DAVID Y. IGE
GOVERNOR OF HAWAII

VIRGINIA PRESSLER, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
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WRITTEN ONLY

Testimony in SUPPORT of SB1220, SD1
RELATING TO CHAPTER 245, HAWAII REVISED STATUTES

SENATOR JILL N. TOKUDA, CHAIR

SENATE COMMITTEE ON WAYS AND MEANS
Hearing Date: February 27, 2015 Room Number: 211

Fiscal Implications: None.

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

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

According to the Centers for Disease Control and Prevention, "increasing the price of tobacco products is the single most effective way to prevent initiation among nonsmokers and to reduce consumption."[1,2] The 2014 CDC Office on Smoking and Health document, "Best Practices for Comprehensive Tobacco Control Programs," reports that smoking and tobacco use

are the leading causes of preventable death and disease in Hawaii, claiming 1,200 lives each year and creating $526 million in annual health care costs.

Offered Amendments: No amendments are requested.

Thank you for the opportunity to testify.

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

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

DAVID Y. IGE
GOVERNOR

SHAN TSUTSUI
LT. GOVERNOR

MARIA E. ZIELINSKI
DIRECTOR OF TAXATION

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

To: The Honorable Jill N. Tokuda, Chair
and Members of the Senate Committee on Ways and Means

Date: Friday, February 27, 2015
Time: 1:00 P.M.
Place: Conference Room 211, State Capitol

From: Maria E. Zielinski, Director
Department of Taxation

Re: S.B. 1220, S.D. 1, Relating to Chapter 245, Hawaii Revised Statutes

The Department of Taxation (Department) provides the following comments on S.B. 1220, S.D. 1 for your consideration, and defers to the Department of Health regarding the effect taxing such products would have on the State's health and wellness.

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

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

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

Thank you for the opportunity to provide comments.

TAX FOUNDATION OF HAWAII

126 Queen Street, Suite 304 Honolulu, Hawaii 96813 Tel. 536-4587

SUBJECT: TOBACCO, Increase tax; imposition on nicotine

BILL NUMBER: SB 1220, SD-1

INTRODUCED BY: Senate Committee on Commerce and Consumer Protection

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

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

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

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

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

EFFECTIVE DATE: July 1, 2015

STAFF COMMENTS: Currently tobacco products, other than cigarettes and large cigars, are taxed at 70% of the wholesale price of the product. Under the bill, beginning on 1/1/16 tobacco products, other than cigarettes and large cigars, would be taxed at 80% of the wholesale value. The measure also amends the definition of tobacco products to include any product containing nicotine that does not contain any tobacco. If it is the intent of this measure to also tax e-cigarettes under the tobacco tax law, the definition should be revised because not all e-cigarettes contain nicotine.

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

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

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

Digested 2/26/15

UNIVERSITY OF HAWAIʻI SYSTEM
Legislative Testimony

Written Testimony Presented Before the
Senate Committee on Ways and Means
February 27, 2015 at 1:00 pm
By
Robert Bley-Vroman, Chancellor
and
Jerris Hedges, MD, MS, MMM
Dean, John A. Burns School of Medicine
Interim Director, University of Hawaiʻi Cancer Center
University of Hawaiʻi at Mānoa

SB 1220 SD1 – RELATING TO CHAPTER 245, HAWAII REVISED STATUTES

Chair Tokuda, Vice Chair Kouchi, and Members of the Committee:

The University of Hawaiʻi Cancer Center strongly 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 Hawaiʻi 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 Hawaiʻi very seriously. Whereas the UH Cancer Center always has supported strong tobacco control measures in Hawaiʻi, 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 Hawaiʻi adolescents and young adults who are participants in **original research conducted by our own faculty**. Research conducted in Hawaiʻi high schools by Thomas Wills, PhD, has confirmed that rates of e-cigarette use by Hawaiʻi 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

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.

SB1220
Submitted on: 2/26/2015
Testimony for WAM on Feb 27, 2015 13:00PM in Conference Room 211

Submitted By	Organization	Testifier Position	Present at Hearing
rhonda benigno	808 Smokes LLC	Oppose	No

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.

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

February 26, 2015

Senate Committee on Ways and Means
Senator Jill Tokuda, Chair
Senator Ron Kouchi, Vice Chair

Public Decision Making: February 27, 1:00 pm

SB 1220, SD1 – RELATING TO CHAPTER 245, HAWAII REVISED STATUTES

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

Thank you for the opportunity to provide written comments in support of SB 1220, SD1, which increases the tax on other tobacco products other than large cigars to 80% of the wholesale price, amends the definition of tobacco products, and also includes automatic excise tax increases on other tobacco products in conjunction with an increase in cigarette taxes.

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

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

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

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

- Nicotine addiction.

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

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

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Lung HelpLine
1-800- LUNG-USA
(586-4872)

Fighting for Air

February 26, 2015

AMERICAN LUNG ASSOCIATION. IN HAWAII

To: Sen. Jill N. Tokuda, Chair, Committee on Ways and Means
Sen. Ronald D. Kouchi, Vice Chair, Committee on Ways and Means
Members, Senate Committee on Ways and Means

Re: Strong Support for SB 1220 SD1, Relating to Chapter 245, Hawaii Revised Statutes

Hrg: February 27, 2015 at 1:00 PM in Room 211

Thank you for the opportunity to submit testimony in support of SB 1220 SD1. I serve as the Hawai`i director for the American Lung Association of the Mountain Pacific; our mission is to save lives by improving lung health and preventing lung disease. We support increasing the tax on other tobacco products (OTPs) to 80% to create parity between cigarettes and OTPs.

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

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

Kind regards,

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

COALITION FOR A TOBACCO-FREE HAWAI'I

To: The Honorable Jill N Tokuda, Chair, Committee on Ways and Means
The Honorable Ronald D. Kouchi, Vice Chair, Committee on Ways and Means
Members, Senate Committee on Ways and Means

From: Jessica Yamauchi, Executive Director
Date: February 26, 2015
Hrg: Senate Committee on Ways and Means; Fri., February 27, 2015 at 1:00 p.m. in Rm 211
Re: **Strong Support for SB 1220, SD1, Relating to Chapter 245, Hawaii Revised Statutes**

Thank you for the opportunity to offer testimony in **strong support of** SB 1220, SD1, which raises the taxes on other tobacco products to 80% of the wholesale price to achieve parity between cigarette taxes and other tobacco products (OTPs).

