
2860 Waialae Ave.
Apt. 114
Honolulu, HI 96826

From: [Karli Bergheer](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 10:24:57 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

Thank you for the opportunity to submit testimony in support of SB 1220. I support increasing the tax on other tobacco products (OTPs) to 80% to create parity between cigarettes and OTPs.

Increasing the tax on OTPs will decrease use, ultimately saving lives. Serious health conditions like cancer, gum disease, and cardiovascular disease caused by snuff and chew will be reduced, saving lives and money to the state. Youth are more sensitive to prices than adults. Increasing the tax on OTPs is an additional disincentive for youth to use tobacco products.

As cigarette tax increases, smokers will look towards quitting or they will find cheaper means to continue using tobacco. We must be sure taxes on all tobacco products are equitable so that those who are addicted to nicotine will quit. More smokers quitting, means less cost to our state in tobacco-related medical expenses.

Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Karli Bergheer
221 Mahalani Street, Suite 99
Wailuku, HI 96793

From: [Kathryn Sthay](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 11:04:06 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Kathryn Sthay
5414 Kirkwood Place
Honolulu, HI 96821

From: [Kim Nguyen](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 9:17:57 PM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Kim Nguyen
2442 Tusitala St
Apt 302
Honolulu, HI 96815

From: [Kim Swartz](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 10:05:17 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Kim Swartz
98-1394 Hinu Pl, #B
Pearl City, HI 96782

From: [Maile Goo](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 1:45:49 PM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo,
Maile Goo
Board Member at Large
Coalition for a Tobacco-Free Hawaii

Maile Goo
3683 Woodlawn Terrace Place
Honolulu, HI 96822

From: [Michelle Gray](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 11:49:14 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Michelle Gray
430 Lanipuaa Street
Honolulu, HI 96825

From: [Michelle Kwock](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 3:36:51 PM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Michelle Kwock
100 N. Beretania St.
Honolulu, HI 96817

From: [Michelle Schiff](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 1:29:00 PM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Michelle Schiff
1655 Kanapuu Dr
Kailua, HI 96734

From: [Mark Vasconcellos](#)
To: [CPN Testimony](#)
Subject: OTP TAX INCREASE BILL! SB1220 - Relating to Chapter 245, Hawaii Revised Statutes
Date: Wednesday, February 04, 2015 1:06:46 PM

Aloha

I support SB 1220 to increase the tax on other tobacco products. Many people think that only tobacco products that are smoked are dangerous, but smokeless tobacco products are just as dangerous to health and is linked to the onset of many types of cancers and other serious health issues. Currently these products are not taxed at the same level as cigarettes, and we should treat all tobacco products the same.

*Mahalo,
Mark Vasconcellos*

From: [Mary Goldsworthy](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 4:01:26 PM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Mary Goldsworthy, B.S

Mary Goldsworthy

Honolulu, HI 96813

From: [pat fleck](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 10:26:32 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Respectfully Submitted,

Patricia Fleck

pat fleck
75-5660 Kopico Street, Ste. C7-330
kailua kona, HI 96740

From: [Rebecca Knight](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 9:42:04 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Rebecca Knight

Honolulu, HI 96826

From: [Boyd, Manager Richard Boyd](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 11:57:33 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Boyd, Manager Richard Boyd
250 Kawaihae St
250 Kawaihae St
Honolulu, HI 96825

From: [Roxine Iijima](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 6:55:01 PM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Roxine Iijima
45-610 Hinamoe Loop
Kaneohe, HI 96744

From: [shay Chan Hodges](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 10:09:29 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

shay Chan Hodges
37 Puu Koa Place
Haiku, HI 96708

From: [Shelly Ogata](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Wednesday, February 04, 2015 9:40:12 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Shelly Ogata
POB 2104
Keaau, HI 96749

From: [Tyler Ralston](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 11:11:45 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Tyler Ralston
PO Box 10528
Honolulu, HI 96816

From: [Valerie Yontz](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 5:52:48 PM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Your support of this SB1220 bill is a very important public health intervention to help the citizens of Hawaii. Many thanks. Valerie Yontz

Valerie Yontz
677 Auwina Street
677 Auwina Street Kailua, HI 96734-3430
Kailua, HI 96734

From: [Vija Sehgal](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 9:05:28 PM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Vija Sehgal

Waianae, HI 96792

From: [Vija Sehgal](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 9:05:28 PM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Vija Sehgal

Waianae, HI 96792

From: [Wamya Ogata](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 11:21:55 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Wamya Ogata
94-392 Keehuhiwa St.
Mililani, HI 96789

From: [Yukiko Morimoto](#)
To: [CPN Testimony](#)
Subject: Support SB1220
Date: Tuesday, February 03, 2015 10:21:45 AM

February 3, 2015

To: Sen. Rosalyn H. Baker, Chair, Committee on Commerce and Consumer Protection
Sen. Brian T. Taniguchi, Vice Chair, Committee on Commerce and Consumer Protection
Members, Senate Committee on Commerce and Consumer Protection

Re: Strong Support for SB 1220, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 5, 2015 at 9:00 a.m. in Room 229

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Thank you for the opportunity to provide testimony in support of this measure.

Mahalo.

Yukiko Morimoto
2550 Kuhio Avenue, Apt. 2205
Honolulu, HI 96815

From: mailinglist@capitol.hawaii.gov
To: [CPN Testimony](#)
Cc: haynfolife@yahoo.com
Subject: Submitted testimony for SB1220 on Feb 5, 2015 09:00AM
Date: Wednesday, February 04, 2015 3:10:56 PM

SB1220

Submitted on: 2/4/2015

Testimony for CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Chad agbayani	Individual	Oppose	No

Comments: I have used tobacco for over 16 yrs and have tried to quit numerous times. Vaping or using electronic cigarettes has given me a second chance on life. I can breathe better and I truly believe it has saved my life. By passing this bill you are not only putting our economy in jeopardy by strong arming shops to charge more than what the consumer can pay. But more importantly you are putting the health of hawaii residents in jeopardy. It's two sided some people will pay this rediculous tax but most will take it into there hands and start to make thier own e-juice and that will open up a whole new health hazard because there will be no quality control. In closing there is no reputable evidence that vaping causes any health issues unlike alcohol and tobacco but yet you propose a bill to basically smother out this new healthier alternative. What type of bills and tax do you have on alcohol? All in all please reconsider passing this bill. Please let me be here for my kids..please let me exercise my right as an American to choose what kind of lifestyle I wish to live. Aloha

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Date: Tuesday, February 03, 2015 8:22:34 AM

SB1220

Submitted on: 2/3/2015

Testimony for CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Chris Wells	Individual	Oppose	No

Comments: The research center need spend its' money a little better first.

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SB1220

Submitted on: 2/3/2015

Testimony for CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
danyl pang	Individual	Oppose	No

Comments: I believe vaping is the best smoking cessation available to people now. Implementing anything that may hinder this would cause more people to return to traditional cigarettes and be counter productive.

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SB1220

Submitted on: 2/2/2015

Testimony for CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Falisha Herbic	Individual	Oppose	No

Comments: I AM AN INDIVIDUAL TESTIFYING IN STRONG OPPOSITION TO SB1220, RELATING TO CHAPTER 245, HAWAII REVISED STATUTES There is considerable evidence that nicotine is present in human foods and drinks. This list includes, but is not limited to, tomatoes, potatoes, eggplant, black tea, pepper, cauliflowers, and the leaves of the coco plant. To “[expand] the definition of ‘tobacco products’ to include any product containing nicotine, but not containing tobacco” and then “[impose] an excise tax equal to 80 percent of the wholesale price” would, by definition, be to include this taxation on any products containing tomatoes, potatoes, eggplant, black tea, pepper, cauliflower, etc. Nicotine and tobacco are NOT synonymous and this bill should be rejected. It is my opinion that this bill is fostered by special interests and not in the best interest of the people of Hawaii; yet another example of limiting the rights and freedoms we inherit as American people for the purpose of satisfying the whims of a select few (and financially powerful). I feel this bill is an attempt to manipulate the system into taxing and regulating eCigarettes. If that is the case, it is my opinion that legislation speaking more to that specific purpose of the bill should be written; without attempt to deceive the people. Thank you for the opportunity to submit testimony on this matter.

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Subject: Submitted testimony for SB1220 on Feb 5, 2015 09:00AM
Date: Wednesday, February 04, 2015 8:33:48 AM

SB1220

Submitted on: 2/4/2015

Testimony for CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
garett uyesugi	Individual	Oppose	No

Comments: oppose to anti vaping. Its the 21st century answer to end smoking. also a large portion of users dont even use nicotine in the product.

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Senate Committee on Commerce and Consumer Protection

*February 4, 2015
9:00 am
Conference Room 229*

In OPPOSITION of Senate Bill No. 1266

Chair Baker, Vice Chair Taniguchi, and Committee Members:

My name is Gordon Tom, I am a Hawaii-licensed CPA, and I OPPOSE bill no. 1266, relating to public accountancy mobility.

In order for CPAs to offer fast and efficient service to clients nationwide, barriers to interstate practice for CPAs should be eliminated. At the same time, we need to ensure that the public is adequately protected. This legislation will not achieve either of these objectives. Mobility legislation that is substantially different from this legislation has already been passed in 49 U.S. states and Hawaii would be the **only** state without mobility legislation that is not substantially equivalent to the rest of the nation if this this legislation passes.

In addition, the passage of this legislation will create an administrative and accounting burden on Hawaii taxpayers due to its imposition of a duty on the Hawaii taxpayer to: (1) withhold general excise tax from amounts paid to out of state CPAs; (2) collect business registration information from vendors; and (3) mandate the imposition of a minimum \$2 million liability insurance requirement. In addition, current regulations and forms promulgated by the Department of Taxation and Department of Commerce and Consumer Affairs provide no administrative process to achieve the intent of this legislation.

