

ON THE FOLLOWING MEASURE: H.B. NO. 349, RELATING TO ELECTRONIC SMOKING DEVICES. BEFORE THE: HOUSE COMMITTEE ON CONSUMER PROTECTION AND COMMERCE

DATE:	Wednesday, February 4, 2015	TIME: 2:45 p.m.
LOCATION:	State Capitol, Room 325	
TESTIFIER(S):	RUSSELL A. SUZUKI, Attorney Gener Earl R. Hoke, Jr., Deputy Attorney General Blair A. Goto, Deputy Attorney General	eral

Chair McKelvey and Members of the Committee:

The Department of the Attorney General supports the general intent of this legislation and recognizes the complexities related to the regulation of electronic smoking devices. To that end the Department of the Attorney General provides this testimony, which: strongly urges deletion of section 8 (page 5, line11, through page 6, line 16) and section 9 (page 6, line 17, through page 11, line 5); offers clarifying amendments to section 3 (page 2, line 19, through page 3 line 2), section 6 (page 4, lines 13 through 16), and section 7 (page 5, line 7 through 10); and provides comments to section 2 (page 2, lines 10-12) of this bill.

As noted previously the Department of the Attorney General strongly urges deletion of sections 8 and 9 from this bill. Section 9 amends the definition of "cigarettes" in section 675-2, Hawaii Revised Statutes (HRS), to include electronic smoking devices. This amended definition of "cigarettes" will have the unintended consequence of adversely affecting the amount of moneys Hawaii receives from the Tobacco Master Settlement Agreement (MSA).

On November 23, 1998, leading United States tobacco product manufacturers entered into the Master Settlement Agreement with the State of Hawaii and 51 other states, territories, and political subdivisions. The MSA amongst other things obligates these manufacturers, in return for a release of past, present, and certain future claims against them, to pay substantial sums to the State. It is important to understand that section 675-2, HRS, originated from language that was negotiated as part and parcel of the MSA that was memorialized as the Model Statute, which was appended as Exhibit T to the MSA, and is not to be changed or amended Testimony of the Department of the Attorney General Twenty-Eighth Legislature, 2015 Page 2 of 4

unilaterally by a State. To that end, one of the obligations that the State took on, as part of the MSA, was a duty to have the model statute in full force and effect throughout an entire calendar year and diligently enforce the model statute and provisions of the MSA. Accordingly, the State of Hawaii must demonstrate that it has continually had a Model Statute in full force and effect throughout an entire calendar year in each year that the MSA exists in order to maximize its share of the annual Master Settlement Agreement payment from the tobacco industry. Accordingly, amending section 675-2, HRS, in a unilateral manner, unnecessarily endangers the State's ability to demonstrate that it has had a Model Statute in full force and effect for an entire calendar year. Moreover, the proposed amendment expands the State of Hawaii's obligations under the MSA in a manner that was never contemplated by the parties to the MSA.

Additionally, given the complexities related to regulating electronic smoking devices, amending the definition of "cigarettes" in section 486P-1, HRS, as proposed in section 8 to include electronic smoking devices as the term is defined in section 709-908, HRS, unnecessarily complicates the regulatory structure currently in place to address cigarettes and roll-your-own tobacco products as contemplated by the MSA. For example, an electronic smoking device as defined in section 709-908, HRS, includes, "an electronic cigarette, electronic cigar, electronic cigarillo, or electronic pipe, and any cartridge or other component of the device or related product." We note that chapter 486P, HRS, was intended to gather information on cigarettes and roll-your-own tobacco products, not electronic components or other parts which comprise an electronic smoking device. Chapter 486P-1, HRS, was enacted to require tobacco product manufacturers selling cigarettes to consumers in the State of Hawaii to submit certain information to the Attorney General as part of the State of Hawaii's diligent enforcement obligations as set forth in chapter 675, HRS, and the MSA. The definition of "cigarette" as negotiated by the parties to the MSA and as set forth in sections 675-2, HRS, and 486P-1, HRS, does not include electronic smoking devices.

In sum, section 8 and section 9 of this bill seek to unilaterally amend the definition of "cigarette" in section 486P-1, HRS, and section 675-2, HRS, to a definition of cigarette that was not negotiated as part of the Model Statute, and unnecessarily places the State of Hawaii's payments from the MSA at risk. Further, such an amendment would lead to the unintended consequence of imposing on the State of Hawaii the responsibility for policing electronic

Testimony of the Department of the Attorney General Twenty-Eighth Legislature, 2015 Page 3 of 4

smoking devices, when electronic smoking devices were not intended to be part and parcel of the MSA by any of the parties when the MSA was negotiated.

With regard to clarifying amendments to section 3 (page 2, line 19, through page 3, line 2), section 6 (page 4, lines 13 through 16), and section 7 (page 5, line 7 through 10), we note that the term electronic smoking device is not defined (other than to state what it may be used for). We recommend that the committee amend the wording of these lines to read as follows: ""Smoke" or "smoking" includes the use of an electronic smoking device, as that term is defined in section 709-908." Using the definition in section 709-908 clarifies that an electronic smoking device or related product that can be used as stated in the definition.

With regard to section 2 (page 2, lines 10-12), which seeks to amend a section of chapter 245, HRS, of the tax code, we would defer to the Department of Taxation as to the technical implications of such an amendment. Nonetheless we feel that it is important to provide the following comment. As drafted, section 2 amends the definition of "cigarettes" in section 245-1, HRS, to include electronic smoking devices as that term is defined in section 709-908, HRS. An electronic smoking device as defined in section 709-908, HRS, includes, "an electronic cigarette, electronic cigar, electronic cigarillo, or electronic pipe, and any cartridge or other component of the device or related product." It is important to note that including electronic smoking devices as defined in section 709-908, HRS, as a cigarette under the tax code impacts upon other sections of chapter 245 and unnecessarily complicates the administration and enforcement of cigarettes under chapter 245. By way of example, chapter 245 specifically taxes cigarettes in a particular manner through the use of tax stamps as proof of taxes paid. Section 245-21, HRS, provides, "The tax imposed under section 245-3 upon the sale or use of cigarettes shall be paid by licensees through the use of stamps." Further, section 245-22, HRS, requires that no individual package of cigarettes may be sold without an affixed tax stamp. Additionally, under the tax code section 245-3, HRS, cigarettes are taxed at a particular tax rate of .16 cents for each cigarette. We note that the application of tax stamps and method of taxing cigarettes does not readily translate to the definition of "cigarette" under the tax code if the definition of "cigarette" is expanded to include an electronic smoking device as defined in section 709-908, HRS, which

Testimony of the Department of the Attorney General Twenty-Eighth Legislature, 2015 Page 4 of 4

includes, "an electronic cigarette, electronic cigar, electronic cigarillo, or electronic pipe, and any cartridge or other component of the device or related product."