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

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

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

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

COALITION FOR A TOBACCO-FREE HAWAI'I

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

In a recent poll conducted by SMS for the Coalition, Hawaii residents overwhelmingly agree (89%) that it is important for the state to earmark some of the revenue from cigarette and tobacco taxes to fund tobacco prevention and quit smoking programs (currently $0 from cigarette and OTP taxes is earmarked for tobacco prevention and cessation). When the price of tobacco increases, more seek help to quit. We ask that you earmark a portion of these new funds to tobacco prevention and tobacco dependence treatment services.

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

Thank you for the opportunity to testify on this matter.

Jessica Yamauchi, M.A.
Executive Director

PC GAMERZ HAWAII
LAN CENTER ♦ VAPE LOUNGE ♦ COMPUTER SERVICES

99-082 Kauhale St, Suite #B1
Aiea, Hawaii 96701
(808) 486-0402
Devin@pcgamerzhawaii.com

February 25, 2015

To: WAM

From: Devin Wolery, PC Gamerz, Inc., Director of Operations

RE: SB1220 – Oppose.

Thank you for the opportunity to submit testimony.

PC Gamerz, is the only LAN center focused on eSports gaming in the state of Hawaii. We are also a Vape Lounge, operating as such for the last 6 years. We have had many customers that have switched from smoking cigarettes to using advanced vaporizer devices. We stand in Strong Opposition to the bills listed above for the following:

- The increase of 80% tax on whole sale is outrageous. And would make most eliquid bottles go from $18 retail for a 30ml bottle to $32 retail. Most of our customers can use a 30ml bottle over the course of 4-7 days. And many of them have multiple bottles on hand to change the flavor they are using. I personally carry 3-5 bottles of eliquid on me. To change the flavor depending on my mood.

- One of the main issues with this excessive bill is it would force people to buy 0mg nicotine eliquid. That would not be taxed. Then they would purchase FDA approved nicotine ONLINE and then add their own nicotine to their bottles. This is not only unsafe, but could have future problems.
  - The Nicotine that they would purchase is the same nicotine used in NRT products.
  - http://wizardlabs.us/index.php?route=product/product&product_id=80
  - Our consumers prefer to buy Eliquid products that are made in food grade or ISO certified labs. Eliq Cube is one of our highest quality e liquids. You can see their lab here http://www.youtube.com/watch?v=4WChdzYwKJ0

- Nicotine is addictive, yes. The reason Big tobacco add all the other chemicals to cigarettes is to increase the addictive nature of them. E cigarettes do not have those added chemicals and a new study has shown that e cigarettes are far less addictive than cigarettes and LESS than nicotine gum.
  - http://acsh.org/2015/01/new-study-shows-addictive-potency-e-cigs-far-less-cigarettes-less-nicotine-gum/
  - Nicotine does not cause cancer. http://www.nysmokefree.com/Subpage.aspx?P=40&P1=4030
  - The Tar, 4000+ chemicals and smoke created from combustion is what causes cancer from smoking cigarettes.
  - E-Cigarettes when used correctly have 90%~ less chemicals in them.

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- This increase would cause multiple hardships with current businesses in the state.
  - Because of the steep increase it would force many consumers to purchase online, thus reducing money staying in the state.
  - It would force businesses to close up shop due to the increased costs.
  - This would raise the unemployment rate on the island and create additional hardships for those programs.

- With this increase, it would force people to make their own eliquid. People can buy all of the ingredients except nicotine at Wal-mart, whole foods, down to earth, Kmart, Target and many other shops. As well as online through Amazon. There are only 3-4 total ingredients in E Liquid.
  - Propylene Glycol - http://www.amazon.com/Propylene-Glycol-Food-Grade-Quart/dp/B005PZBRUC/ref=sr_1_1?ie=UTF8&qid=1424918017&sr=8-1&keywords=propylene+glycol
  - Vegetable Glycerin - http://www.walmart.com/ip/Nature-39-s-Answer-Pure-Vegetable-Glycerin-Alcohol-Free-4-fl-oz/26967633
  - Flavoring - http://www.amazon.com/Capella-Flavor-Drops-Cheesecake-Concentrate/dp/B005FMA7WE/ref=sr_1_2?ie=UTF8&qid=1424919058&sr=8-2&keywords=capellas+flavor+drops
  - Nicotine can be purchased online from multiple vendors, all FDA approved.

- We do not want a black market created, This bill could very easily create a black market overnight. With people turning to craigslist, Facebook groups and reddit to distribute their e liquids. When most shops currently carry higher quality eliquid that is made in labs with quality control and child safe packaging.

- This bill seems to be basing it's focus on old products, that really only the big tobacco company's use.
  - Cigalikes, which cost $10-20 per unit and $10-20 per pack of cartridges.

- When the majority of the market is using open systems and eliquid that you purchase separately. Some examples of the retail cost of eliquid. If this bill passes it would basically double the price of everything below.
  - 10ml bottle - $8-10
  - 15ml bottle - $12-15
  - 30 ml bottle - $18-25
  - 60ml bottle - $33-40
  - 120ml bottle - $60-70

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- These products are already more expensive than standard tobacco products. They are already illegal to purchase for under 18. And nicotine does not cause cancer.

Please defer this bill for more discussion. Let the FDA come out with their ruling on the products before making decisions that can affect everyone. Please AUDIT the cancer research center, they are already getting a lot of money. Apparently they are not managing it correctly.

Thank you for your time and consideration. If you have any questions, please feel free to contact me.