Finally, adoption of this legislation may be unconstitutional because of the unequal penalties for out-of-state CPAs and Hawaii licensed CPAs, and further passage could result in unintended consequences for all current Hawaii-licensed CPAs being subject to the penalty provisions in the proposed Chapter 466-A, subsection (d) relating to class B felony.

I humbly ask for your OPPOSITION of Senate Bill No.1266.



Gordon Tom
House District 17
Senate District 9

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Subject: Submitted testimony for SB1220 on Feb 5, 2015 09:00AM
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SB1220

Submitted on: 2/3/2015

Testimony for CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Gregory Arianoff	Individual	Oppose	No

Comments: Taxation is Theft! It is not Government's job to regulate the markets.
Please review your Constitution and the Oath of Office. Mahalo!

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SB1220

Submitted on: 2/3/2015

Testimony for CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Israel Smith	Individual	Oppose	No

Comments: On Behalf of Hawaii's Vaping Community I Oppose sb1220 I used to to be a smoker and was having health issues caused by the carcinogens from cigarets. I was lucky to have come across Vaping and have been tobacco free for 2 years. I do enjoy vaping and it is not intrusive like tobacco products and is a very safe alternative. If both sb1220 and sb1032 are passed it would cause the price to become unaffordable and effectively cause people to pick up tobacco once again and due to health risks and medical costs associated with tobacco use can this state afford to make Vaping unaffordable? thank you for considering my opinion.. Israel Smith

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Date: Monday, February 02, 2015 6:03:58 PM

SB1220

Submitted on: 2/2/2015

Testimony for CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
jason graham	Individual	Oppose	No

Comments: I personally oppose this law from being enacted solely due to the fact the reasoning why is so the state can make more money off of a clearly healthier option. I have had two heart surgeries and currently have high blood pressure. Since using ecigs I am in a lot better health. If you personally want to be anti smoking as this state claims to be you would hit cigarette companies harder, but due to the fact that people stopped using cigarettes by using ecigs and not enrolling through the state's way of anti smoking via make money..they lobby, possibly through major tobacco companies want to assure people either go back to cigarettes, our pay high outrageous taxes on healthier alternatives until those companies cannot afford to. So please do not highly tax this clearly healthier, the people using ecigs can clearly tell you how more healthy and vibrant they are without the use of patches, gums, or cigarettes

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Date: Tuesday, February 03, 2015 7:22:28 PM

SB1220

Submitted on: 2/3/2015

Testimony for CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Joel Cruz	Individual	Comments Only	No

Comments: 25 plus year smoker and I quit almost 3 years ago from the help of Ecig. Health hasn't been this great since I was 10 years old. If this Bill passes, this will make a lot of former smokers deter from buying any form of ecig products due of being expensive. I opposed

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Cc: hilyfevaporz@gmail.com
Subject: Submitted testimony for SB1220 on Feb 5, 2015 09:00AM
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SB1220

Submitted on: 2/3/2015

Testimony for CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Jostin Iriarte	Individual	Comments Only	No

Comments: Aloha,my name is Jostin I will like to share my thoughts on this bill SB1220 and others that affect our being. I've been a smoker for most of my life and I quit just over 3 years. I found a new alternative that helps me stay away from the harmfulness of smoking. vaping has helped me not touch a cigarettes and allowed me to be part of a community that has been very supportive and very family oriented. Now I live a much healthier lifestyle and became part of a community that stands by my side. Ive helped many people quit as well as my family members. Every time I look a these new bills coming out I see tobacco prpducts,I don't understand how it is claimed to be tobacco or how there are claims to say Vaping is more harmful then cigarettes there isn't any scientic researches nor there is proven medically of issues with vaping. It is funny how some people that make these claims and put it out there as problems or issues and even compare it to be the same as smoking cigarettes. I've been Vaping nearly a year now and my family and friends have found out how inspirational I've become because of vaping. We have actually started our own company called Hi Lyfe Vaporz,LLC and have bacame a part of such a close knit community, we survive on our business and now this has become part of our livelyhood. With some of these bills coming may cause extreme cost increase and problems for small family business like our to fall. Please hear us out as we are trying to help people live a healthier lifestyle and become better people in the community. We don't only help smokers we help those that are addicted to drugs and other bad habits to quit entirely. I hope whoever can see or read this please understand that this that is happening just makes it more difficult for all of us. We already pay taxes and there is not enough if any proven facts about Vaping or e cigarettes. We all in the Vape community enjoy a positive vibe with friendship and family. Please don't take this away from us and may whoever is making false statements about Vaping do more research and get actual facts that it is harmful or worst than smoking. Also these tax concerns affect all of us and may end up turning people away from an healthier way of life that is legal and by any means bad for the public. Thank you and have a blessed day.

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SB1220

Submitted on: 2/2/2015

Testimony for CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Mariner Revell	Individual	Oppose	No

Comments: I strongly oppose SB1220. Every day a person switches to ecigs from tobacco cigarettes a life is prolonged and saved. I urge the senators to vote on this bill based on REAL SCIENTIFIC PROVEN FACTS. Do not base your decision on fear, bias research, or pharmaceutical lobbyist (The Coalition For A Tobacco Free Hawaii). As representatives of the people go out to the stores that sell ecigs interact with ecig users ask them about the pros and cons of ecig use. See the truth behind ecigs not the fear and stigma that ecig are the same as tobacco as they are not! Last year a similar bill was introduced, the people have spoken the masses do not want this or similar bills to be passed. It hinders people trying to quit smoking, it costs lives in result of people staying on tobacco, and it hurts local business. Please listen to the people We do not want this! What proven factual scientific research are you basing this bill one? What tests have you personally conducted to prove that ecigs should be placed into a category of tobacco? Please do proper research before you vote on this issue. Mahalo.

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Date: Tuesday, February 03, 2015 8:36:32 PM

SB1220

Submitted on: 2/3/2015

Testimony for CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Mauliola J Watson	Individual	Oppose	No

Comments: My name is Mauliola J Watson. I started smoking at the age of 18. I quit smoking in January of 2014. The reason I quit was because a change in lifestyle I made by choosing electronic cigarettes; otherwise known as vaping. This bill proposed, will significantly damage and even take away a lifestyle that has changed my life. My health has improved and I have had not a single cigarette since I quit. I feel very strongly opposed to this bill. But the facts are electronic cigarettes are a healthy alternative to smoking. The facts are cigarettes are bad for your health. If quitting smoking and choosing a healthier life style is good how does this bill help the lifestyles of people that smoke cigarettes. My testimony I am submitting is against this bill. I see a very high potential for people to make a healthy decision in their life by the influence of the community that supports electronic cigarettes. I believe this bill will have a negative effect on the electronic cigarette community and industry.

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SB1220

Submitted on: 2/2/2015

Testimony for CPN on Feb 5, 2015 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Melissa Stone	Individual	Oppose	No

Comments: Classifying something that does not contain tobacco as a tobacco product is ridiculous. If people addicted to smoking cigarettes wanted to quit right now, vaping ecigarettes is a cheaper, less harmful alternative. If ecigarettes were taxed 80%, there would be significantly less incentive to switch from smoking to vaping. In that sense, this measure is supporting tobacco companies keep their customers addicted to their product.

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Chair Baker, Vice-Chair Taniguchi, and members of the committee,

Thank you for the opportunity to testify in STRONG OPPOSITION to SB1220. The imposition of new taxes is never something to be taken lightly, but the imposition of new taxes for no reason and to no benefit, as in this bill, is to be avoided in all cases. Additional taxes on ecigarettes and other vapor products has no scientific basis and is bad policy in every way.

The current scientific evidence shows that ecigarettes are a low-risk, effective replacement for tobacco smoking. Current estimates are that millions of lives worldwide could be saved by the promotion and adoption of ecigarettes over smoking tobacco, which makes it part of the solution to the problems claimed in the measure. As the measure notes, an increase in taxes discourages adoption; this is contrary to the interests of public health in the case of ecigarettes.

Furthermore, the ecigarette/vapor industry in Hawaii is an important and growing part of our local economy. Imposing a huge state tax will make our local business uncompetitive with those in other states. People will simply opt to order online, which will hurt local businesses, kill local jobs, and reduce the potential tax collections.

I have attached a current review of the science regarding ecigarettes which illustrates the fact that ecigarettes are a beneficial alternative to smoking tobacco, and that there is no justification for taxation or the discouragement of adoption.

Finally, the exclusion of large cigars from this measure lays bare its logical and moral bankruptcy. There is no reason that other forms of tobacco and related non-tobacco products should be so taxed and large cigars not. Large cigars are no less of a health risk than the least risky of these other products, and they are literal tobacco products. Exempting them is flat out nonsensical, unjustified, and unjust.

This measure should be rejected in its entirety.

P. Kuromoto

Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review

Konstantinos E. Farsalinos and Riccardo Polosa

Abstract: Electronic cigarettes are a recent development in tobacco harm reduction. They are marketed as less harmful alternatives to smoking. Awareness and use of these devices has grown exponentially in recent years, with millions of people currently using them. This systematic review appraises existing laboratory and clinical research on the potential risks from electronic cigarette use, compared with the well-established devastating effects of smoking tobacco cigarettes. Currently available evidence indicates that electronic cigarettes are by far a less harmful alternative to smoking and significant health benefits are expected in smokers who switch from tobacco to electronic cigarettes. Research will help make electronic cigarettes more effective as smoking substitutes and will better define and further reduce residual risks from use to as low as possible, by establishing appropriate quality control and standards.