As such, we respectfully urge that section 8 and section 9 of this bill be deleted from this measure in total; that the amendments to sections 3, 6, and 7 clarifying the definition of an electronic smoking device be adopted for consistency and clarification; and finally, with regard to section 2, that the complexities of the administration and enforcement of cigarette regulation, under chapter 245, HRS, not be complicated by including electronic smoking devices as defined in section 709-908, HRS, as a "cigarette" under chapter 245, HRS, of the tax code.

SHAN TSUTSUI LT. GOVERNOR





STATE OF HAWAII DEPARTMENT OF TAXATION P.O. BOX 259 HONOLULU, HAWAII 96809 PHONE NO: (808) 587-1540 FAX NO: (808) 587-1560

To: The Honorable Angus L.K. McKelvey, Chair and Members of the House Committee on Consumer Protection & Commerce

Date:Wednesday, February 4, 2015Time:2:45 P.M.Place:Conference Room 325, State Capitol

From: Maria E. Zielinski, Director Department of Taxation

Re: H.B. 349, Relating to Electronic Smoking Devices

The Department of Taxation (Department) offers the following comments on H.B. 349 for your consideration.

H.B. 349, among other things, amends the Cigarette and Tobacco Tax Law by amending the definition of "cigarette" to include electronic smoking devices and their nicotine refills.

The Department defers to the Department of Health with respect to the effect taxing such devices would have on the State's health and wellness. The Department also defers to the Department of Health with respect to what amounts constitute suitable fees for the privilege of operating in the state as a tobacco retailer or wholesaler.

Under current law and regulations, cigarettes are taxed through the use of cigarette tax stamps. Stamps are purchased by sellers and affixed to the bottom of each pack of cigarettes. Thus, each stamp is worth the equivalent of the tax on 20 cigarettes.

Because electronic smoking devices and their nicotine refills are not packaged and sold in a largely uniform manner the way cigarettes are, the Department recommends a different approach for taxing such items. For instance, all tobacco products except cigarettes and large cigars are taxed at 70% of the wholesale price. Imposing the tax as a percentage of the wholesale price of such items would be easier to enforce and easier for taxpayers to comply with.

Thank you for the opportunity to provide comments.

From:	mailinglist@capitol.hawaii.gov
Sent:	Tuesday, February 03, 2015 1:52 PM
То:	CPCtestimony
Cc:	tobacco2@doh.hawaii.gov
Subject:	*Submitted testimony for HB349 on Feb 4, 2015 14:45PM*

<u>HB349</u>

Submitted on: 2/3/2015 Testimony for CPC on Feb 4, 2015 14:45PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Tina Vidinha	DOH	Support	Yes

Comments:

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.



American Cancer Society Cancer Action Network 2370 Nu`uanu Avenue Honolulu, Hawai`i 96817 808.432.9149 www.acscan.org

February 3, 2015

Representative Angus McKelvey, Chair Representative Justin Woodson, Vice Chair Members of the House Committee on Consumer Protection and Commerce

Public Hearing: February 4, 2:45 pm

HB 585 - RELATING TO THE REGULATION OF ELECTRONIC SMOKING DEVICES.

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

Thank you for the opportunity to provide testimony in support of HB 349, which amends several statues to include electronic smoking devices into the definition of cigarettes of those respective provisions.

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.

Electronic smoking devices are often designed to look like cigarettes, right down to the glowing tip. When the user puffs on it, the system delivers an aerosol that is inhaled. A growing number of studies have examined the contents of electronic smoking device aerosol. Unlike a vapor, an aerosol contains fine particles of liquid, solid, or both. Propylene glycol, nicotine, and flavorings were most commonly found in electronic smoking device aerosol. Other studies have found the aerosol to contain heavy metals, volatile organic compounds and tobacco-specific nitrosamines, among other potentially harmful chemicals. The electronic smoking device is often marketed as a way for a smoker to get nicotine in places where smoking is not allowed.

While the health effects of electronic smoking devices are currently under study, there are still serious questions about the safety of inhaling the substances in an electronic smoking device aerosol. Studies have shown that the use of electronic smoking devices can cause short-term lung changes and irritations, while the long-term health effects are unknown. Both exposure to and health effects of secondhand aerosol from electronic

smoking devices require further research, but preliminary studies indicate nonusers can be exposed to the same potentially harmful chemicals as users, including nicotine, ultrafine particles and volatile organic compounds. This exposure could be especially problematic for vulnerable populations such as children, pregnant women, and people with heart disease depending on the level of exposure.

Since the introduction of electronic smoking devices to the U.S. market, the marketing and use of these products have significantly increased. A U.S. Centers for Disease Control survey published in 2013 showed that electronic smoking device usage in middle school and high school students doubled between 2011 and 2012, increasing from 3.3 to 6.8 percent.

While electronic smoking device manufacturers may claim the ingredients are just "water vapor" or "safe," without federal regulation there is no sure way for electronic smoking device users to know what they are consuming. Nor is there any way of knowing what nonusers are exposed to and the extent of the risk to their health. Additionally, there are hundreds of types of electronic smoking devices on the market today and the products vary considerably by ingredients, and quality control and assurance. Prohibiting the use of electronic smoking devices in workplaces, restaurants, and bars can protect the public health by preventing nonusers from being exposed to nicotine and other potentially harmful chemicals in these products.

We support including electronic smoking devices into 328J, HRS, which is Hawaii's smoke-free workplace chapter, and also restrictions on the sale and distribution at certain places such as vending machines and lunchwagons.

We recommend the following definition for electronic smoking devices to include all types of electronic smoking device products:

"Electronic Smoking Device" means any product containing or delivering nicotine or any other substance intended for human consumption that can be used by a person to simulate smoking through inhalation of vapor or aerosol from the product. The term includes any such device, whether manufactured, distributed, marketed, or sold as an e-cigarette, e-cigar, e-pipe, e-hookah, or vape pen, or under any other product name or descriptor.

We take no position as to the other provisions of the measure and defer to the State Fire Council and the Attorney General over application of those provisions.

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



HB 349, Relating to Electronic Smoking Devices House Committee on Consumer Protection and Commerce Hearing—February 4, 2015 at 2:45 PM

Dear Chairman McKelvey and Members of the House Committee on Consumer Protection and Commerce:

My name is Paula Yoshioka and I am a Senior Vice President at The Queen's Health Systems. I would like to take this opportunity to provide our support for HB 349, relating to electronic smoking devices.