Sincerely,

Devin Wolery

Director of Operations

www.PCGamerzhawaii.com

SB1220
Submitted on: 2/25/2015
Testimony for WAM on Feb 27, 2015 13:00PM in Conference Room 211

Submitted By	Organization	Testifier Position	Present at Hearing
Dorian De Witt	Vapor Etc.	Oppose	No

Comments: I oppose bill SB1220. The increase of 80% tax on whole sale is outrageous. And would make most eliquid bottles go from $18 retail for a 30ml bottle to $32 retail. This bill would put local businesses at a huge disadvantage and drive business out of state, along with discouraging the use of e cigarettes which are proven to be healthier than smoking and help quitting. We do not want a black market created, This bill could very easily create a black market overnight. With people turning to craigslist, Facebook groups and reddit to distribute their e liquids. When most shops currently carry higher quality eliquid that is made in labs with quality control and child safe packaging. These products are already more expensive than standard tobacco products. They are already illegal to purchase for under 18. And nicotine does not cause cancer. Please defer this bill for more discussion. Let the FDA come out with their ruling on the products before making decisions that can affect everyone. Please AUDIT the cancer research center, they are already getting a lot of money. Apparently they are not managing it correctly. Thank you for your time and consideration.

February 26, 2015

To: The Honorable Rosalyn H. Baker, Kidani, Ruderman, Wakai

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

RE: SB1220 – oppose.

Thank you for the opportunity to submit testimony.

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

- SB1220 states in its justification that products that contain nicotine have the same risk profile as all other tobacco products and thus should be taxed at the same rate which is an entirely baseless statement not rooted in science. There currently exists a growing body of evidence in support of harm reduction strategies and e-cigarettes that contain nicotine are leading the way in proving as a highly effective tool in helping smokers lower their risk and break their addiction to tobacco and nicotine altogether.

- SB1220 attempts to levy an 80% tax on any product that contains nicotine and yet exempts traditional NRT products that contain nicotine even though electronic cigarettes are being shown to be a much more effective tool for helping people quit smoking.

- The average cost for an industry standard bottle of e-liquid that contains nicotine is $13 and is already higher than the cost of a pack of cigarettes. When you factor in the average cost of a reusable starter kit, which can range anywhere from $45 to more than $300 for a premium device, and the accessories one must regularly purchase to keep their device in normal working order,

users are already paying a comparable or higher price than they would be if they were using a traditional tobacco product. Even most one-time use electronic cigarettes are priced comparably to a traditional pack of cigarettes and provide a user a comparable amount of puffs. Yet in many instances, users choose a much lower dose of nicotine than you would ever get from a cigarette and this bill does not make any distinction in that regard.

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

- SB 1220 would put Hawaii-based electronic cigarette companies at a competitive disadvantage in the national market for vapor products. In Hawaii, many customers of our brick and mortar locations will turn to the Internet if faced with a sudden price increase. Additionally, our wholesale and retail partners on the mainland will undoubtedly scoff at price hikes and will turn to suppliers in the 48 states that do not tax electronic cigarettes. This could force us to either move out of state, taking the jobs and revenue with us, or close the business altogether. This would mean a loss of both jobs and GET tax revenues.

- Over the years that we have been in business in the state, we have provided a product that tens of thousands of customers use every day to greatly reduce their tobacco use or quit smoking altogether. This has improved the lives of smokers and ex-smokers in this state. The removal of secondhand smoke has helped non-smokers as well and has cut down on the amount of butt discard in our community.

- VOLCANO Fine Electronic Cigarettes is currently one of the largest electronic cigarette suppliers in the mainland U.S. We are also the number one FedEx shipper in the State of Hawaii. We bring money into the local economy from the mainland and have provided a much-needed boost to Hawaii by hiring local employees. Throughout the recession we have grown our business and our taxable revenues every year.

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

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

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

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

RESEARCH REPORT doi:10.1111/add.12623

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

Jamie Brown[1,2], Emma Beard[1], Daniel Kotz[1,3], Susan Michie[2,4] & Robert West[1,4]

Cancer Research UK Health Behaviour Research Centre, University College London, London, UK,[1] Department of Clinical, Educational and Health Psychology, University College London, London, UK,[2] Department of Family Medicine, CAPHRI School for Public Health and Primary Care, Maastricht University Medical Centre, Maastricht, the Netherlands[3] and National Centre for Smoking Cessation and Training, London, UK[4]

ABSTRACT

Background and Aims Electronic cigarettes (e-cigarettes) are rapidly increasing in popularity. Two randomized controlled trials have suggested that e-cigarettes can aid

smoking cessation, but there are many factors that could influence their real-world effectiveness. This study aimed to assess, using an established methodology, the effectiveness of e-cigarettes when used to aid smoking cessation compared with nicotine replacement therapy (NRT) bought over- the-counter and with unaided quitting in the general population. **Design and Setting** A large cross-sectional survey of a representative sample of the English population. **Participants** The study included 5863 adults who had smoked within the previous 12 months and made at least one quit attempt during that period with either an e-cigarette only (n = 464), NRT bought over-the-counter only (n = 1922) or no aid in their most recent quit attempt (n = 3477). **Measurements** The primary outcome was self-reported abstinence up to the time of the survey, adjusted for key potential confounders including nicotine dependence. **Findings** E-cigarette users were more likely to report absti- nence 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 solu- tion 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, cru- cially two randomized controlled trials have suggested that e-cigarettes may aid smoking cessation [10,11]. However, there are many factors that influence real- world effectiveness, including the brand of e-cigarette, the way they are used and who chooses to use them [12]. Therefore, it is a challenge to establish probable contribu- tion 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 effective- ness of currently popular brands as chosen by the mil- lions of smokers across the world who are using them in an attempt to stop smoking [6–9].

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

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

e-cigarettes as a reported aid to cessation among the general population in England since July 2009 [30]. This programme has established a method of assessing real- world effectiveness of aids to cessation by comparing the success rates of smokers trying to quit with different methods and adjusting statistically for a wide range of factors that could bias the results, such as nicotine dependence [31]. The method has been able to detect effects of behavioural support and prescription medica- tions 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 observa- tion 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 con- tribution 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 rep- resentative samples of the population of adults in England conducted monthly between July 2009 and Feb- ruary 2014. To examine the comparative real-world effectiveness of e-cigarettes, the study compared the self- reported abstinence rates of smokers in the general popu- lation 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 sam- pling, 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 pre- ceding 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 fol- lowing: e-cigarettes; NRT bought over-the-counter; a pre- scription stop-smoking medication; or face-to-face behavioural support. We excluded those who used either e-cigarettes or NRT bought over-the-counter in combina- tion with one another, a prescription stop-smoking medi- cation or face-to-face behavioural support.