Keywords: electronic cigarettes, e-liquid, e-vapor, harm reduction, nicotine, safety, tobacco

Introduction

Complete tobacco cessation is the best outcome for smokers. However, the powerful addictive properties of nicotine and the ritualistic behavior of smoking create a huge hurdle, even for those with a strong desire to quit. Until recently, smokers were left with just two alternatives: either quit or suffer the harmful consequences of continued smoking. This gloomy scenario has allowed the smoking pandemic to escalate, with nearly 6 million deaths annually and a predicted death toll of 1 billion within the 21st century [World Health Organization, 2013]. But a third choice, involving the use of alternative and much safer sources of nicotine with the goal to reduce smoking-related diseases is now available: tobacco harm reduction (THR) [Rodu and Godshall, 2006].

Electronic cigarettes (ECs) are the newest and most promising products for THR [Polosa *et al.* 2013b]. They are electrically-driven devices consisting of the battery part (usually a lithium battery), and an atomizer where liquid is stored and is aerosolized by applying energy and generating heat to a resistance encircling a wick. The liquid used mainly consists of propylene glycol, glycerol,

distilled water, flavorings (that may or may not be approved for food use) and nicotine. Consumers (commonly called ‘vapers’) may choose from several nicotine strengths, including non-nicotine liquids, and a countless list of flavors; this assortment is a characteristic feature that distinguishes ECs from any other THR products. Since their invention in 2003, there has been constant innovation and development of more efficient and appealing products. Currently, there are mainly three types of devices available [Dawkins, 2013], depicted in Figure 1. (1) First-generation devices, generally mimicking the size and look of regular cigarettes and consisting of small lithium batteries and cartomizers (i.e. cartridges, which are usually prefilled with a liquid that bathes the atomizer). Batteries may be disposable (to be used once only) or rechargeable. (2) Second-generation devices, consisting mainly of higher-capacity lithium batteries and atomizers with the ability to refill them with liquid (sold in separate bottles). In the most recent atomizers you can simply change the atomizer head (resistance and wick) while keeping the body of the atomizer, thus reducing the operating costs. (3) Third-generation devices (also called ‘Mods’, from modifications),

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Università di Catania,
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Figure 1. Examples of electronic cigarette devices currently available on the market.

consisting of very large-capacity lithium batteries with integrated circuits that allow vapors to change the voltage or power (wattage) delivered to the atomizer. These devices can be combined with either second-generation atomizers or with rebuildable atomizers, where the consumers have the ability to prepare their own setup of resistance and wick.

Awareness and use (vaping) of ECs has increased exponentially in recent years. Data obtained from the HealthStyles survey showed that, in the US, awareness of ECs rose from 40.9–57.9% from 2010 to 2011, with EC use rising from 3.3–6.2% over the same time period [King *et al.* 2013]. In the United Kingdom, EC use in regular smokers increased from 2.7% in 2010 to 6.7% in 2012 [Dockrell *et al.* 2013]. Similar findings were obtained from the International Tobacco Control Four-Country Survey [Adkison *et al.* 2013]. A recent prospective study in Swiss army recruits showed that 12% of smokers who tried ECs progressed to daily use [Dauptcheva *et al.* 2013]. It must be noted that this increase in EC use has occurred despite the concerns raised by public health authorities about the safety and appropriateness of using these products as alternatives to smoking [National Association of Attorneys General, 2013; Food and Drug Administration, 2009; Mayers, 2009].

The popularity of ECs may be due to their ability to deal both with the physical (i.e. nicotine) and the behavioral component of smoking addiction. In particular, sensory stimulation [Rose and Levin, 1991] and simulation of smoking behavior and cigarette manipulation [Hajek *et al.* 1989] are important determinants of a product's effectiveness in reducing or completely substituting smoking. These features are generally absent in nicotine replacement therapies (NRTs) and oral

medications for nicotine dependence, whereas ECs are unique in that they provide rituals associated with smoking behavior (e.g. hand-to-mouth movement, visible 'smoke' exhaled) and sensory stimulation associated with it [Farsalinos *et al.* 2013b]. This explains why these products can be effective in reducing consumption of tobacco smoking [Bullen *et al.* 2013; Caponnetto *et al.* 2013b; Polosa *et al.* 2011] and are efficient as long-term substitutes of conventional cigarettes [Farsalinos *et al.* 2013b].

Methods

For this systematic review (Figure 2), we searched the PubMed electronic database by using keywords related to ECs and/or their combination (e-cigarette, electronic cigarette, electronic nicotine delivery systems). We obtained a total of 354 results, and selected 41 studies we judged relevant to research on EC safety/risk profile. Reference lists from these studies were also examined to identify relevant articles. We searched additional information in abstracts presented at scientific congresses (respiratory, cardiovascular, tobacco control, toxicology), and in reports of chemical analyses on EC samples that were available online. We also looked for selected studies on chemicals related to EC ingredients (e.g. nicotine, propylene glycol, glycerol, cinnamaldehyde, microparticles emission, etc.), but not specifically evaluated in EC research. In total, 97 publications were found, from which 15 chemical analyses of single or a limited number of EC samples were excluded because they were discussed in a review paper [Cahn and Siegel, 2011]. In total, 114 studies are cited in this paper.

Risk differences compared with conventional cigarettes and the issue of nicotine

Conventional cigarettes are the most common form of nicotine intake. Smoking-related diseases are pathophysiologically attributed to oxidative stress, activation of inflammatory pathways and the toxic effect of more than 4000 chemicals and carcinogens present in tobacco smoke [Environmental Protection Agency, 1992]. In addition, each puff contains $>1 \times 10^{15}$ free radicals [Pryor and Stone, 1993]. All of these chemicals are emitted mostly during the combustion process, which is absent in ECs. Although the addictive potential of nicotine and related compounds is largely documented [Guillem *et al.*

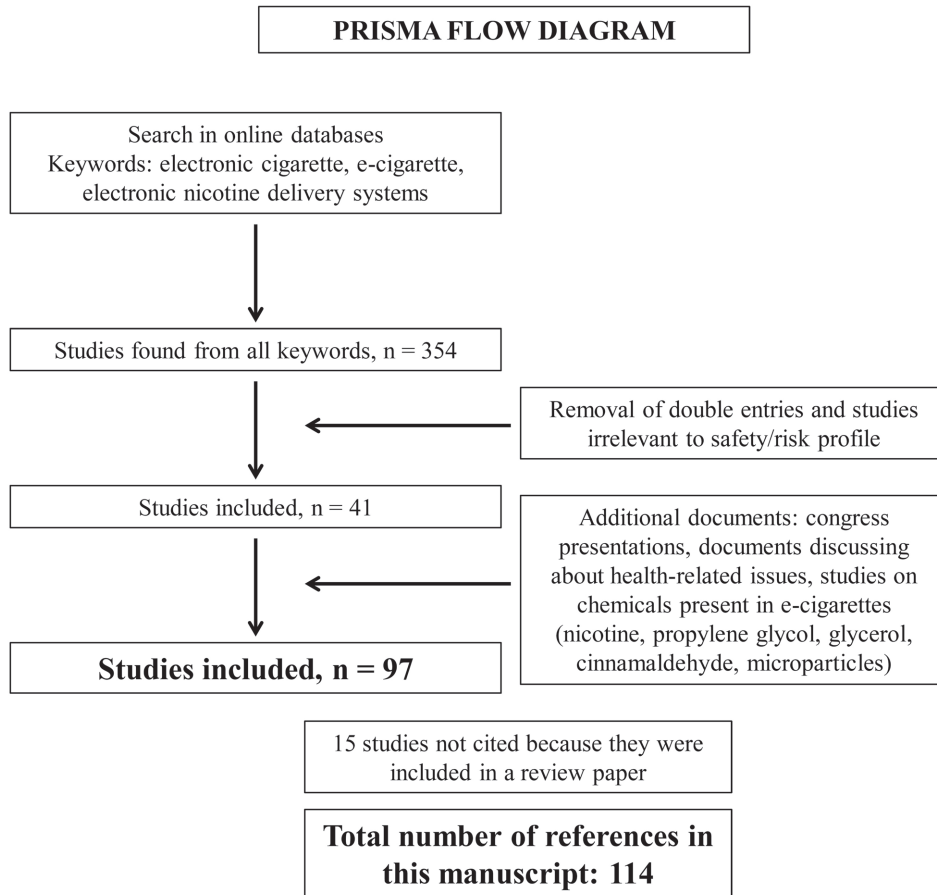


Figure 2. Methodology for literature research and selection of studies.

2005], much less dissemination has been given to the notion that nicotine does not contribute to smoking-related diseases. It is not classified as a carcinogen by the International Agency for Research on Cancer [WHO-IARC, 2004] and does not promote obstructive lung disease. A major misconception, commonly supported even by physicians, is that nicotine promotes cardiovascular disease. However, it has been established that nicotine itself has minimal effect in initiating and promoting atherosclerotic heart disease [Ambrose and Barua, 2004]. It does not promote platelet aggregation [Zevin *et al.* 1998], does not affect coronary circulation [Nitenberg and Antony, 1999] and does not adversely alter the lipid profile [Ludviksdottir *et al.* 1999]. An observational study of more than 33,000 smokers found no evidence of increased risk for myocardial infarction or acute stroke after NRT subscription, although follow up was only 56 days [Hubbard *et al.* 2005]. Up to 5 years of nicotine gum use in the Lung Health Study was unrelated

to cardiovascular diseases or other serious side effects [Murray *et al.* 1996]. A meta-analysis of 35 clinical trials found no evidence of cardiovascular or other life-threatening adverse effects caused by nicotine intake [Greenland *et al.* 1998]. Even in patients with established cardiovascular disease, nicotine use in the form of NRTs does not increase cardiovascular risk [Woolf *et al.* 2012; Benowitz and Gourlay, 1997]. It is anticipated that any product delivering nicotine without involving combustion, such as the EC, would confer a significantly lower risk compared with conventional cigarettes and to other nicotine containing combustible products.