As an organization, we believe that the use of tobacco and nicotine products can result in the degradation of community health. We support efforts to prevent tobacco use and to promote smoking cessation. The intent of this bill is consistent with that mission. Because of the benefits to our state's community health, I would ask for your support of this legislation.

Thank you for your time and consideration of this matter.

The mission of The Queen's Health Systems is to fulfill the intent of Queen Emma and King Kamehameha IV to provide in perpetuity quality health care services to improve the well-being of Native Hawaiians and all of the people of Hawai'i.



- To: The Honorable Angus L.K. McKelvey, Chair, Committee on Consumer Protection & Commerce The Honorable Justin H. Woodson, Vice Chair, Committee on Consumer Protection & Commerce Members, House Committee on Consumer Protection & Commerce
 From: Jessica Yamauchi, Executive Director
 Date: February 3, 2015
- Hrg: House Committee on Consumer Protection & Commerce; Wednesday, February 4, 2015 at 2:45 p.m. in Rm 325

Re: Support intent for HB 349, Relating to Electronic Smoking Devices

Thank you for the opportunity to offer testimony in **support of** House Bill 349, which regulates electronic smoking devices (ESDs).

The Coalition for a Tobacco Free Hawaii (Coalition) is a program under the Hawai'i 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.

The Coalition supports the intent of HB 349.

The Coalition supports the intent of HB 349 and appreciates the comprehensive approach to regulate ESDs, however we have concerns about defining ESDs as cigarettes. The Coalition recommends revising the definitions for ESD in 709-908 HRS and "smoke" or "smoking" in 328J-1 which has been approved by the State Attorney General for consistency in legislation to read:

An ESD is "any electronic product that can be used to aerosolize and deliver nicotine or other substances to the person inhaling from the device, including but not limited to an electronic cigarette, electronic cigar, electronic cigarillo, or electronic pipe, hookah pipe, or hookah pen, and any cartridge or other component of the device or related product, whether or not sold separately."

"Smoke" or "smoking" means "inhaling, exhaling, burning, or carrying any lighted or heated tobacco product or plant product intended for inhalation in any manner or in any form. "smoking" includes the use of an electronic smoking device."

The Coalition supports Section 3, including ESDs in Hawai`i State smoke-free air laws, which will provide for further consistency and protections of our residents and visitors.

HB 349 amends 328J and adds important definitions of the law, which are critical to allowing consistency among all of Hawai'i State smoking laws. ESDs, often referred to as e-cigarettes,



heat and vaporize a solution that typically contains nicotine, and are often designed to mimic the look and feel of a real cigarette.¹

Currently ESDs are not regulated at any level (federal or state); therefore, all emissions and chemicals released in exhalation are also unregulated. ESDs do not emit only "harmless water vapor" as claimed by the industry. "Secondhand aerosol (incorrectly called vapor by the industry) from ESDs contains nicotine, ultrafine particles and levels of toxins."² It is vital that we protect everyone from the dangers of secondhand aerosol. According to Dr. Stanton Glantz, Director for the Center for Tobacco Control Research and Education at the University of California, San Francisco, "If you are around somebody who is using e-cigarettes, you are breathing an aerosol of exhaled nicotine, ultra-fine particles, volatile organic compounds, and other toxins."³ The World Health Organization (WHO) recommends that "legal steps should be taken to end use of e-cigarettes indoors in public and work places. Evidence suggest that exhaled e-cigarette aerosol increases the background air level of some toxicants, nicotine and particles."⁴

The Coalition is concerned about e-cigarettes for several reasons, including secondhand aerosol, dual usage, and youth usage. Emerging research shows dual use where cigarette users switch to ESDs in locations they are not permitted to smoke.⁵ Allowing the use of ESDs in locations where smoking is prohibited is problematic as ESD use puts innocent bystanders around the ESD user who breathe ESD aerosol at risk for illness, creates distractions in the workplace, threatens the social norm, and undercuts years of progress by tobacco control groups.

Restricting ESD use is a growing trend across the U.S. More than 225 municipalities and three states restrict the use of ESDs in smoke-free environments including New York City, Los Angeles, Long Beach, San Diego, and Boston.

The Coalition is also extremely concerned about the rising trend of youth use. In Hawai`i, high school tobacco use rate has continued to drop over the last decade from 24.5% in 2000 to 8.7% in 2011, however the use of e-cigarettes is on the rise.⁶ Youth usage of ESDs is at an alarming rate especially in the state of Hawai`i where teen use is twice as high as the national average. According to the Hawai`i Youth Tobacco Survey (2013) youth usage (at least once in the past 30 days) tripled (18%) among high school students and quadrupled (8%) among middle school students. The Centers for Disease Control and Prevention reports more than a quarter-million youth who had never smoked a cigarette used e-cigarettes in 2013.

¹ Americans for Nonsmokers' Rights, "Electronic Smoking Devices (ESDs) and Smokefree Laws", available at www.no-smoke.org/eigs.html.

² Americans for Nonsmokers' Rights, "Electronic Smoking Devices and Secondhand Aerosol", available at www.no-smoke.org/pdf/ecigarette-secondhand-aerosol.pdf.

³ Ibid

⁴ Noncommunicable diseases and mental health: Background on WHO report on regulation of e-cigarettes and similar products." Available at: http://www.who.int/nmh/events/2014/backgrounder-e-cigarettes/en

⁵ Centers for Disease Control and Prevention (CDC). Notes from the field: electronic cigarette use among middle and high school students -- United States, 2011-2012. MMWR Morb Mortal Wkly Rep. 2013;62:729-730. Available at <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm?s_cid=mm6235a6_w</u>

⁶ The Hawaii Health Data Warehouse, State of Hawaii, Hawaii School Health Survey, Youth Tobacco Survey Module. Available at:

http://www.hhdw.org/cms/uploads/Data%20Source_%20YTS/YTS_Prevalence_IND_00001.pdf. 850 Richards Street, Suite 201• Honolulu, HI 96813 • (808) 591-6508 • www.tobaccofreehawaii.org



ESDs have not been regulated by the FDA and are not an FDA approved cessation device. In a synopsis of the WHO report, they concluded that "there was currently insufficient evidence to conclude that e-cigarettes help users quit smoking or not. Therefore, WHO currently recommends that smokers should first be encouraged to quit smoking and nicotine addiction by using a combination of already-approved treatments."⁷ There is no way for users to know how much nicotine or other potentially harmful chemicals they are inhaling because ESDs are not FDA regulated.

The Coalition also supports Section 5 of HB 349.