Measurement of effect: quitting method

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

Measurement of outcome: self-reported non-smoking

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

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

Measurement of potential confounders

We measured variables potentially associated with the different quitting methods and that may also have an effect on the outcome. These potential confounders were chosen a priori. The most important factor was nicotine dependence, for which we used two questions. First, time spent with urges to smoke was assessed by asking all respondents: 'How much of the time have you felt the urge to smoke in the past 24 hours? Not at all (coded 0), a little of the time (i), some of the time (ii), a lot of the time (iii), almost all of

the time (iv), all of the time (v)'. Sec- ondly, 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 ques- tion. 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 char- acteristics assessed were age, sex and social grade (dichotomized into two categories: ABC1, which includes managerial, professional and intermediate occupations; and C2DE, which includes small employers and own- account workers, lower supervisory and technical occu- pations, 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 quit- ting methods and potentially confounding socio- demographic and smoking history variables were assessed with χ^2 tests and one-way analyses of variance (ANOVA)s for categorical and continuous variables, respectively. Significant omnibus results were investi- gated 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 interven- tion 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 quit- ting, adjusting for the time since the quit attempt started.

In the analysis of the associations between quitting method and abstinence, we used a logistic regression model in which we regressed the outcome measure (self- reported non-smoking compared with smoking) on the effect measure (use of e-cigarettes compared with either NRT bought over-the-counter or no aid). The primary analysis was an adjusted model that included the poten- tial 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 analy- sis ('fully adjusted model'; model 4), we constructed a simple model including only the effect measure ('unad- justed 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 meth- odology [32,33]. First, the time since the initiation of the quit attempt was included using the following six catego- ries: '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 report- ing 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 effec- tiveness 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 prescrip- tion stop-smoking medication or face-to-face behavioural support in combination with either NRT bought over-the- counter (n = 173) or e-cigarettes (n = 25). Thus, the study population consisted of 5863 smokers who had made an attempt to quit in the previous year, of whom 7.9% (464) had used e-cigarettes, 32.8% (1922) had used NRT bought over-the-counter and 59.3% (3477) had used no aid to cessation. Quitting method did not differ by sex or the number of quit attempts in the past year but was associated with age, social grade, time since the quit attempt started, CPD, smoking less than one CPD, the measures of dependence (time with and strength of urges and HSI) and whether the attempt had begun abruptly (see Table 1). The *post-hoc* comparisons showed that those who used either e-cigarettes or no aid were younger than those using NRT over-the-counter, and that those who used NRT over-the-counter or no aid were more likely to hold a lower social grade than those using e-cigarettes. As would be expected, given the recent advent of e-cigarettes, the quit attempts of e-cigarette users were less

likely to have begun more than 6 months previously than those using NRT over-the-counter or no aid. Those using NRT bought over-the-counter smoked more cigarettes and scored higher than either of the other two groups on all measures of dependence. E-cigarette users smoked more cigarettes, and were more dependent by the strength of urges measure and HSI than those using no aid. Finally, those using no aid were more likely to have smoked less than one CPD and stopped abruptly than the other two groups.

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

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

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

Mean (SD) age% (*n*) Female% Social grade C2DEMean (SD) cigarettes per day[¶]% (*n*) < 1 cigarettes per day[¶]% (*n*) Time since quit attempt started >26 weeks Mean (SD) quit attempts in the past yearMean (SD) time spent with urges to smoke (0–5) Mean (SD) strength of urges to smoke (0–5)Mean (SD) heaviness of smoking index[†]% (*n*) Abrupt attempt (no gradual cutting down first)

E-cigarettes (n = 464)

39.0 (15.6)[a] 47.2 (219) 59.3 (275)[cd] 12.6 (8.0)[ef]

0.7 (3)[h] 23.7 (110)[jk]

1.6 (0.9) 1.9 (1.3)[l] 2.0 (1.2)[no] 2.0 (1.5)[qr]

50.4 (234)[t]

NRT over-the-counter[§] (n = 1922)

41.2 (15.3)[ab] 51.1 (982) 65.9 (1266)[c] 13.8 (8.5)[eg]

0.8 (15)[i] 36.4 (700)[j] 1.6 (0.9)

2.2 (1.3)[lm] 2.2 (1.1)[np] 2.3 (1.5)[qs] 52.5 (1010)[u]

No aid(n = 3477) P

37.5 (16.2)[b] *** 48.9 (1699) NS 65.5 (2277)[d] * 10.9 (8.1)[fg] ***

2.8 (94)[hi] *** 36.5 (1269)[k] *** 1.5 (0.9) NS 1.8 (1.3)[m] *** 1.8 (1.1)[op] *** 1.6 (1.5)[rs] *** 59.0 (2051)[tu] ***

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

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

Method of quitting n

E-cigarettes 371 NRT over-the-counter 1728 No aid 2942

Mean (SD) strength of urgesto smoke in smokers n

2.3 (1.1) 93 2.3 (1.0) 194 2.0 (1.0) 535

Mean (SD) strength of urges to smoke in non-smokers

0.8 (1.1) 1.2 (1.3) 0.7 (1.1)

Mean difference (95% CI) in strength of urges to smoke

1.4 (1.2–1.7) 1.2 (1.0–1.3) 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 replace- ment 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, Table3). The primary analyses revealed that the fully adjusted odds of non-smoking in users of e-cigarettes were 1.63 (95% CI = 1.17–2.27) times higher compared with users of NRT bought over- the-counter and 1.61 (95% CI = 1.19–2.18) times higher compared with those using no aid (see model 4, Table 3). The relative magnitudes of the ORs from the fully adjusted model with the other three unadjusted and par- tially 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 com- pared with those using no aid (OR = 1.63, 95% CI = 1.18–2.24). Similarly, the exclusion of respondents

Table 3 Associations between quitting method and abstinence.