The importance of using nicotine in the long-term was recognized several years ago by Russell, indicating that the potential of nicotine delivery systems as long-term alternatives to tobacco should be explored in order to make the elimination of tobacco a realistic future target [Russell, 1991]. However, current regulations restrict the

long-term use of pharmaceutical or recreational nicotine products (such as snus) [Le Houezec *et al.* 2011]. In other words, nicotine intake has been demonized, although evidence suggests that, besides being useful in smoking cessation, it may even have beneficial effects in a variety of disorders such as Parkinson's disease [Nielsen *et al.* 2013], depression [McClernon *et al.* 2006], dementia [Sahakian *et al.* 1989] and ulcerative colitis [Guslandi, 1999]. Obviously, the addictive potential is an important factor in any decision to endorse nicotine administration; however, it should be considered as slight 'collateral damage' with minimal impact to vapers' health compared with the tremendous benefit of eliminating all disease-related substances coming from tobacco smoking. In fact, smokers are already addicted to nicotine; therefore the use of a 'cleaner' form of nicotine delivery would not represent any additional risk of addiction. Surveys have shown that ECs are used as long-term substitutes to smoking [Dawkins *et al.* 2013; Etter and Bullen, 2012]. Although consumers try to reduce nicotine use with ECs, many are unable to completely stop its intake, indicating an important role for nicotine in the ECs' effectiveness as a smoking substitute [Farsalinos *et al.* 2013b].

Nicotine overdose or intoxication is unlikely to occur with vaping, since the amount consumed [Farsalinos *et al.* 2013c] and absorbed [Nides *et al.* 2014; Dawkins and Corcoran, 2013] is quite low. Moreover, although not yet proven, it is expected that vapers will self-titrate their nicotine intake in a similar way to tobacco cigarettes [Benowitz *et al.* 1998]. Last, but not least, there is evidence suggesting that nicotine cannot be delivered as fast and effectively from ECs compared to tobacco cigarettes [Farsalinos *et al.* 2014]. Therefore, it seems that ECs have a huge theoretical advantage in terms of health risks compared with conventional cigarettes due to the absence of toxic chemicals that are generated in vast quantities by combustion. Furthermore, nicotine delivery by ECs is unlikely to represent a significant safety issue, particularly when considering they are intended to replace tobacco cigarettes, the most efficient nicotine delivery product.

Studies on the safety/risk profile of ECs

Findings on the safety/risk profile of ECs have just started to accumulate. However, this research must be considered work in progress given that the safety/risk of any product reflects an evolving

body of knowledge and also because the product itself is undergoing constant development.

Existing studies about the safety/risk profile of ECs can be divided into chemical, toxicological and clinical studies (Table 1). Obviously, clinical studies are the most informative, but also the most demanding because of several methodological, logistical, ethical and financial challenges. In particular, exploring safety/risk profile in cohorts of well-characterized users in the long-term is required to address the potential of future disease development, but it would take hundreds of users to be followed for a substantial number of years before any conclusions are made. Therefore, most research is currently focused on *in vitro* effects, with clinical studies confined into evaluation of short-term use or pathophysiological mechanisms of smoking-related diseases.

Chemical studies

Chemical studies are relatively simple and cheap to perform and provide quick results. However, there are several disadvantages with this approach. Research is usually focused on the known specific chemicals (generally those known to be toxic from studies of cigarette smoke) and fails to address unknown, potentially toxic contaminants that could be detected in the liquid or the emitted aerosol. Problems may also arise from the detection of the chemicals in flavors. Such substances, although approved for use in the food industry, have largely unknown effects when heated and inhaled; thus, information on the presence of such substances is difficult to interpret in terms of *in vivo* effects. In fact, chemical studies do not provide any objective information about the effects of use; they can only be used to calculate the risk based on theoretical models and on already established safety levels determined by health authorities. An overview of the chemical studies performed on ECs is displayed in Table 2.

Laugesen performed the first studies evaluating the chemical composition of EC aerosols [Laugesen, 2008, 2009]. The temperature of the resistance of the tested EC was 54°C during activation, which is approximately 5–10% of the temperature of a burning tobacco cigarette. Toxic chemicals such as heavy metals, carcinogenic polycyclic aromatic hydrocarbons and phenols were not detected, with the exception of trivial amounts of mercury (0.17 ng per EC) and traces of formaldehyde and acetaldehyde. Laugesen

Table 1. Types of studies performed to determine safety and to estimate risk from EC use.

Type of studies	Research subject	Advantages	Disadvantages
Chemical studies	Evaluate the chemical composition of liquids and/or aerosol. Examine environmental exposure (passive 'vaping').	Easier and faster to perform. Less expensive. Could realistically be implemented for regulatory purposes.	Usually targeted on specific chemicals. Unknown effects of flavorings when inhaled. No validated protocols for vapor production. Provide no objective evidence about the end results (effects) of use (besides by applying theoretical models).
Toxicological studies	Evaluate the effects on cell cultures or experimental animals.	Provide some information about the effects from use.	Difficult to interpret the results in terms of human <i>in vivo</i> effects. More expensive than chemical studies. Need to test aerosol and not liquid. Standards for exposure protocols have not been clearly defined.
Clinical studies	Studies on human <i>in vivo</i> effects.	Provide definite and objective evidence about the effects of use.	Difficult and expensive to perform. Long-term follow up is needed due to the expected lag from initiation of use to possible development of any clinically evident disease. For now, limited to acute effects from use.

evaluated emissions based on a toxicant emissions score and reported a score of 0 in ECs compared with a score of 100–134 for tobacco cigarettes (Figure 3). The US Food and Drug Administration (FDA) also performed chemical analyses on 18 commercially available products in 2009 [Westenberger, 2009]. They detected the presence of tobacco-specific nitrosamines (TSNAs) but did not declare the levels found. Small amounts of diethylene glycol were also found in one sample, which was unlikely to cause any harm from normal use. Another study identified small amounts of amino-tandafil and rimonabant in EC liquids [Hadwiger *et al.* 2010]. Subsequently, several laboratories performed similar tests, mostly on liquids, with Cahn and Siegel publishing a review on the chemical analyses of ECs and comparing the findings with tobacco cigarettes and other tobacco products [Cahn and Siegel, 2011]. They reported that TSNA levels were similar to those measured in pharmaceutical NRTs. The authors concluded that, based on chemical analysis, ECs are far less harmful compared with tobacco cigarettes. The most comprehensive study on TSNAs has been performed recently by a South Korean group, evaluating 105 liquids obtained from local retailers [Kim and Shin, 2013]. On average, they found 12.99 ng TSNAs per ml of liquid, with the amount of daily exposure to the users estimated to be similar to users of NRTs [Farsalinos *et al.* 2013d]. The estimated daily exposure to nitrosamines from tobacco cigarettes (average consumption of 15 cigarettes per day) is estimated to be up to 1800 times higher

compared with EC use (Table 3). Etter and colleagues evaluated the accuracy of nicotine labeling and the presence of nicotine impurities and degradation products in 20 EC liquid samples [Etter *et al.* 2013]. They found that nicotine levels were 85–121% of what was labeled, while nicotine degradation products were present at levels of 0–4.4%. Although in some samples the levels were higher than those specified in European Pharmacopoeia, they are not expected to cause any measurable harm to users.

Besides the evaluation for the presence of TSNAs, analyses have been performed for the detection of carbonyl compounds. It is known that the thermal degradation of propylene glycol and glycerol can lead to the emission of toxic compounds such as aldehydes [Antal *et al.* 1985; Stein *et al.* 1983]. Goniewicz and colleagues evaluated the emission of 15 carbonyls from 12 brands of ECs (mostly first-generation) [Goniewicz *et al.* 2013]. In order to produce vapor, researchers used a smoking machine and followed a regime of 1.8-second puffs with a very short 10-second interpuff interval, which does not represent realistic use [Farsalinos *et al.* 2013c]; although the puff duration was low, interpuff interval was remarkably short, which could potentially lead to overheating. In addition, the same puff number was used in all devices tested, although there was a significant difference in the design and liquid content between devices. Despite these limitations, out of 15 carbonyls, only 3 were detected (formaldehyde, acetaldehyde and acrolein); levels were

Table 2. Summary of chemical toxicity findings.

Study	What was investigated?	What were the key findings?	
		Liquid	Vapor
Laugesen [2009]	Evaluation of 62 toxicants in the EC vapour from Ruyan 16 mg and mainstream tobacco smoke using a standard smoking machine protocol.	N/A	No acrolein, but small quantities of acetaldehyde and formaldehyde found. Traces of TSNAs (NNN, NNK, and NAT) detected. CO, metals, carcinogenic PAHs and phenols not found in EC vapour. Acetaldehyde and formaldehyde from tobacco smoke were 55 and 5 times higher, respectively.
Westenberger [2009]	Evaluation of toxicants in EC cartridges from two popular US brands.	TSNAs and certain tobacco specific impurities were detected in both products at very low levels. Diethylene glycol was identified in one cartridge.	N/A
Hadwiger <i>et al.</i> [2010]	Evaluation of four refill solutions and six replacement cartridges advertised as containing Cialis or rimonabant.	Small amounts of amino-tadalafil and rimonabant present in all products tested.	N/A
Cahn and Siegel [2011]	Overview of 16 chemical toxicity studies of EC liquids/vapours.	TSNAs levels in ECs 500- to 1400-fold lower than those in conventional cigarettes and similar to those in NRTs. Other chemicals found very low levels, which are not expected to result in significant harm.	
Pellegrino <i>et al.</i> [2012]	Evaluation of PM fractions and PAHs in the vapour generated from cartomizers of an Italian EC brand.	N/A	PM fractions were found, but levels were 6–18 times lower compared with conventional cigarettes. Traces of PAHs detected.
Kim and Shin [2013]	TSNAs (NNN, NNK, NAT, and NAB) content in 105 refill liquids from 11 EC brands purchased in Korean shops.	Total TSNAs averaged 12.99 ng/ml EC liquid; daily total TSNA exposure from conventional cigarettes estimated to be up to 1800 times higher.	N/A
Etter <i>et al.</i> [2013]	Nicotine degradation products, ethylene glycol and diethylene glycol evaluation of 20 EC refill liquids from 10 popular brands	The levels of nicotine degradation products represented 0–4.4% of those for nicotine, but for most samples the level was 1–2%. Neither ethylene glycol nor diethylene glycol were detected.	N/A
Goniewicz <i>et al.</i> [2013]	Vapours generated from 12 brands of ECs and a medicinal nicotine inhaler using a modified smoking machine protocol	N/A	Carbonyl compounds (formaldehyde, acetaldehyde and acrolein), VOCs (toluene and trace levels of xylene), trace levels of TSNAs (NNN and NNK) and very low levels of metals (cadmium, nickel and lead) were found in almost all examined EC vapours. Trace amounts of formaldehyde, acetaldehyde, cadmium, nickel and lead were also detected from the Nicorette inhalator. Compared with conventional cigarette, formaldehyde, acetaldehyde and acrolein were 9–450 times lower; toluene levels 120 times lower; and NNN and NNK levels 380 and 40 times lower respectively.