The Coalition also supports section five of HB 349, which would include ESDs in Section 328J-17. This section makes it unlawful to distribute sample cigarette or tobacco products, cigarette or tobacco promotional materials, and coupons redeemable for cigarette or tobacco products or promotional materials. This would also apply to ESDs.

According to Dr. Stan Glantz in response to the FDA proposed rule: "The meaningful action of e-cigarettes will remain at the state and local level, especially including them in clean indoor air laws (I hope that the state and local policy makers do not swallow the inevitable [sic] arguments that they don't need anything because the FDA is taking care of it.)⁸ In Hawai`i, the State has made some movement towards protecting employees, first prohibiting the use in all Department of Health facilities, then by extending it to all buildings under Department of Accounting and General Services. In December, Hawai`i County Council passed a bill that includes ESDs in all their smoke-free ordinances.

Hawai'i needs to join the more than 225 municipalities and three states that restrict the use of ESDs where smoking is currently prohibited in an effort to protect our residents and visitors. We respectfully ask you to pass this measure to ensure the safety of everyone. Thank you for the opportunity to testify on this matter.

Respectfully,

Tamauch

Jessica Yamauchi, MA Executive Director

⁷ Noncommunicable diseases and mental health: Background on WHO report on regulation of e-cigarettes and similar products." Available at: http://www.who.int/nmh/events/2014/backgrounder-e-cigarettes/en

⁸ Stan Glantz, "First reaction to e-cigarette deeming (based on press reports): FDA leaves ecigarette marketing unscathed."

⁸⁵⁰ Richards Street, Suite 201• Honolulu, HI 96813 • (808) 591-6508 • www.tobaccofreehawaii.org



Hearing on 1-30-15

Testimony in Strong Opposition to House Bill 349

Dear House CPC,

The <u>Hawaii Smokers Alliance STRONGLY OPPOSES HB 349</u> relating to attacks on constituents and visitors that enjoy e-cigarette. These products have NOT been found to be harmful by any credible independent research. Therefore HB-349 is unreasonable.

A large number of anti-e-cigarette bills are currently being pushed at the legislature and city council, many states on the mainland, and overseas. As the old saying goes, if you want to find out the truth about something – follow the money.

At first it was a little surprising to see the anti-smoking lobby oppose these products that are a safe alternative to tobacco products and more shocking still to see the anti-smoking lobby opposing a product that has helped so many quit smoking tobacco.

Dr. Carmona, the Former Surgeon General from 2002-2006 recently made this statement. "I believe that it is essential that we provide adult smokers with high-quality, innovative alternatives to traditional cigarettes. The current data indicate that electronic cigarettes may have a very meaningful harm reduction potential, and NJOY [e-cigarettes] is committed to the further development of the science in this area. I look forward to working with NJOY in this important capacity."

However all is not well for giant pharmaceutical companies such as GSK/Johnson and Johnson, Pfizer and so on. Their expensive, unenjoyable, and sometimes dangerous NRT products are getting hit hard in sales by e-cigarettes. Let us keep in mind that the lobbyist ring called "Tobacco Free Hawaii" lists Pfizer as a "Major Funder" for their group. Other groups such as the American Lung Association and Heart Association also receive big bucks from Pharma. Most of the rest came from the settlement and from tax payers via the health dept. Pfizer is the manufacturer of Chantix, which carries a "Black Box Warning" due to significant dangers being found.

"Sophie Ragot, marketing manager at Glaxo Smith Klein laboratories [which markets J&J NRT products] confirms the latest figures, and adds that the situation of the NRT (nicotine replacement therapy) market in the last quarter alone is even worse. She claims sales in this time

frame have dropped by 17% in general and 35% in the case of nicotine patches. The situation is very similar in other European countries as well, and I'm sure NRT sales in the US aren't what they used to be either." <u>http://vaperanks.com/how-e-cigarettes-are-killing-the-nicotine-patch-market-in-europe/</u>

Take for example this article pinning down what's going on from the **Oklahoma Constitution** newspaper.

"The funds that our state receives each year from Tobacco Master Settlement Agreement is invested and managed by Tobacco Settlement Endowment Trust or TSET. So far, the tobacco Master Settlement Agreement has provided \$1.04 billion in payouts to Oklahoma and 75% of those funds go directly to TSET.

TSET uses the profits from its investments of MSA money to fund a range of endeavors including the Oklahoma Tobacco Helpline. According to a 2006 Tobacco Cessation Leadership Network document featuring the tobacco control accomplishments of TSET, the purpose for integrating the anti-tobacco policies (higher taxation, public prohibitions and insurance coverage for pharmaceutical cessation products) with smoking cessation service is to increase demands for these services and to create new demand for them. According to TSET, Oklahoma has systematically integrated its anti-smoking policies with tobacco cessation promotion. TSET also funds the Oklahoma Insurance Department, Oklahoma Hospital Association, Oklahoma Dept. of Mental Health and Substance Abuse, and Oklahoma Healthcare Authority."

"The smoking cessation drug market has been a lucrative one for the pharmaceutical companies, but the popularity of electronic cigarettes has them worried. Already in England, electronic cigarettes have surpassed conventional cessation product sales. I could write a book on the pervasive pharmaceutical influence present throughout our state's public health system, but it's not necessary because you can see it plain enough in our state and local anti-tobacco policies. However, if you'd like to further investigate their role in Oklahoma health policy, start with the Oklahoma Turning Point Initiative and the Robert Wood Johnson Foundation. The Robert Wood Johnson Foundation is one of Johnson & Johnson's largest shareholders. Johnson & Johnson just happens to own or manufacture a variety of pharmaceutical drugs including some of the very same smoking cessation products promoted by the state through the Oklahoma Tobacco Helpline."

http://www.oklahomaconstitution.com/ns.php?nid=534&commentary=1

From Bloomberg News:

"<u>GlaxoSmithKline Plc (GSK)</u> is pushing for more stringent regulation of electronic cigarettes, which compete with its <u>Nicorette</u> gum and other smoking cessation products, according to e-mails from a company executive."

<u>http://webcache.googleusercontent.com/search?q=cache:wYLRdF1XHOgJ:www.bloomberg.co</u> <u>m/news/2014-02-19/glaxo-memo-shows-drug-industry-lobbying-on-e-</u> <u>cigarettes.html+&cd=1&hl=en&ct=clnk&gl=us</u>

From Rueters:

"There are more than 2,000 papers on e-cigarettes in the scholarly journals covered by the Web of Science, a database. Of those in the highest impact journals, most have been funded by public bodies. Only a few contain original research; methodological problems or potential bias are common, scientists have found.

Last month, in an attempt to clear matters up, Bullen and other scientists in Britain and New Zealand published their assessment of the most impartial studies. Known as a Cochrane Review - a study of the best science on a subject - it aimed to see if e-cigs can help people stop smoking.