Full sample (*n* = 5863) % (*n*) Self-reported

non-smoking

Subsample: quit attempt % (*n*) Self-reported

non-smoking

Subsample: quit attempt % (*n*) Self-reported

non-smoking

(1) e-Cigarettes

20.0 (93/464)

(2) NRT over-the-counter

10.1 (194/1922)

(3) No aid

15.4 (535/3477)

14.6 (323/2208)

16.7 (212/1269)

(1) versus (2)Model 1: OR (95% CI) Model 2: OR (95% CI) Model 3: OR (95% CI) Model 4: OR (95% CI)

2.23 (1.70–2.93)*** 1.88 (1.40–2.52)*** 1.63 (1.17–2.28)** 1.63 (1.17–2.27)**

(1) versus (3)Model 1: OR (95% CI) Model 2: OR (95% CI) Model 3: OR (95% CI) Model 4: OR (95% CI)

1.38 (1.08–1.76)* 1.21 (0.92–1.58) 1.62 (1.19–2.19)** 1.61 (1.19–2.18)**

started ≤26 weeks (*n* = 3784) 20.3 (72/354) 11.0 (135/1222)

started >26 weeks (*n* = 2079) 19.1 (21/110) 8.4 (59/700)

1.49 (1.12–1.98)** 1.39 (1.01–1.90)* 1.88 (1.32–2.68)***

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 com- pared with users of NRT bought over-the-counter or those using no aid in the fully adjusted models (see Table 3).

DISCUSSION

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

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

ting method among those who use these methods to aid cessation in real-world conditions. However, this was not a randomized controlled trial and there were

differences in the characteristics of those using different methods. For example, more dependent smokers tended to be more likely to use treatment, and smokers from lower social grades were less likely to use e-cigarettes. Although the adjustments go beyond what is typically undertaken in these types of real-world studies [28,29,41–44], it was not possible to assess all factors that may have been asso- ciated 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, motiva- tion 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

2.06 (1.50–2.82)*** 1.80 (1.27–2.55)*** 1.56 (1.06–2.29)* —

2.56 (1.49–4.42)*** 1.98 (1.11–3.53)**1.64 (0.83–3.24) —

1.18 (0.72–1.94) 0.91 (0.54–1.55) 1.10 (0.59–2.06)

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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], contrib- utes 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 ces- sation [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 asso- ciated 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 estab- lished. However, the existing evidence suggests the asso- ciated 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 numer- ous 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 con- tribute 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 medica- tions 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 depend- ence in real-world studies of smoking cessation is illus- trated by the difference in the ORs between the models with and without this adjustment. The optimal method of adjusting for dependence would be to assess this in all participants prior to their quit attempt. However, in a wholly cross-sectional study, we believe the particular method used to adjust for dependence, established in two previous studies, is valid [32,33]. One of the most commonly used alternative measures of dependence— HIS—relies upon the number of cigarettes smoked and time to first cigarette of the day [40]. When smokers relapse they tend to do so with reduced consumption, which can lead to a false estimation of prior dependence in cross-sectional studies. This potential confound was avoided in the primary analysis by using a validated measure involving ratings of current urges to smoke and statistical adjustment of the urges for the time since the quit attempt was initiated [39]. The value of strength of urges as a measure of dependence in cross-sectional research would be limited if different methods of stopping were linked differentially to lower or higher levels of urges in abstinent compared with relapsed smokers. For example, a method of stopping that led to a relatively higher reduction in urges could underestimate the effectiveness of that method by making it seem that those using it were less dependent. However, we have not previously found evidence in this population data set that urges to smoke in smokers versus quitters differs as a function of method [33], and it was true again in this study. Regardless, the pattern of results remained the same in both a sensitivity analysis that also included HSI and in a subgroup

analysis that excluded very light smokers. It is unlikely, therefore, that differential dependence between the users of different treatments has led to a substantial over- or underestimation of the relative effectiveness of e-cigarettes in the current study. Nevertheless, future studies may be able to draw stronger inferences by including a broader array of dependence measures or assessing dependence prior to a quit attempt.

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

social pressure and the related rate of misreporting is low and it is generally considered acceptable to rely upon self- reported data [38]. A related issue is the assessment of abstinence by asking respondents whether they were 'still not smoking'. This definition classified as abstinent those who had one or more lapses but resumed not smoking. This limitation would be serious if the rate of lapsing was associated with method of quitting, and should be assessed in future studies. By contrast, advantages of this measure were the assessment of prolonged abstinence, as advocated in the Russell Standard, and a clear relation- ship 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 sup- ported 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 differen- tiate 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 fre- quency of usage and experience of unanticipated side effects—that it is important to examine real-world effec- tiveness. However, it also means that we cannot make more exact statements about relative effectiveness of dif- ferent products and ways in which they may be used. Given this huge variability it may be many years before one could accumulate enough real-world data to address these questions. Finally, the prevalence of e-cigarettes has been increasing in England over the study period and this may affect real-world effectiveness. Although the evidence does not yet suggest an 'early adopters' effect—the current results persisted after adjusting for the year of survey and in a subgroup analysis limiting the data to a period when e-cigarette usage had become prevalent—these findings will need to be revisited to establish whether or not the apparent advantage of e-cigarettes is sustained.

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

Declaration of interests

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

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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 recom- mendations were followed.

Acknowledgements

The research team is part of the UK Centre for Tobacco and Alcohol Studies. We would like to thank Martin Jarvis, Lion Shahab and Tobias Raupach for providing valuable comments on a draft of the manuscript. The full data set, which includes individual level data, and statis- tical code are all available from the corresponding author at jamie.brown@ucl.ac.uk. Participants gave informed consent for anonymized data sharing.

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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.

Journal of Public Health Policy advance online publication, 9 December 2010; doi:10.1057/jphp.2010.41

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 programs[2]) and alcohol use (for example, designated driver programs[3]), 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 recrea- tional 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 avail- able 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 compo- nents of cigarette addiction. Electronic cigarettes are not manu- factured 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 B5300 of the estimated 10000–100000 chemicals in cigarette smoke have ever been identified,[4] we already have more comprehen- sive 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 elec-

tronic 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 8.2ng/g.[6] This com- pares with a similar level of 8.0ng 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 detec- ted 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 conven- tional nicotine replacement products.

Table 1: Laboratory studies of the components in and safety of electronic cigarettes[5–17]

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] Characterization of Liquid ‘Smoke Juice’

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.

for Electronic Cigarettes[8]

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.