(Continued)

Table 2. (Continued)

Study	What was investigated?	What were the key findings?	
		Liquid	Vapor
Williams <i>et al.</i> [2013]	Vapour generated from cartomizers of a popular EC brand using a standard smoking machine protocol	N/A	Trace levels of several metals (including tin, copper, silver, iron, nickel, aluminium, chromium, lead) were found, some of them at higher level compared with conventional cigarettes. Silica particles were also detected. Number of microparticles from 10 EC puffs were 880 times lower compared with one tobacco cigarette.
Burstyn [2014]	Systematic review of 35 chemical toxicity studies/technical reports of EC liquids/vapours.	No evidence of levels of contaminants that may be associated with risk to health. These include acrolein, formaldehyde, TSNAs, and metals. Concern about contamination of the liquid by a nontrivial quantity of ethylene glycol or diethylene glycol remains confined to a single sample of an early technology product and has not been replicated.	

Abbreviations. CO, carbon monoxide; EC, electronic cigarette; NAT, N-Nitrosoanatabine; NNK, 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone; NNN, N-Nitrosornicotine; PAHs, polycyclic aromatic hydrocarbons; PM, particulate matter; TSNAs, tobacco-specific nitrosamines; VOCs, volatile organic carbons.

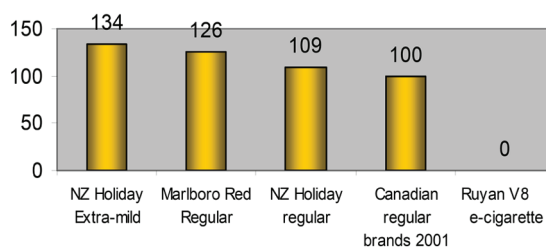


Figure 3. Toxic emissions score, adjusted for nicotine, for electronic cigarette and popular cigarette brands. [Reproduced with permission from Laugesen [2009]].

9–450 times lower compared with emissions from tobacco cigarettes (derived from existing literature but not tested in the same experiment). Formaldehyde and acetaldehyde were also emitted from the nicotine inhalator, although at lower levels. In addition, they examined for the presence of 11 volatile organic carbons and found only trace levels of toluene (at levels from 0.2–6.3 μg per 150 puffs) and xylene (from 0.1–0.2 μg per 150 puffs) in 10 of the samples; toluene levels were 120 times lower compared with tobacco cigarettes (again derived from existing literature but not tested in the same experiment).

Given that ECs have several metal parts in direct contact with the e-liquid, it is quite obvious to expect some contamination with metals in the vapor. Goniewicz and colleagues examined samples for the presence of 12 metals and found

nickel, cadmium and lead emitted [Goniewicz *et al.* 2013]; the levels of nickel were similar to those present in a pharmaceutical nicotine inhalator, while lead and cadmium were present at 2–3 times higher levels compared with the inhalator. Still, the absolute levels were very low (few nanograms per 150 puffs). Williams *et al.* [2013] focused their research on the presence of heavy metals and silicate particles emitted from ECs. They tested poor quality first-generation cartomisers and found several metals emitted in the aerosol of the EC, specifying that in some cases the levels were higher compared with conventional cigarettes. As mentioned earlier, it is not unusual to find trace levels of metals in the vapor generated by these products under experimental conditions that bear little relevance to their normal use; however, it is unlikely that such small amounts pose a serious threat to users' health. Even if all the aerosol was absorbed by the consumer (which is not the case since most of the aerosol is visibly exhaled), an average user would be exposed to 4–40 times lower amounts for most metals than the maximum daily dose allowance from impurities in medicinal products [US Pharmacopeia, 2013]. Silicate particles were also found in the EC aerosol. Such particles come from the wick material, however the authors did not clarify whether crystalline silica oxide particles were found, which are responsible for respiratory disease. In total, the number of microparticles (< 1000 nm) estimated to be inhaled by EC users from 10 puffs were 880 times lower compared

Table 3. Levels of nitrosamines found in electronic and tobacco cigarettes. Prepared based on information from Laugesen [2009], Cahn and Siegel [2011] and Kim and Shin [2013].

Product	Total nitrosamines levels (ng)	Daily exposure (ng)	Ratio ⁴
Electronic cigarette (per ml)	13	52 ¹	1
Nicotine gum (per piece)	2	48 ²	0.92
Winston (per cigarette)	3365	50 475 ³	971
Newport (per cigarette)	3885	50 775 ³	976
Marlboro (per cigarette)	6260	93 900 ³	1806
Camel (per cigarette)	5191	77 865 ³	1497

¹Based on average daily use of 4ml liquid
²Based on maximum recommended consumption of 24 pieces per day
³Based on consumption of 15 cigarettes per day
⁴ Difference (number-fold) between electronic cigarette and all other products in daily exposure to nitrosamines

with one tobacco cigarette. Similar findings concerning microparticles were reported by Pellegrino and colleagues who found that, for each particulate matter fraction, conventional cigarettes released 6–18 times higher amounts compared with the EC tested [Pellegrino *et al.* 2012].

Burstyn has recently reviewed current data on the chemistry of aerosols and the liquids of ECs (including reports which were not peer-reviewed) and estimated the risk to consumers based on workplace exposure standards (i.e. Threshold Limit Values [TLVs]) [Burstyn, 2014]. After reviewing all available evidence, the author concluded that there was no evidence that vaping produced inhalable exposure to contaminants of aerosol that would warrant health concerns. He added that surveillance of use is recommended due to the high levels of propylene glycol and glycerol inhaled (which are not considered contaminants but ingredients of the EC liquid). There are limited data on the chronic inhalation of these chemicals by humans, although there is some evidence from toxicological studies (which are discussed later in this paper).

In conclusion, chemical studies have found that exposure to toxic chemicals from ECs is far lower compared with tobacco cigarettes. Besides comparing the levels of specific chemicals released from tobacco and ECs, it should be taken into consideration that the vast majority of the >4000 chemicals present in tobacco smoke are completely absent from ECs. Obviously, surveillance of use is warranted in order to objectively evaluate the *in vivo* effects and because the effects of inhaling flavoring substances approved for food use are largely unknown.

Toxicological studies

To date, only a handful of toxicological studies have been performed on ECs, mostly cytotoxicity studies on established cell lines. The cytotoxicity approach also has its flaws. Findings cannot be directly applied to the *in vivo* situation and there is always the risk of over- (as well as under-)estimating the interpretation of the toxic effects in these investigational models. An ample degree of results variability is to be expected from different cell lines and, sometimes, also within the same cell line. Comparing the potential cytotoxicity effects of EC vapor with those resulting from the exposure of cigarette smoke should be mandatory, but standards for vapor production and exposure protocols have not been clearly defined.

Bahl and colleagues [Bahl *et al.* 2012] performed cytotoxicity tests on 36 EC liquids, in human embryonic stem cells, mouse neural stem cells and human pulmonary fibroblasts and found that stem cells were more sensitive to the effects of the liquids, with 15 samples being moderately cytotoxic and 12 samples being highly cytotoxic. Propylene glycol and glycerol were not cytotoxic, but a correlation between cytotoxicity and the number and height of the flavoring peaks in high-performance liquid chromatography was noted. Investigations were just restricted to the effect of EC liquids and not to their vapors, thus limiting the importance of the study findings; this is not a trivial issue considering that the intended use of these products is by inhalation only and that it is unlikely that flavoring substances in the EC liquids will still be present in the aerosol in the same amount due to differences in evaporation temperature [Romagna *et al.* 2013]. Regrettably, a set of experiments with cigarette smoke extracts as

comparator was not included. Of note, the authors emphasized that the study could have underestimated the cytotoxicity by 100 times because when they added the EC liquids to the cell, medium final concentration was 1%. However, cells were cultured for 48 hours with continuous exposure to the liquid, while in real use the lungs come in contact with aerosol instead of liquid, the contact lasts for 1–2 seconds per puff and most of the aerosol is visibly exhaled. Finally, Cinnamon Ceylon, the liquid found to be mostly cytotoxic in this study, was not a refill liquid but a concentrated flavor which is not used in ECs unless it is diluted to 3–5%.

Romagna and colleagues [Romagna *et al.* 2013] performed the first cytotoxicity study of EC vapor on fibroblast cells. They used a standardized ISO 10993-5 protocol, which is used for regulatory purposes of medical devices and products. They tested the vapor of 21 liquid samples containing the same amount of nicotine (9 mg/ml), generated by a commercially available EC device. Cells were incubated for 24 hours with each of these vapors and with smoke from a conventional cigarette. Only one sample was found to be marginally cytotoxic, whereas cigarette smoke was highly cytotoxic (approximately 795% more cytotoxic), even when the extract was diluted up to 25% of the original concentration.