The review concluded that e-cigs may help smokers quit, and that there is little sign that they hurt users.

But it found the evidence thin and data poor. Of almost 600 studies analyzed, only 13 published papers were up to the Cochrane standard. Just two were randomized controlled trials, the most rigorous test.

Big Pharma is not helping. The pharmaceutical industry has backed efforts to restrict ecigarettes and is not sponsoring a single current e-cigarette trial in the U.S. National Institutes of Health database.

For drugs firms, smoking cessation is a small business, generating \$2.4 billion in sales in 2013, according to Euromonitor. That's just a fraction of the \$206 billion the industry generated in global consumer health products."

I won't call billions of dollars small.

http://www.reuters.com/article/2015/01/22/us-health-ecigarettes-research-insightidUSKBN0KV11J20150122

And From the Washington Examiner: Nov 19th, 2013.

"E-cigarette manufacturers, of course, lobbied like crazy to block the proposal, and it seems they won. But the drugmakers fought for stricter regulations, for obvious reasons: E-cigarettes compete with prescription drugs that are supposed to help people stop smoking. *GlaxoSmithKline sells Nicorette gum and Johnson & Johnson manufactures nicotine patches. The New York Times reported these companies helped lead "strong opposition" to e-cigarettes.*

In the U.S., the Food and Drug Administration is about to announce new proposed rules on ecigarettes. Big Pharma's shadow hangs over the rule-making."



https://www.google.com/search+pharmaceutical+companies+behind+e-cigarette+bans

This graph in millions of Euros shows the point where e-cigarette sales overtook NRT sales in France. Clearly the big pharma companies are pushing the anti-smoking groups they fund to crack down on the e-cigarette competition using legislation. Clearly this bill is an abuse of the free market system and the State legislative process.

Without a doubt, e-cigarettes are being targeted for taxes and bans to destroy the competition for alternates to tobacco smoking. As this bill is currently written, it is now plainly obvious that the only tobacco alternates to tobacco that the drug companies want on the market is their products. Furthermore the "non-profit" groups promoting a ban are themselves filling their pockets with drug company dollars.



Sincerely,

Michael Zehner, Co-chair of the Hawaii Smokers Alliance.

808-952-0275. Hawaiismokersalliance.net

TAXBILLSERVICE

126 Queen Street, Suite 304

TAX FOUNDATION OF HAWAII

Honolulu, Hawaii 96813 Tel. 536-4587

SUBJECT: TOBACCO, Electronic smoking devices

BILL NUMBER: HB 349

INTRODUCED BY: Nishimoto, Belatti and Luke

BRIEF SUMMARY: Amends HRS section 245-1 to amend the definition of "cigarette" to mean an electronic smoking device as defined in HRS section 709-908.

Makes other nontax amendments to provide that electronic smoking devices shall be subject to the antismoking laws and the laws regulating the sale, distribution, or display of such devices similarly to cigarettes and other tobacco products.

EFFECTIVE DATE: July 1, 2015

STAFF COMMENTS: The proposed measure would amend the definition of "cigarette" to include "electronic smoking devices" thereby making them subject to the tobacco tax. While traditional cigarettes have been proven to be a health hazard, electronic smoking devices have appeared on the market in 2004. Even though such devices contain nicotine, they do not produce other hazardous substances associated with a traditional cigarette.

Given the fact that there is no tobacco being consumed with these electronic smoking devices, it is questionable why this particular product should be placed under the tobacco tax. While it may be a substitute for a tobacco product, so are other products like nicotine gum. How should these latter products be taxed, if at all? As noted many times before, if the health department believes that products such as cigarettes, chewing tobacco, and other forms of tobacco consumption are bad for the community's health, then those products should be banned altogether. Apparently, lawmakers do not want to give up the revenues they reap from the heavy taxes imposed on these products.

Digested 2/3/15

From:	mailinglist@capitol.hawaii.gov
Sent:	Thursday, January 29, 2015 8:22 PM
То:	CPCtestimony
Cc:	joyamarshall0416@gmail.com
Subject:	Submitted testimony for HB349 on Feb 4, 2015 14:45PM

<u>HB349</u>

Submitted on: 1/29/2015 Testimony for CPC on Feb 4, 2015 14:45PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing	
Joy Marshall	Individual	Support	No	

Comments: Certinaly there are so many questions that arise when one considers the vaping devices. One, that sends up a red flag is that actual concentrated nicotine is being used ,and nicotine being one of the most addictive substances in use today is a very dangerous and addictive drug Two, just the use of these unlicensed and unregulated devices is a redflag and as some early studies reveal, at high heat produce dangerous additional chemicals. And last of all, they seem to be very popular with our youngest citizens, and I would consider them "Gateway drug/devices" Joy Marshall, RN

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.

From:	mailinglist@capitol.hawaii.gov
Sent:	Monday, February 02, 2015 7:18 AM
То:	CPCtestimony
Cc:	starjenchan@gmail.com
Subject:	*Submitted testimony for HB349 on Feb 4, 2015 14:45PM*

<u>HB349</u>

Submitted on: 2/2/2015 Testimony for CPC on Feb 4, 2015 14:45PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing	
Jenny Chan	Individual	Oppose	No	

Comments:

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From:	mailinglist@capitol.hawaii.gov
Sent:	Monday, February 02, 2015 8:13 AM
То:	CPCtestimony
Cc:	antonchris10@gmail.com
Subject:	*Submitted testimony for HB349 on Feb 4, 2015 14:45PM*

<u>HB349</u>

Submitted on: 2/2/2015 Testimony for CPC on Feb 4, 2015 14:45PM in Conference Room 325

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

Comments:

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From:	mailinglist@capitol.hawaii.gov
Sent:	Monday, February 02, 2015 11:47 AM
То:	CPCtestimony
Cc:	mikenakas@hotmail.com
Subject:	*Submitted testimony for HB349 on Feb 4, 2015 14:45PM*

<u>HB349</u>

Submitted on: 2/2/2015 Testimony for CPC on Feb 4, 2015 14:45PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Michael S. Nakasone	Individual	Oppose	No

Comments:

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From:	mailinglist@capitol.hawaii.gov
Sent:	Monday, February 02, 2015 12:47 PM
То:	CPCtestimony
Cc:	808aprilpacheco@gmail.com
Subject:	Submitted testimony for HB349 on Feb 4, 2015 14:45PM

<u>HB349</u>

Submitted on: 2/2/2015 Testimony for CPC on Feb 4, 2015 14:45PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing	
April Pacheco	Individual	Oppose	No	

Comments: Vaping products help people quit smoking. It makes so sense to attack these product with bill 349.