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%).

Cahn and Siegel

Analysis of Components from Gamucci Gamucci Electronic Cigarette Cartridges, UltraLight Smoking Liquid[9]

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 GamucciElectronic Cigarette Cartridges,Tobacco Flavour Zero, SmokingLiquid[9] (0.77%), and a,3,4-tris[(trimethylsilyl)oxy]Benzeneacetic acid

NJOY e-Cigarette Health Risk NJOY Assessment[10]

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 inLife Electronic Cigarettes[11]

No DEG was detected in the cartridge liquid or vapors.

Characterization of Regal Cartridges for inLife Electronic Cigarettes – Phase II[12]

No TSNAs were detected in the e-cigarette liquid (limit of detection was 20 ppm).

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

(0.39%) 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.

Table 1 continued

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,. a.,.a.4-trimethyl (0.4%). No other compounds detected. 1,3-bis(3-phenoxyphenoxy)Benzene is non-hazardous. Vanillin and 3- cyclohexene-1-menthol,.a.,.a.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.

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

Product

Nicorette gum (4 mg)[18] NicoDerm CQ patch (4 mg)[18] Electronic cigarettes[6]Swedish snus[18]Winston (full)[18]Newport (full)[18]Marlboro (ultra-light)[18] Camel (full)[18]Marlboro (full)[18]Skoal (long cut straight)[18]

NNN NNK

2.00 ND ND 8.00 3.87 1.46 980 180

2200 580 1100 830 2900 750 2500 900 2900 960 4500 470

NAT

ND ND 2.16

790

560
1900
1100
1700
2300
4100
NAB Total

ND 2.00 ND 8.00 0.69 8.18

60 2010 25 3365 55 3885 58 4808 91 5191

100 6260 220 9290

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[a]The concentrations here represent nanograms (ng) of toxin detecteddose cartridge (which contains approximately 1gm of e-liquid). They are compared to the amount of toxin contained in approximately one tobacco cigarette (approximately 1gm of tobacco) or one unit of nicotine replacement product.Abbreviations: NNN=4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone; NNK=N^0-nitrosonor- nicotine; NAT=N^0-nitrosoanatabine; NAB=N^0-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 electro- nic cigarettes deliver nicotine effectively, more rapidly than a nico- tine 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. Eissenberg[20] 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

in 1 ruyan 16-mg multi-

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

Study	Effect of an E-Cigarette on Cravings and Withdrawal, Acceptability and Nicotine Deliver: Randomized Cross-Over Trial[19]	Electronic Nicotine Delivery Devices: Ineffective Nicotine Delivery and Craving Suppression after Acute Administration[20]
Brand tested	Ruyan	
Summary of findings	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.

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.

NJOY and Crown Seven

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desire to smoke in the first 10min[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] Barrett[21] found that denicotinized cigarettes reduce cravings more than a nicotinized inhaler, supporting Buchhalter et al's[22] conclusion that although some withdrawal symptoms can be treated effecti- vely 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]

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The Most Common Arguments against Harm Reduction

Our review of the existing literature identified five primary argu- ments 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 expo- sures 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 combus- tion precludes safer cigarettes, and therefore attempts to develop them should be abandoned.[25]

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

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

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

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

Pierce[27] 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 Colgrove[28] 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.

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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 y 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 electro- nic 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 invest- ment 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 dedi- cation 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 regu- latory 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 pro- ducts because 'much less is known about the safety of E-Cigarettes' and 'it may be possible for E-Cigarettes y 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] Regard- less of the court's decision, we believe a better regulatory approach would not actively discourage producers of harm reduction products.

Fairchild and Colgrove[28] 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 reduc- tion now manifested as deep cynicism about electronic cigarettes – a distinct product that actually does reduce risk and threatens cigarette makers – the tobacco industry is ironically benefiting from its own past duplicity. The push to ban electronic cigarettes may repeat the mistakes of the past in the name of avoiding them. Regulatory policy for electronic cigarettes and other novel nicotine products must be guided by an accurate understanding of how they compare to tobacco cigarettes and NRT in terms of reducing toxic exposures and helping individual smokers quit.

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DRUPOL-633; No. of Pages 5

Abstract

International Journal of Drug Policy xxx (2007) xxx–xxx

Editorial

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

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.

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

Introduction

In efforts aimed at reducing the risk of death, injury or dis- ease 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 regu- lation, 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 disagree- ment 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

0955-3959/$ – see front matter
doi:10.1016/j.drugpo.2006.11.013

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 prod- ucts. 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 pub- lic health approach rationally combines the various possible interventions in pursuit of the greatest achievable reduction in deaths, injuries and disease.

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

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

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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 pan- demic of cancers, heart disease, respiratory diseases and other deadly results of tobacco consumption. Nicotine itself is com- paratively 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 inhala- tion 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 Swe- den 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 1Examples of western world smoke-free alternatives to cigarettes

Transdermal nicotine patch (of various strengths and regimens) Nicotine chewing gum (range of flavours and 2 strengths) Nicotine inhaler [‘puffers’]Nicotine nasal spray

Medicinal nicotine lozenges (range of flavours and 3 strengths, including sublingual)

Ultra-low nitrosamine tobacco lozenges [Ariva, Stonewall] Swedish snusHard tobacco [Oliver Twist]Moist snuff [Skoal, Copenhagen]

Spit-free tobacco pouches Chewing tobacco

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

Smokeless tobacco products do cause disease – but at very low rates compared to cigarettes. The disease risk of smokeless tobacco can be made lower still through changes in manufacturing techniques that reduce toxins such as tobacco- specific nitrosamines. It has been estimated that modern smokeless tobacco products are least 90%, and perhaps closer to 99%, less deadly than smoking cigarettes (Levy et al., 2004; RCP, 2002). While there is popular recognition that ‘smokeless tobacco causes oral cancer’ few recognize that the risk of oral cancer from the sort of high nitrosamine smoke- less products that used to be on Western markets (and upon which the oral cancer risk was based) was actually consider- ably 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 medici- nal 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 nico- tine and fail to distinguish inter-product risks helps to explain why a vast number of smokers incorrectly believe that nico- tine itself causes cancer.