The same group also investigated the cytotoxic potential of 20 EC liquid samples in cardiomyoblasts [Farsalinos *et al.* 2013a]. Vapor was produced by using a commercially available EC device. Samples contained a wide range of nicotine concentrations. A base liquid mixture of propylene glycol and glycerol (no nicotine and no flavorings) was also included as an additional experimental control. Four of the samples examined were made by using cured tobacco leaves in a steeping process, allowing them to impregnate a mixture of propylene glycol and glycerol for several days before being filtered and bottled for use. Of note, this was the first study which evaluated a limited number of samples with an EC device delivering higher voltage and energy to the atomizer (third-generation device). In total, four samples were found to be cytotoxic; three of them were liquids made by using cured tobacco leaves, with cytotoxicity observed at both 100% and 50% extract concentration, while one sample (cinnamon flavor) was marginally cytotoxic at 100% extract concentration only. In comparison, smoke from three tobacco cigarettes was highly cytotoxic, with toxicity observed even when the

extract was diluted to 12.5%. The samples made with tobacco leaves were three times less cytotoxic compared with cigarette smoke; this was probably due to the absence of combustion and the significantly lower temperature of evaporation in EC use. Concerning high-voltage EC use, the authors found slightly reduced cell viability without any of the samples being cytotoxic according to the ISO 10993-5 definition. Finally, no association between cell survival and the amount of nicotine present in the liquids was noted.

A recent study evaluated in more detail the cytotoxic potential of eight cinnamon-flavored EC liquids in human embryonic stem cells and human pulmonary fibroblasts [Behar *et al.* 2014]. The authors found that the flavoring substance predominantly present was cinnamaldehyde, which is approved for food use. They observed significant cytotoxic effects, mostly on stem cells but also on fibroblasts, with cytotoxicity associated with the amount of cinnamaldehyde present in the liquid. However, major methodological issues arose from this study. Once again, cytotoxicity was just restricted to EC liquids and not to their vapors. Moreover, the authors mentioned that the amount of cinnamaldehyde differed between liquids by up to 100 times, and this raises the suspicion of testing concentrated flavor rather than refills. By searching the internet and contacting manufacturers, based on the names of samples and suppliers mentioned in the manuscript, it was found that at least four of their samples were not refills but concentrated flavors. Surprisingly, the levels of cinnamaldehyde found to be cytotoxic were about 400 times lower than those currently approved for use [Environmental Protection Agency, 2000].

Few animal studies have been performed to evaluate the potential harm of humectants in EC liquids (i.e. propylene glycol and glycerol) when given by inhalation. Robertson and colleagues tested the effects on primates of inhaling propylene glycol vapor for several months and found no evidence of toxicity on any organ (including the lungs) after post-mortem examination of the animals [Robertson *et al.* 1947]. Similar observations were made in a recent study in rats and dogs [Werley *et al.* 2011]. Concerns have been raised in human use, based on studies of people exposed to theatrical fog [Varughese *et al.* 2005; American Chemistry Council, 2003] or propylene glycol used in the aviation industry [Wieslander *et al.* 2001]. Irritation of the respiratory tract was found, but no permanent lung injury or other

long-term health implications were detected. It should be reminded that, in these circumstances, nonpharmaceutical purity propylene glycol is used and in some cases oils are added, making it difficult to interpret the results in the context of EC use. Evidence for the potential harm of inhaled glycerol is sparse. A study using Sprague–Dawley rats found minimal to mild squamous metaplasia of the epiglottis epithelium in the high-dose group only, without any changes observed in lungs or other organs [Renne *et al.* 1992]. No comparative set of experiments with cigarette smoke was included, but it is well known that exposure to tobacco smoke in similar animal models leads to dramatic changes in the lungs, liver and kidneys [Czekaj *et al.* 2002].

In conclusion, toxicological studies have shown significantly lower adverse effects of EC vapor compared with cigarette smoke. Characteristically, the studies performed by using the liquids in their original liquid form have found less favorable results; however, no comparison with tobacco smoke was performed in any of these studies, and they cannot be considered relevant to EC use since the samples were not tested in the form consumed by vapers. More research is needed, including studies on different cell lines such as lung epithelial cells. In addition, it is probably necessary to evaluate a huge number of liquids with different flavors since a minority of them, in an unpredictable manner, appear to raise some concerns when tested in the aerosol form produced by using an EC device.

Clinical studies and research surveys

Clinical trials can be very informative, but they require monitoring of hundreds of users for many years to adequately explore the safety/risk profile of the products under investigation. Research surveys of EC users, on the other hand, can quickly provide information about the potential harm of these products and are much cheaper to run. However, self-reported data, highly self-selected study populations, and the cross-sectional design are some of the most common limitations of research surveys. Taken together, findings from surveys and follow-up studies of vapers have shown that EC use is relatively safe.

Polosa and colleagues followed up smokers for 24 months, after a 6-month period of intervention during which ECs were given [Polosa *et al.* 2013a]. Only mild symptoms such as mouth and throat

irritation and dry cough were observed. Farsalinos and colleagues retrospectively evaluated a group of 111 EC users who had completely quit smoking and were daily EC users for a median period of 8 months [Farsalinos *et al.* 2013b]. Throat irritation and cough were the most commonly reported side effects. Similar findings have been observed in surveys [Dawkins *et al.* 2013; Etter *et al.* 2011]. However, it is expected that dedicated users who have more positive experiences and fewer side effects compared with the general population participate in such studies, therefore interpretation should be done with caution. The only two existing randomized controlled trials have also included detailed EC safety analysis. The ECLAT study [Caponnetto *et al.* 2013b], a three-arm, controlled, randomized, clinical trial designed to compare efficacy and safety of a first-generation device with 7.2, 5.4, or 0 mg nicotine cartridges, reported clinically significant progressive health improvements already by week two of continuous use of the device, and no serious adverse events (i.e. major depression, abnormal behavior or any event requiring an unscheduled visit to the family practitioner or hospitalization) occurred during the study. The ASCEND study [Bullen *et al.* 2013], a three-arm, controlled, randomized, clinical trial designed to compare the efficacy and safety of a first-generation device (with or without nicotine) with nicotine patches, reported no serious adverse events in any of the three study groups.

Few clinical studies have been performed to evaluate the short-term *in vivo* effects of EC use in current or former smokers. Vardavas and colleagues evaluated the acute effects of using an EC for 5 minutes on respiratory function [Vardavas *et al.* 2012]. Although they did not report the results of commonly-used spirometry parameters, they found that a sensitive measure of airways resistance and nitric oxide levels in exhaled breath were adversely affected. Similar elevations in respiratory resistance were reported by other research groups [Palamidas *et al.* 2013; Gennimata *et al.* 2012], who also documented some bizarre elevation in exhaled carbon monoxide levels after EC use; this finding has been challenged by several other studies [Farsalinos *et al.* 2013f; Nides *et al.* 2014; Van Staden *et al.* 2013]. Schober and colleagues found that EC use led to elevated exhaled nitric oxide [Schober *et al.* 2013], contradicting the findings from Vardavas and colleagues [Vardavas *et al.* 2012]. Characteristically, none of the above studies performed any comparative tests after smoking tobacco cigarettes. Flouris and colleagues found

that only smoking had an acute adverse effect on respiratory function [Flouris *et al.* 2013]; no difference was observed after the group of smokers was exposed to active or passive EC use.

Two studies have evaluated the short-term effects of ECs on the cardiovascular system. Farsalinos and colleagues evaluated the acute effects of using ECs with an 11 mg/ml nicotine-containing liquid on hemodynamics and left ventricular function, in comparison with the effects of cigarette smoking [Farsalinos *et al.* 2012]. They found that EC use resulted in a slight elevation in diastolic blood pressure while, after smoking, both systolic and diastolic blood pressure and heart rate were significantly elevated. Obviously, this was due to the relatively low nicotine content of the EC (which is considered medium strength). Diastolic dysfunction was observed in smokers after smoking, which was in line with findings from previous studies. However, no adverse effects were observed in EC users after using the device *ad lib* for 7 minutes. Another study by the same group [Farsalinos *et al.* 2013f], evaluated the acute effects of EC use on coronary flow. In particular, they measured the flow velocity reserve of the left anterior descending coronary artery by echocardiography after intravenous infusion of adenosine, representing the maximal ability of the artery to deliver blood to the myocardium. Smoking was associated with a decline in flow velocity reserve by 16% and an elevation in resistance to flow by 19%. On the contrary, no difference was observed in any of these parameters after using the EC. Blood carboxyhemoglobin levels were also measured in participants; baseline values were significantly higher in smokers compared with vapers and were further elevated after smoking but were not altered after EC use. Similar observations for carboxyhemoglobin levels were observed by Van Staden and colleagues [Van Staden *et al.* 2013].

A clinical case report of a smoker suffering from chronic idiopathic neutrophilia was published. According to that report [Farsalinos and Romagna, 2013], switching from smoking to EC use led to a reversal of the condition after 6 months. In addition, C-reactive protein levels, which were consistently elevated for more than 6 years, decreased to normal levels. Another case report of a patient with lipoid pneumonia was published, with the condition attributed to glycerin-based EC liquids used by the patient [McCauley *et al.* 2012]. However, glycerin is an alcohol (polyol) and thus it is impossible to cause

lipoid pneumonia. Only oil-based liquids could be the cause for this condition; such liquids should not be used with ECs.

One study evaluated the acute effects of tobacco and EC use on white blood cell count [Flouris *et al.* 2012]. Smoking one tobacco cigarette caused an immediate elevation in white blood cells, neutrophils and lymphocytes, indicating acute inflammatory distress. On the contrary, no differences were observed after using ECs.