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From:	mailinglist@capitol.hawaii.gov
Sent:	Monday, February 02, 2015 1:30 PM
То:	CPCtestimony
Cc:	ryan.oswald@aol.com
Subject:	*Submitted testimony for HB349 on Feb 4, 2015 14:45PM*

<u>HB349</u>

Submitted on: 2/2/2015 Testimony for CPC on Feb 4, 2015 14:45PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing	
Ryan Oswald	Individual	Oppose	No	

Comments:

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From:	mailinglist@capitol.hawaii.gov
Sent:	Tuesday, February 03, 2015 8:14 AM
То:	CPCtestimony
Cc:	chevyriderhhh@gmail.com
Subject:	Submitted testimony for HB349 on Feb 4, 2015 14:45PM

<u>HB349</u>

Submitted on: 2/3/2015 Testimony for CPC on Feb 4, 2015 14:45PM in Conference Room 325

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

Comments: The government needs to stay out of our lives more not less.

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From:	mailinglist@capitol.hawaii.gov
Sent:	Tuesday, February 03, 2015 9:25 AM
То:	CPCtestimony
Cc:	dustinandrewsoahu@gmail.com
Subject:	Submitted testimony for HB349 on Feb 4, 2015 14:45PM

<u>HB349</u>

Submitted on: 2/3/2015 Testimony for CPC on Feb 4, 2015 14:45PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing	
Dustin Andrews	Individual	Oppose	No	

Comments: This bill is total bullshit.

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.

February 2, 2015

To: Representative Angus L.K. McKelvey, Chair Representative Justin H. Woodson, Vice Chair Representatives of the Committee on Consumer Protection and Commerce

From: Jacquelyne Howard

Subject: Support of House Bill 349, Electronic Smoking Devices

Aloha! My name is Jacquelyne Howard, and I am currently a senior at Kalaheo High School in Kailua. I strongly believe in HB 349, and would like to ask for your support. As it stands at the current time, Electronic Cigarettes are not being regulated as Tobacco Products. Electronic Cigarettes need to be regulated in order to protect and prevent minors due to lack of sufficient data supporting that e-cigarettes are "safe." The most common concern being nicotine is the main factor e-cigarettes need to be regulated. The American Journal of Preventive Medicine released a study of 2,136 current and former smokers. The study found that former smokers were nearly three times as likely to be regular users of e-cigarettes as current every day smokers, a finding that suggests that smokers often use e-cigarettes to stop smoking. Moreover, rather than helping smokers quit, they simply lead smokers to use both cigarettes and e-cigarettes.

Therefore, Electronic Cigarettes are not necessarily for preventative use but rather a new form of the same life threatening substance, nicotine. There's no evidence whether e-cigarettes pose more or less risk of cancer than traditional cigarettes. Although, a study found some electronic cigarette cartridges contained diethylene glycol, a toxic chemical commonly used in antifreeze. The new concoctions of chemicals may turn out to be worse than the tobacco products with further research.

A 2014 study in England published in the medical journal Addiction surveyed 6,000 smokers who tried to quit. Among the respondents that had used e-cigarettes in their most recent quit attempt, 20 percent had successfully broken their tobacco habit. Although the tobacco habit was cut, the true addiction is nicotine; therefore the nicotine is what needs to be controlled. Whether or not Electronic Cigarettes are grouped in with tobacco products or not the harmful substance, nicotine, will be controlled and regulated.

Thank you for your time and consideration, and I truly hope that you will support House Bill 349.

I am submitting personal testimony on HB 349 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 HB 349 "regulates electronic smoking devices as cigarettes for purposes such as cigarette and tobacco taxes, smoking restrictions, tobacco products reporting, and tobacco liability."

I support this legislation because our research indicates that use of electronic smoking devices (hereafter, e-cigarettes) is quite prevalent among adolescents in Hawaii. Our most recent publication 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 use is consistent with studies conducted with adolescents in other areas of the US. In fact, it is considerably higher than what is found in most current studies. Moreover, our study showed that 12% of Hawaii high school students used both e-cigarettes and cigarettes. These findings indicate that e-cigarettes are regarded as acceptable to use by adolescents. However, using e-cigarettes in most instances exposes adolescents to nicotine, which is a highly addictive substance. Moreover, several recent research studies have shown that using e-cigarettes increases adolescents susceptibility to smoking tobacco cigarettes, a known risk factor for lung cancer and heart disease.

Because of the evidence that e-cigarettes are regarded by adolescents as acceptable to use, and the evidence that this may increase risk for smoking, I think action is needed to prevent e-cigarette use by adolescents. This can be done by placing restrictions on adolescents ability to obtain e-cigarettes and by restricting use of e-cigarettes in places where cigarette smoking is currently banned. HB 349 would help to achieve this goal. **I support HB349** for these reasons.

Thomas A. Wills Interim Director, Cancer Prevention and Control Program University of Hawaii Cancer Center 701 Ilalo Street Honolulu, HI 96813

tel (808) 441-7708



Legislative Testimony



Written Testimony Presented Before the House Committee on Consumer Protection and Commerce February 4, 2015 at 2:45 pm By Robert Bley-Vroman, Chancellor and Jerris Hedges, MD, MS, MMM Dean, John A. Burns School of Medicine Interim Director, University of Hawai'i Cancer Center University of Hawai'i at Mānoa

HB 349 - RELATING TO ELECTRONIC SMOKING DEVICES

Chair McKelvey, Vice Chair Woodson, and Members of the Committee:

The University of Hawai'i Cancer Center supports this bill.

The UH Cancer Center is one of only 68 institutions in the U.S. that hold the prestigious National Cancer Institute (NCI) designation, and is the only NCI-designated center in the Pacific. The NCI designation provides greater access to federal funding and research opportunities. More importantly, it gives the people of Hawai'i and the Pacific region access to innovative and potentially life-saving clinical trials without the necessity of traveling to the mainland.

Our passion at the UH Cancer Center is to be a world leader in eliminating cancer through research, education and improved patient care. Because tobacco consumption is a leading preventable cause of cancer, we take all issues related to tobacco in Hawai'i very seriously. Whereas the UH Cancer Center always has supported strong tobacco control measures in Hawai'i, the recent emergence of electronic smoking devices presents new challenges for tobacco control and tobacco-related legislation.