Current cigarettes and cigarette-like products are at the high end of a continuum of risk. Moving down the con- tinuum, 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 haz- ardous than smoking. Even tinkering with the toxicity levels of cigarettes, through such things as lowering nitrosamine levels in the tobacco leaf, has potential to reduce mortality. Non-combustion products, and particularly low nitrosamine smokeless tobacco and medicinal nicotine products are at the least hazardous end of this risk continuum.

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

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abstinence-only approaches to tobacco are rational public- health campaigns. This is not to say that all smokers would or should necessarily switch to snus or current forms of medic- inal 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 con- sidered it is clear that there is a wide range of possibilities on the continuum of risk. The variation of risk among inter- changeable 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 signif- icant number of those who would likely otherwise smoke cigarettes also raises key issues about just what sort of prod- ucts 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 bene- fits 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 accu- rate 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 associ- ated 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 mortal- ity. 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 prag- matism 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 con- text of deadly viral infections potentially spread through drug delivery systems (i.e., needle and syringe), are well known. In many countries, battles still rage over what to tell people – especially adolescents – about sex and in particular whether to encourage them to use condoms or simply to abstain from sex outside of marriage. While tobacco use has not yet elicited the same emotional intensity as have concerns about addiction and teen sex, the failure to establish a rational and evidence- based public-health approach to tobacco use can be traced to similar sorts of pragmatism–moralism debates.

And the situation with tobacco might be even more com- plicated than the debate over illicit drug use. One of the challenges facing tobacco control efforts is that the advo- cates 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 impos- sible 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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DRUPOL-633; No. of Pages 5

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 sen- timents of the public-health profession worked in favour of promoting harm-reduction interventions for sex-related harms (condoms) and drug-injection-related harms (syringe exchange), rather than insist that people cease engaging in activities that are potentially risky but impossible to eradicate. To a pragmatist – that is, to the public-health professional – the reason for a behaviour is less important than the fact that the behaviour is going to continue. The public-health profession supported the harm-reduction stance on sex and illicit-drug use even before the safety of those interventions had been established. With tobacco, by contrast, the public- health profession has yet to support tobacco HR despite the strong, consistent, and increasingly extensive evidence that many alternative nicotine delivery systems would be safer than smoking.

An understanding of the public-health profession's posi- tion is important, because its voice would sound loud in the policy debate were it to renounce its support of cessation- only approaches. We see two ingredients to the public-health establishment's reluctance to embrace the concept of a con- tinuum 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 par- ticular. Two of the foundations of public health, occupational hygiene and worker safety, were built on direct opposition to industry; another, environmental monitoring and main- tenance, has depended on advocacy to overcome industry standards that tolerated pollution. And the collusion of private business with government regulators that has produced seri- ous public-health disasters – the Triangle fire in New York, the Bhopal disaster in India, mad cow disease in the U.K. – increases the profession's antipathy.

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

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

on alternative delivery systems now being carried out is funded by industry: research on smokeless tobacco products is financed by the tobacco companies, and research on nico- tine 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 fund- ing 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 situ- ation 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 reg- ulations 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 pro- liferation of alternative products can combine with changing corporate vested interests and political pressure to fundamen- tally 'morph' a market. The fundamental change with respect to pure foods and pharmaceuticals did not come with legis- lation per se (e.g., the U.S.'s Food and Drug Act of 1906), but from two broader cultural phenomena: the growth and professionalization of the craft of medicine, and changes in the social contract that

demanded more public responsibility from private manufacturers (with concomitantly expanded compliance by the courts). In America, the medical trade advocated for greater regulation of products having to do with health so that it might dominate the market in health- risk avoidance. The movement for purer foods developed in tandem with awareness of nutritional public health, positioning food regulation across both the medical and consumer arenas. Thus, the role of both the health-care industry and the public-health agencies was essential to the development of policies that reduced food- and prescription-drug-associated harms.

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

There are many regulatory strategies that could be reason- ably 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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4 October 2006

Editorial / International Journal of Drug Policy xxx (2007) xxx–xxx 5

Please cite this article in press as: Sweanor, D., et al., Tobacco harm reduction: How rational public policy could transform a pandemic, International Journal of Drug Policy (2007), doi:10.1016/j.drugpo.2006.11.013

I oppose bill SB1220. The increase of 80% tax on whole sale is outrageous. And would make most eliquid bottles go from $18 retail for a 30ml bottle to $32 retail. The average modern vape user goes through a 30ml bottle in roughly 1-2 days. This could easily mean an increase of hundreds of dollars per month to people that are just trying to stay of cigarettes, which ironically would be the *cheaper* option if this bill would to pass.

This bill would put local businesses at a huge disadvantage and drive business out of state, along with discouraging the use of e cigarettes which are proven to be healthier than smoking and help quitting.

We do not want a black market created, This bill could very easily create a black market overnight. With people turning to craigslist, Facebook groups and reddit to distribute their e liquids. When most shops currently carry higher quality eliquid that is made in labs with quality control and child safe packaging, in short this will result in low quality bootleg products becoming the norm simply because the average vapor would not be able to sustain the increased expense to buy legitimate products.

The way the bill is written, referring to any "product" containing nicotine... does this include tomatoes, eggplant, green and black teas, and cauliflower? All these things contain nicotine naturally...

Many of Vapor products are already more expensive than standard tobacco products. They are already illegal to purchase for under 18. And nicotine does not cause cancer.

Please defer this bill for more discussion. Let the FDA come out with their ruling on the products before making decisions that can affect everyone. The cancer research center has recently had a lot of controversy about over spending and mismanagement and I do not believe that throwing even more money at them will help them achieve anything they could not with their current budget.

IF this bill is to pass I URGE you to exempt any and all Vaping/ Electronic Cigarette products including e-liquid from this bill as it will crush the local vape industry in Hawaii. One of the few new industries to spring up in Hawaii in a long, long time.

Thank you for your time and consideration.