In conclusion, clinical studies evaluating the effects of short-term EC use on selected cardiovascular and respiratory functional outcomes have shown that even if some harmful effects of vaping are reported, these are considerably milder compared with smoking conventional cigarettes. However, it is difficult to assess the prognostic implications of these studies; longer-term data are needed before any definite conclusions are made.

Passive vaping

Passive smoking is an established risk factor for a variety of diseases [Barnoya and Navas-Acien, 2013]. Therefore, it is important from a public health perspective to examine the impact of EC use on bystanders. Indirect data can be derived from chemical studies in vapor mentioned above, which show that the potential of any significant adverse effects on bystanders is minimal. In fact, since side-stream exposure is nonexistent in EC (aerosol is produced only during activation of the device, while tobacco cigarettes emit smoke even when no puffs are taken), such studies are undoubtedly overestimating the risk of environmental exposure.

Few studies have focused on second-hand vaping. McCauley and colleagues [McCauley *et al.* 2012], although mentioning indoor air quality in the title of their study and finding minimal health-related impact, did not in fact evaluate second-hand vaping because aerosol was produced from an EC device and was evaluated without previously being inhaled by any user. Moreover, there were some problems with cross-contamination with tobacco cigarette smoke, which made the results somewhat questionable, at least for some of the parameters tested. Schripp and colleagues [Schripp *et al.* 2013] evaluated the emissions from an EC by asking a volunteer to use three different EC devices in a closed 8 m³ chamber. From a selection of 20 chemicals analyzed, only formaldehyde, acrolein, isoprene, acetaldehyde and acetic acid were

detected. The levels were 5–40 times lower compared with emissions from a conventional cigarette. For formaldehyde, the authors specifically mentioned that the levels were continuously rising from the time the volunteer entered the room, even before he started using the EC. Moreover, no acute elevation was observed when the smoker used the three EC devices, contrary to the acute elevation and spiking of levels when a tobacco cigarette was lit. The authors concluded that formaldehyde was not emitted from the ECs but was due to human contamination, since low amounts of formaldehyde of endogenous origin can be found in exhaled breath [Riess *et al.* 2010]. Romagna and colleagues [Romagna *et al.* 2012] evaluated chemicals released in a realistic setting of a 60 m³ room, by asking five smokers to smoke *ad lib* for 5 hours and five vapers to use ECs *ad lib* for a similar period of time on two separate days. Nicotine, acrolein, toluene, xylene and polycyclic aromatic hydrocarbons were detected in room air after the smoking session, with the amount of total organic carbon (TOC) reaching to 6.66 mg/m³. In contrast, after the EC session, only glycerol was detected in minimal levels (72 µg/m³), while TOC reached a maximum level of 0.73 mg/m³. Characteristically, the amount of TOC accumulated after 5 hours of EC use was similar to the amount found after just 11 minutes of smoking. The study on heavy metals mentioned previously [Williams *et al.* 2013] could also be used to examine any potential risk of bystanders' exposure to toxic metals. The levels of heavy metals found in vapor were minimal, and considering the dispersion of these molecules in the whole room air, it is unlikely that any of these metals could be present in measurable quantities in the environment. Therefore, the risk for bystanders would be literally nonexistent. Contrary to that, Schober and colleagues [Schober *et al.* 2013] found that levels of aluminum were raised by 2.4 times in a 45 m³ room where volunteers were asked to use ECs for 2 hours. This is a highly unexpected finding which cannot be supported by the findings of the study by Williams and colleagues [Williams *et al.* 2013]; because the levels found in the latter could not result in such elevation of the environmental levels of aluminum, unless nothing is retained in or absorbed from the lungs. Moreover, Schober and colleagues [Schober *et al.* 2013] found that levels of polycyclic aromatic hydrocarbons (PAHs) were raised by 20% after EC use. However, a major methodological problem of this study is that control environmental measurements were performed on a separate day and not on the same day of EC

use. This is a major limitation, because the levels of environmental PAHs have significant diurnal and day-to-day variations [Ravindra *et al.* 2008]; therefore, it is highly likely that the differences in levels of PAHs (which are mainly products of combustion and are not expected to be emitted from EC use) represented changes due to environmental conditions and not due to EC use. Bertholon and colleagues [Bertholon *et al.* 2013] examined the EC aerosol exhaled from a user, in comparison with exhaled smoke from a smoker. The authors found that particle size diameters were 0.29–0.033 µm. They observed that the half life of EC aerosol was 11 seconds compared with 20 minutes for cigarette smoke, indicating that risk of passive vaping exposure is significantly lower compared with passive smoking.

The recent findings by Czogala and colleagues [Czogala *et al.* 2013] led to similar conclusions. The authors compared the emissions of electronic and conventional cigarettes generated by experienced dual users in a ventilated full-sized room and found that ECs may emit detectable amounts of nicotine (depending on the specific EC brand tested), but no carbon monoxide and volatile organic carbons. However, the average ambient levels of nicotine of ECs were 10 times lower than those of conventional cigarettes (3.32 ± 2.49 versus 31.60 ± 6.91 µg/m³).

In his review and comparison with TLVs, Burstyn found that emissions from ECs to the environment are not expected to pose any measurable risk for bystanders [Burstyn, 2014].

An issue that needs further clarification relates to the findings of microparticles emitted from ECs. In most studies, these findings are presented in a way implying that the risk is similar to environmental or smoking microparticles. In reality, it is not just the size but the composition of the microparticles that matters. Environmental microparticles are mainly carbon, metal, acid and organic microparticles, many of which result from combustion and are commonly called particulate matter. Particulate matter exposure is definitely associated with lung and cardiovascular disease [Peters, 2005; Seaton *et al.* 1995]. In the case of ECs, microparticles are expected to consist mostly of propylene glycol, glycerol, water and nicotine droplets. Metal and silica nanoparticles may also be present [Williams *et al.* 2013], but, in general, emissions from ECs are incomparable to environmental particulate matter or cigarette smoke microparticles.

Flouris and colleagues [Flouris *et al.* 2013] performed the only clinical study evaluating the respiratory effects of passive vaping compared with passive smoking. Researchers found significant adverse effects in spirometry parameters after being exposed to passive smoking for 1 hour, while no adverse effects were observed after exposure to passive vaping.

Although evaluating the effects of passive vaping requires further work, based on the existing evidence from environmental exposure and chemical analyses of vapor, it is safe to conclude that the effects of EC use on bystanders are minimal compared with conventional cigarettes.

Miscellaneous safety issues

Specific subpopulations: psychiatric and chronic obstructive pulmonary disorder patients

A challenging population subgroup with unique smoking patterns is that of psychiatric patients and in particular schizophrenic patients. This subpopulation is characterized by a very high smoking prevalence [De Leon and Diaz, 2005] with an excess of smoking-related mortality [Brown *et al.* 2000]. Currently, only NRTs are recommended to treat nicotine dependence in this specific subpopulation, but in general they are not particularly effective [Aubin *et al.* 2012]. ECs could be used as an alternative to smoking products in this group. Caponnetto and colleagues performed a prospective 12-month pilot study to evaluate the efficacy of EC use in smoking reduction and cessation in a group of 14 patients with schizophrenia [Caponnetto *et al.* 2013a]. In 50% of participants, smoking consumption went from 30 to 15 cigarettes per day at 52 weeks of follow up, while 14.3% managed to quit smoking. Importantly, no deterioration in their psychiatric condition was observed, and side effects were mild and temporary. The results were promising although an outdated EC device was used in this study.

There is also anecdotal evidence that successful smoking cessation could be attained by using an EC in smokers with other psychiatric conditions such as depression [Caponnetto *et al.* 2011a]. Both patients described in this case series stated that EC use was well tolerated and no adverse events were reported.

Considering that first-line oral medications for nicotine addiction are contraindicated in such patients (prescribing information for bupropion and varenicline carry a ‘black-box’ warning for certain psychiatric conditions), ECs may be a promising tool in these challenging patient groups.

Another subpopulation that may benefit from regular EC use is that of respiratory patients with chronic obstructive pulmonary disease (COPD), a progressive disease characterized by a persistent inflammatory response to tobacco smoke that generally leads to decline in lung function, respiratory failure, cor pulmonale and death. Consequently, smoking cessation plays a crucial part in the management of COPD patients. However, the available evidence in the medical literature indicates that COPD patients who smoke respond poorly to smoking cessation efforts [Schiller and Ni, 2006]. To date, no formal efficacy and safety assessment of EC use in COPD patients has been conducted. There is only evidence from a case report of inveterate smokers with COPD and a documented history of recurring relapses, who eventually quit tobacco smoking on their own by using an EC [Caponnetto *et al.* 2011b]. Significant improvement in quality of life and reduction in the number of disease exacerbations were noted. EC use was well tolerated with no reported adverse events.

Accidental nicotine exposure

Accidental ingestion of nicotine, especially by children, or skin contact with large amounts of liquid or highly concentrated nicotine solution can be an issue. However, the historically referenced lethal dose of 60 mg has recently been challenged in a review by Mayer [Mayer, 2013]; he found that the lethal levels currently reproduced in every document originated from dubious experiments performed in the 19th century. Based on post-mortem studies, he suggested that the acute dose associated with a lethal outcome would be 500–1000 mg. Taking into account that voluminous vomiting is the first and characteristic symptom of nicotine ingestion, it seems that far higher levels of nicotine need to be ingested in order to have lethal consequences.

A surveillance system of adverse events has been developed by the FDA, which identifies safety concerns in relation to tobacco products. Since 2008, 47 adverse events were reported for ECs

[Chen, 2013]. Eight of them were serious events such as hospitalizations for pneumonia, heart failure, seizures and hypotension and burns. A case of second-degree burns was caused by a battery explosion, which is generally a problem observed in lithium batteries and has occurred in other products (such as mobile phones). The author emphasized that the reported events were not necessarily associated with EC use but may have been related to pre-existing conditions or other causes. No condition was characteristically associated with EC use.