The UH Cancer Center perspective on electronic smoking devices is informed by data recently obtained from Hawai'i adolescents and young adults who are participants in **original research conducted by our own faculty**. Research conducted in Hawai'i high schools by Thomas Wills, PhD, has confirmed that rates of e-cigarette use by Hawai'i adolescents are at least double the rate of e-cigarette use observed in studies of mainland adolescents. Furthermore, his study published in the peer-reviewed journal *Pediatrics* clarified a reason why e-cigarette use is growing nationally among teens, as his data suggest that e-cigarettes may be operating to recruit lower-risk adolescents to smoking. And recently Pallav Pokhrel, PhD, and Thaddeus Herzog, PhD, published on the topic of e-cigarettes and motivation to quit smoking. Drs. Pokhrel and Herzog also assessed differences between smokers who used e-cigarettes to quit versus those who used FDA-approved nicotine replacement therapy. Additionally, these

HB 349 – RELATING TO ELECTRONIC SMOKING DEVICES February 4, 2015 Page 2 of 2

researchers have published on the effects of e-cigarette marketing on harm perceptions, as well as e-cigarette use expectancies and their impact on e-cigarette use among young adults.

This research is vital to gaining an evidence-based understanding of what drives acceptance of this emerging technology, what users believe regarding its safety, and what the consequences are for adolescents, whose brains are particularly susceptible to nicotine.

Despite the complexities of the larger debate regarding electronic smoking devices, we believe this bill represents reasonable legislation that balances the rights of adults to use electronic smoking devices in appropriate venues while restricting use in public places where conventional cigarettes are banned. We also support the prohibition of the sale of electronic smoking devices to minors, and we support the provisions in this bill that enhance the ability of authorities to enforce these laws.

As scientific research on electronic smoking devices progresses, we will have a stronger basis to adjust laws according to evidence. At the present time, however, caution is warranted. As others have noted, the FDA currently does not regulate e-cigarettes, and thus the consumer has no assurances regarding e-cigarette ingredients. Further, because of the novelty of e-cigarettes, the long term effects of using these devices are unknown. A further concern, not often discussed, is the potential for electronic smoking devices to be used as drug delivery devices for substances other than nicotine.

We respectfully urge you to pass this bill.





February 3, 2015

- To: The Honorable Angus L.K. McKelvey, Chair The Honorable Justin H. Woodson, Vice Chair Members, House Committee on Commerce and Consumer Protection
- From: Cory Smith, VOLCANO Fine Electronic Cigarettes[®] CEO and Owner

RE: HB349 – 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 HB349 for the following:

- Although vapor products contain NO tobacco, often times contain NO nicotine, and ultimately emit NO smoke, **HB349 aims to falsely classify all vapor products as "cigarettes" and deceptively redefines "smoking" to include the use of a vapor product**. This attempt to bring vapor products into the same regulatory framework as traditional tobacco cigarettes will have very dire unintended consequences and threatens to decimate the vapor industry in Hawaii.
- Although the FDA has stated its intention to regulate vapor products under the Tobacco Control Act of 2009, they still have not released a final rule due to the many nuances at play. Recently, leaders in the national House of Representatives went as far as to request changes by the Department of Health and Human Service to the Tobacco Control Act that would create special rules for vapor products due to their vast differences with traditional tobacco cigarettes. These leaders see the trouble with including vapor products in a regulatory framework that was never built with them in mind and we are wary that the same issue is being presented with this bill. http://www.churnmag.com/news/house-leaders-urge-fda-go-easy-ecigs/
- HB349 would create a framework that would allow the state to unfairly impose a tax on all components of a vapor product regardless of whether any part of the product actually contains nicotine. Even if an excise tax is warranted, which we believe it is not, the regulatory scheme proposed by the bill would ultimately drive up costs to a point that we would no longer



be able to compete with traditional tobacco. Some smokers are already hesitant to try electronic cigarettes due to the high start-up costs involved. Applying the same tax framework on vapor products that were established for cigarettes 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 vapor products may send some current users back to smoking tobacco cigarettes. In order to make cigarettes obsolete, vapor products and other harm reduction products should be embraced and allowed to fairly compete on the market with traditional tobacco cigarettes.

- Vapor products have not been demonstrated to have the detrimental effects of combustible tobacco products and thus should not be regulated under the same framework. In fact, Mitch Zeller, Director of the Center for Tobacco Products at the FDA recently stated:
 - "If a current smoker, otherwise unable or unwilling to quit, completely substituted all of the combusting cigarettes that they smoked with an electronic cigarette at the individual level, that person would probably be significantly reducing their risk." <u>http://thedianerehmshow.org/shows/20140121/newhealthriskscigarettesmoking/transcript</u>

It is our belief that this unjustified product classification 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 <u>nipfire@me.com</u>.

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

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

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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. © 2006 Elsevier B.V. All rights reserved.

Keywords: Tobacco; Nicotine; Harm reduction; Cigarette smoking; Policy

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

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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 longterm smokers will die as a direct result of diseases caused by their smoking, and half of those deaths will occur during

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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

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

Examples of western world smoke-free alternatives to cigarettes

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 shortterm 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 tobaccospecific 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 smokefree systems for delivering nicotine demolishes the claim that

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abstinence-only approaches to tobacco are rational publichealth 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 evidencebased 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

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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 publichealth 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 cessationonly 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 publichealth 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 healthrisk 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 evidencebased 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-

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

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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 overthe-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.

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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 realworld 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 selfselected, 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 realworld 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 selfreported 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 overthe-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 ownaccount 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 sociodemographic 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 (selfreported 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-thecounter (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

	E-cigarettes ($n = 464$)	NRT over-the-counter [§] $(n = 1922)$	No aid (n = 3477)	Р
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}	$10.9 \ (8.1)^{\rm fg}$	***
% (<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 [†]	$2.0 (1.5)^{\rm qr}$	$2.3 (1.5)^{qs}$	$1.6 (1.5)^{rs}$	***
% (<i>n</i>) Abrupt attempt (no gradual cutting down first)	50.4 (234) ^t	52.5 (1010) ^u	59.0 (2051) ^{tu}	***

Table 1 Associations between cl	haracteristics of the sample and use of	different quitting methods.
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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 ($P \ge 0.05$). §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.