A recent review of the California Poison Control System database from 2010 to 2012 identified 35 cases (14 children) associated with EC exposure (accidental exposure in 25 cases) [Cantrell, 2013]. A total of five patients were evaluated in an emergency department and all were discharged within 4 hours. Nausea, vomiting, dizziness and oral irritation were most commonly reported. Taken together, data from surveillance systems of adverse events suggest that short-term adverse effects and accidental exposures to EC cartridges are unlikely to result in serious toxicity.

Notwithstanding, avoiding preventable contact with highly concentrated nicotine solution remains important; this can be achieved by specific labeling of the products, child-proof caps and proper education of consumers. There is no evidence that nicotine-containing EC liquids should be treated in any different way compared with other consumer products used every day in households (such as bleach, washing machine powder, etc.).

Electrical accidents and fires

The electronic equipment of ECs may be the cause for accidents. ECs are mainly composed of lithium batteries. There have been reports of explosions of batteries, caused either by prolonged charging and use of improper chargers or by design defects. Similar accidents have occurred with batteries of other popular devices, such as mobile phones. Therefore, this does not occur specifically with ECs, however, quality standards of production should be used in order to avoid such accidents.

Smoking is a major cause of residential fires. Between 2008 and 2010, an estimated annual average of 7600 smoking-related fires occurred in residential buildings in the US [US Fire

Administration, 2012]. They account for only 2% of all residential building fires but for 14% of fire deaths. Since ECs are activated only when used by the person and there is no combustion involved, there is the potential to avoid the risk of smoking-related fires.

Use by youngsters and nonsmokers

Although beyond the scope of this review, it is important to briefly discuss the potential for addiction from EC use. It should be acknowledged that nicotine is addictive, although recent studies have shown that several other chemicals present in tobacco are associated with a significant enhancement of the addictiveness of nicotine [Lotfipour *et al.* 2011; Rose, 2006; Guillem *et al.* 2005]. Still, nicotine intake should not be recommended to nonsmokers. Smokers are already addicted to nicotine, thus ECs will be a cleaner form of nicotine intake, while at the same time they will maintain their sensory stimulation and motor stimulation of smoking; these are important aspects of the addiction to smoking. Regulatory authorities have expressed concern about EC use by youngsters or by never-smokers, with ECs becoming a gateway to smoking or becoming a new form of addiction. However, such concerns are unsubstantiated; research has shown that EC use by youngsters is virtually nonexistent unless they are smokers. Camenga and colleagues [Camenga *et al.* 2013] examined the use of ECs and tobacco in a group of adolescents, in a survey conducted in three waves. In the first wave of the survey (February 2010), 1719 adolescents were surveyed from which only one nonsmoker was found to be using ECs. In the second and third wave of the surveys, only five nonsmoking adolescents were using ECs. In fact, these are adolescents who reported first ever use of ECs in the past 30 days; therefore they were not necessarily regular or daily EC consumers. The increased prevalence of EC use from 0.9% in 2010 to 2.3% in 2011 concerned smoking adolescents, therefore it should be considered a positive finding that smokers are experimenting with the significantly less harmful ECs. Similarly, the Medicines and Healthcare Products Regulatory Agency (MHRA) found that less than 1% of EC users are never-smokers [MHRA, 2013]. Data from the Centers for Disease Control [2013] National Youth Tobacco Survey reported doubling in EC experimentation by 13–18 year old students from 1.1% in 2011 to 2.1% in 2012; however, 90.6% of them were smokers. From the whole population, only 0.5% were nonsmokers experimenting with ECs.

Once again, participants were asked about ever experimenting with an EC in the past 30 days, not regular or daily EC use. Recently, a survey of more than 75,000 students in South Korea was published [Lee *et al.* 2013]. Although they found that 12.6% of them were daily smokers (8.6% were using only tobacco cigarettes and 3.6% were using both tobacco and ECs), only 0.6% of nonsmokers had used ECs in the past 30 days. Although the above mentioned data have been used as arguments to support the fact that a new epidemic of nicotine addiction through the use of ECs is appearing, in reality they are showing that any experimentation with ECs is done by smokers. This is in fact a positive finding, and could lead to reduced smoking prevalence through adoption of EC use. Therefore, ECs could serve as gateway from smoking; on the contrary, there is no evidence indicating that they could be a gateway to smoking. It is promising to see that penetration of EC use in youngsters is virtually nonexistent, especially when you take into consideration that there is currently no official regulation in most countries to prohibit the access to ECs by youngsters.

Conclusion

Existing evidence indicates that EC use is by far a less harmful alternative to smoking. There is no tobacco and no combustion involved in EC use; therefore, regular vapers may avoid several harmful toxic chemicals that are typically present in the smoke of tobacco cigarettes. Indeed, some toxic chemicals are released in the EC vapor as well, but their levels are substantially lower compared with tobacco smoke, and in some cases (such as nitrosamines) are comparable with the amounts found in pharmaceutical nicotine products. Surveys, clinical, chemistry and toxicology data have often been misrepresented or misinterpreted by health authorities and tobacco regulators, in such a way that the potential for harmful consequences of EC use has been largely exaggerated [Polosa and Caponnetto, 2013]. It is obvious that some residual risk associated with EC use may be present, but this is probably trivial compared with the devastating consequences of smoking. Moreover, ECs are recommended to smokers or former smokers only, as a substitute for conventional cigarettes or to prevent smoking relapse; thus, any risk should be estimated relative to the risk of continuing or relapsing back to smoking and the low efficacy of currently approved medications for smoking cessation should be taken into consideration [Moore *et al.* 2009; Rigotti

et al. 2010; Yudkin *et al.* 2003]. Nonetheless, more research is needed in several areas, such as atomizer design and materials to further reduce toxic emissions and improve nicotine delivery, and liquid ingredients to determine the relative risk of the variety of compounds (mostly flavorings) inhaled. Regulations need to be implemented in order to maintain the current situation of minimal penetration of EC use in nonsmokers and youngsters, while manufacturers should be forced to provide proof for the quality of the ingredients used and to perform tests on the efficiency and safety of their products. However, any regulatory decisions should not compromise the variability of choices for consumers and should make sure that ECs are more easily accessible compared with their main competitor, the tobacco cigarette. Consumers deserve, and should make, informed decisions and research will definitely promote this. In particular, current data on safety evaluation and risk assessment of ECs is sufficient enough to avert restrictive regulatory measures as a consequence of an irrational application of the precautionary principle [Saitta *et al.* 2014].

ECs are a revolutionary product in tobacco harm reduction. Although they emit vapor, which resembles smoke, there is literally no fire (combustion) and no 'fire' (suspicion or evidence that they may be the cause for disease in a similar way to tobacco cigarettes). Due to their unique characteristics, ECs represent a historical opportunity to save millions of lives and significantly reduce the burden of smoking-related diseases worldwide.

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TESTIMONY submitted by SHERRIE WHITE
In opposition of SB 1220
02/02/2015

I have lived in Hawaii since 1981 and traveled here as a young child even before that. Exactly when did Hawaii become the "Nanny" state? Many of the laws passed in the past 10 years have been enacted to dictate behavior and penalize freedom. Hawaii has gone from the spirit of Aloha to the goal of profit and capitol gains from its governance. It seems now that Hawaii will look nowhere to reduce its wasteful spending and look everywhere to increase its potential income. As a life long democrat I am disheartened by the introduction of this bill.

Do you know how many people have stopped smoking via e-cigs? I can verify dozens of people I know. I am just one, but it has made a huge difference in my life and my family life as well. Right now, it is cheaper to use an e-cig than buy cigarettes. This alone motivates many people to make the switch. I am healthier. My clothes don't smell like smoke.

And now you want to put an 80% tax on e-cig liquids? What other industry would accept an 80% increase in tax? The Beverage Industry?, The Tourism Industry?, The Gasoline Industry? How about Shipping or Food Imports? All of these industries have far more impact on Hawaii's environment and health than e-cigs, but they have large ad firms and lobbying efforts to make sure no new laws affect them. The Hawaii State Government is taking advantage of a situation/industry where there are few big players in order to increase funding for cancer research, when there are NO proven facts showing e-cigs contribute to a cancer prognosis. Increasing the tax and thus the cost of e-cigs will ensure that more people keep smoking regular cigarettes, whatever the rules.

This tax is indicated to be collected for Cancer Research in Hawaii. The Cancer Research Center of Hawaii is part of the University of Hawaii. Could it be that UH is struggling for funds? Yes. In fact all universities are struggling for funds right now. Maybe we should think of spending less of our taxpayer dollars on sports programs and more on educational tools? Give the salary of the new UH Sports Director to the UH Cancer Program.

What right is bestowed upon our state government to decide when a new tax is enacted for a special interest? Yes, there is the rail tax on Oahu. Many people have already argued with that. So -What's the next step? How about taxing sports? You want to participate? You could cost us money in insurance and medical fees! Same is true for restaurants, bars, taxis Or, maybe we should just tax fun in general? Don't worry - your money is going to a good cause of OUR choosing.

I invite all the lawyers and government leaders to ponder this as they smoke on their tax-free (for now) cigars in smoke filled rooms.

Submitted By	Organization	Testifier Postion
Oakwood Hirata	Individual	Oppose
Anthony Orozco	Individual	Oppose
Michelle Robinson	Individual	Oppose
Kathy Kim	Individual	Oppose
Dustin Andrews	Individual	Oppose
Mark Dietrich	Individual	Oppose
Michael S. Nakasone	Individual	Oppose
Jacob B.	Individual	Oppose
Teddy Kim	Individual	Oppose
Douglas Huntzinger	Individual	Oppose
Chris Wells	Individual	Oppose
Michael Murphey	Individual	Oppose
Josei Alfonsi	Individual	Oppose