Method of quitting	n	Mean (SD) strength of urges to smoke in smokers	п	Mean (SD) strength of urges to smoke in non-smokers	Mean difference (95% CI) in strength of urges to smoke
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 overthe-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

				(1) versus (2)	(1) versus (3)
				Model 1: OR (95% CI)	Model 1: OR (95% CI)
				Model 2: OR (95% CI)	Model 2: OR (95% CI)
		(2) NRT		Model 3: OR (95% CI)	Model 3: OR (95% CI)
	(1) e-Cigarettes	over-the-counter	(3) No aid	Model 4: OR (95% CI)	Model 4: OR (95% CI)
Full sample $(n = 5863)$					
% (n) Self-reported	20.0 (93/464)	10.1 (194/1922)	15.4 (535/3477)	2.23 (1.70-2.93)***	1.38 (1.08-1.76)*
non-smoking				1.88 (1.40-2.52)***	1.21 (0.92-1.58)
				1.63 (1.17-2.28)**	1.62 (1.19-2.19)**
				1.63 (1.17-2.27)**	1.61 (1.19-2.18)**
Subsample: quit attemp	ot started ≤26 wee	eks $(n = 3784)$			
% (<i>n</i>) Self-reported	20.3 (72/354)	11.0 (135/1222)	14.6 (323/2208)	2.06 (1.50-2.82)***	1.49 (1.12-1.98)**
non-smoking				1.80 (1.27-2.55)***	1.39 (1.01-1.90)*
c c				1.56 (1.06-2.29)*	1.88 (1.32-2.68)***
				-	-
Subsample: quit attemp	ot started >26 wee	eks $(n = 2079)$			
% (<i>n</i>) Self-reported	19.1 (21/110)	8.4 (59/700)	16.7 (212/1269)	2.56 (1.49-4.42)***	1.18 (0.72-1.94)
non-smoking	· · · · · ·	· · · · ·	· · · · · · · · · · · · · · · · · · ·	1.98 (1.11-3.53)**	0.91 (0.54–1.55)
U				1.64 (0.83-3.24)	1.10 (0.59-2.06)
				_	_

 Table 3 Associations between quitting method and abstinence.

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 overthe-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 quitting 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 crosssectional 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 selfreported 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

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final role in the study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the paper for publication. All researchers listed as authors are independent from the funders and all final decisions about the research were taken by the investigators and were unrestricted.

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.

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Study	Brand tested	Main findings
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.

Table 1: Laboratory studies of the components in and safety of electronic cigarettes^{5–17}

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 ,3,4-tris[(trimethylsilyl)oxy]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).

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Table 1 continu	ued	
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Study	Brand tested	Main findings
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.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.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 pyrrolidinyl, 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.

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 cigarettes ⁶	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

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

^aThe concentrations here represent nanograms (ng) of toxin detected in 1 ruyan 16-mg multidose 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'-nitrosonornicotine; 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

Study	Brand tested	Summary of findings	
Effect of an E-Cigarette on Cravings and Withdrawal, Acceptability and Nicotine Deliver: 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.	

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

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

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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.

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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

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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.

About the Authors

Zachary Cahn is a graduate student in the political science department at the University of California at Berkeley. His research focuses on the political determinants of substance control policies.

Michael Siegel is a professor of community health sciences at Boston University School of Public Health, where he has studied tobacco epidemiology and public policy and evaluated tobacco-related policies at national, state, and local levels.

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<u>HB349</u>

Submitted on: 2/3/2015 Testimony for CPC on Feb 4, 2015 14:45PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Kathy Kim	Individual	Oppose	No

Comments:

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<u>HB349</u>

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Submitted By	Organization	Testifier Position	Present at Hearing
PM Azinga	Individual	Support	Yes

Comments: Public Testimony forthcoming.

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<u>HB349</u>

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Submitted By	Organization	Testifier Position	Present at Hearing
Michelle Robinson	Individual	Oppose	No

Y P

Comments:

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<u>HB349</u>

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Submitted By	Organization	Testifier Position	Present at Hearing
Anthony Orozco	Individual	Oppose	No

Comments: Leave the e-cigs out of this bill please.

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February 2, 2015



To: Representative Angus L.K. McKelvey, Chair Representative Justin H. Woodson, Vice Chair Representatives of the Committee on Consumer Protection and Commerce

From: Kawika Cavanh

Subject: Against House Bill 349, Electronic Smoking Devices

Aloha! My name is Kawika Cavanh, and I am currently a senior at Kalaheo High School in Kailua. I strongly oppose HB 349, would like to ask for your support. The biggest danger from tobacco is the smoke, and e-cigarettes don't burn. Tests show the levels of dangerous chemicals they give off are a fraction of what you'd get from a real cigarette. The FDA claims that approved stop smoking products are safe, electronic cigarettes are not. Chantix and Zyban are known killers and now have a black box warning because each had over 100 deaths tagged to these brands. But the FDA does not want to take the products off the market.

Also, the FDA stated Tobacco-specific impurities, cotinine, anabasine, myosmine, and β nicotyrine were found in half of the cartridge samples tested. The impurities are specific to nicotine and are found in cosmetics, foods and all kinds of other products including the patch and gum that are FDA approved and deemed safe.

Ecigs are not medicines, as TVECA argued; yet, they are also not tobacco. Other associations, advocates and supporters are pushing for separate regulatory measures on ecigs; measures that will appropriately control the products without compromising their maximum potentials in benefiting the society.

Thank you for your time and consideration, and I truly hope that you will oppose House Bill 349.

From:	mailinglist@capitol.hawaii.gov	
Sent:	Wednesday, February 04, 2015 5:37 PM	
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Cc:	thirr33@gmail.com	
Subject:	Submitted testimony for HB349 on Feb 4, 2015 14:45PM	



<u>HB349</u>

Submitted on: 2/4/2015 Testimony for CPC on Feb 4, 2015 14:45PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Arvid Tadao Youngquist	Individual	Oppose	Yes

Comments: House CPC Committee Chair, Rep. Angus McKelvey Vice Chair, Justin H. Woodson Honorable CPS Committee Members I oppose HB 349 Relating to Electronic Smoking Devices introduced by Representatives: NISHIMOTO, BELATTI, & LUKE. The measure is by intent, meant well and in consideration of public in theaters and other public accommodations like TheBus, a certain degree or amount regulation might be warranted. But to treat the devices and its merchandizing as equivalent to cigarettes and tobacco might be premature until the studies on the effects of formaldehyde on lab animals can be "extrapolated" on how it applies to human subjects. There is an anecdotal example given to us after the meeting that back in April 2014 at a political parties periodic meeting, a leader of a Caucus Chair was smoking an electronic device. A former State Chair, leaders of the Caucus for Labor, PD-HI and other individuals from Districts were "sickened" from close as well as "distant" exposure to the vapors coming from the device. But, even if this example were true, it is important that all three committees exercise due diligence to assure that the claims made by "opponents" are based on science and not based totally on "blind faith". Thank you for this opportunity to provide late testimony in opposition. Mahal o, Arvid Tadao Youngquist Oahu Resident and Voter (Liliha, Downtown, Makiki, Kaimuki, Kalih, Kalihi Valley, Wahiawa, University, Wahiawa, and University)

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