-Justin Wolery

SB1220
Submitted on: 2/25/2015
Testimony for WAM on Feb 27, 2015 13:00PM in Conference Room 211

Submitted By	Organization	Testifier Position	Present at Hearing
Javier Mendez-Alvarez	Individual	Support	No

Comments:

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SB1220
Submitted on: 2/25/2015
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Submitted By	Organization	Testifier Position	Present at Hearing
Vin Kim	Individual	Oppose	No

Comments: The whole point of Electronic Cigarettes is to get people off of cigarettes. Imposing a tax on this will not make things easier for people to quit, which is the whole point. Also, changing "Tobacco Products" to anything that contains nicotine but not containing tobacco, will also make it harder for people to afford Nicotine gum and patches. If you want people to be less dependent on cigarettes, this is not the way to do it.

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Submitted By	Organization	Testifier Position	Present at Hearing
Chase Camacho	Individual	Oppose	No

Comments:

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SB1220
Submitted on: 2/25/2015
Testimony for WAM on Feb 27, 2015 13:00PM in Conference Room 211

Submitted By	Organization	Testifier Position	Present at Hearing
Reid Matsuoka	Individual	Oppose	No

Comments: oppose bill SB1220. The increase of 80% tax on whole sale is outrageous. And would make most eliquid bottles go from $18 retail for a 30ml bottle to $32 retail. This bill would put local businesses at a huge disadvantage and drive business out of state, along with discouraging the use of e cigarettes which are proven to be healthier than smoking and help quitting. We do not want a black market created, This bill could very easily create a black market overnight. With people turning to craigslist, Facebook groups and reddit to distribute their e liquids. When most shops currently carry higher quality eliquid that is made in labs with quality control and child safe packaging. These products are already more expensive than standard tobacco products. They are already illegal to purchase for under 18. And nicotine does not cause cancer. Please defer this bill for more discussion. Let the FDA come out with their ruling on the products before making decisions that can affect everyone. Please AUDIT the cancer research center, they are already getting a lot of money. Apparently they are not managing it correctly. Thank you for your time and consideration.

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SB1220
Submitted on: 2/25/2015
Testimony for WAM on Feb 27, 2015 13:00PM in Conference Room 211

Submitted By	Organization	Testifier Position	Present at Hearing
shaun	Individual	Oppose	No

Comments: I oppose bill SB1220. The increase of 80% tax on whole sale is outrageous. And would make most eliquid bottles go from $18 retail for a 30ml bottle to $32 retail. This bill would put local businesses at a huge disadvantage and drive business out of state, along with discouraging the use of e cigarettes which are proven to be healthier than smoking and help quitting. We do not want a black market created, This bill could very easily create a black market overnight. With people turning to craigslist, Facebook groups and reddit to distribute their e liquids. When most shops currently carry higher quality eliquid that is made in labs with quality control and child safe packaging. These products are already more expensive than standard tobacco products. They are already illegal to purchase for under 18. And nicotine does not cause cancer. Please defer this bill for more discussion. Let the FDA come out with their ruling on the products before making decisions that can affect everyone. Please AUDIT the cancer research center, they are already getting a lot of money. Apparently they are not managing it correctly. Thank you for your time and consideration.

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SB1220
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Testimony for WAM on Feb 27, 2015 13:00PM in Conference Room 211

Submitted By	Organization	Testifier Position	Present at Hearing
Eli Jennings	Individual	Oppose	No

Comments: I oppose bill SB1220. The increase of 80% tax on whole sale is outrageous. And would make most eliquid bottles go from $18 retail for a 30ml bottle to $32 retail. This bill would put local businesses at a huge disadvantage and drive business out of state, along with discouraging the use of e cigarettes which are proven to be healthier than smoking and help quitting. We do not want a black market created, This bill could very easily create a black market overnight. With people turning to craigslist, Facebook groups and reddit to distribute their e liquids. When most shops currently carry higher quality eliquid that is made in labs with quality control and child safe packaging. These products are already more expensive than standard tobacco products. They are already illegal to purchase for under 18. And nicotine does not cause cancer. Please defer this bill for more discussion. Let the FDA come out with their ruling on the products before making decisions that can affect everyone. Please AUDIT the cancer research center, they are already getting a lot of money. Apparently they are not managing it correctly. Thank you for your time and consideration.

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SB1220
Submitted on: 2/26/2015
Testimony for WAM on Feb 27, 2015 13:00PM in Conference Room 211

Submitted By	Organization	Testifier Position	Present at Hearing
Carolyn Kohn	Individual	Oppose	No

Comments: I oppose bill SB1220. The increase of 80% tax on whole sale is outrageous. And would make most eliquid bottles go from $18 retail for a 30ml bottle to $32 retail. This bill would put local businesses at a huge disadvantage and drive business out of state, along with discouraging the use of e cigarettes which are proven to be healthier than smoking and help quitting. We do not want a black market created, This bill could very easily create a black market overnight. With people turning to craigslist, Facebook groups and reddit to distribute their e liquids. When most shops currently carry higher quality eliquid that is made in labs with quality control and child safe packaging. These products are already more expensive than standard tobacco products. They are already illegal to purchase for under 18. And nicotine does not cause cancer. Please defer this bill for more discussion. Let the FDA come out with their ruling on the products before making decisions that can affect everyone. Please AUDIT the cancer research center, they are already getting a lot of money. Apparently they are not managing it correctly. Thank you for your time and consideration.

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To: Senator Jill N. Tokuda, Chair, Senator Ronald D. Kouchi, Vice Chair, and Members of the Ways and Means Committee

Re: Opposition to SB1220

Hearing: WAM, Friday, February 27, 2015 1:00 PM

I oppose bill SB1220.

This draconian regulation on the vapor industry is bad policy in every way. The restriction and taxation of vapor products would create worse health outcomes, causing added long-term costs for the state. Vapor is not tobacco, not smoking, and is proven to help people quit smoking. Discouraging its use and adoption puts the health of thousands of Hawaii residents at added risk.

Furthermore, the tax would not do anything positive. It would be a poor revenue generator at best because of the availability of untaxed options such as internet purchasing. In the end it will put Hawaii businesses at a disadvantage if not outright put them out of business, and will send Hawaii consumer dollars out of state.

SB 1220 is a lose-lose proposition. Please do not advance this measure.

Thank you for your time and consideration.

P Kuromoto
Honolulu, HI

To: Senator Jill N. Tokuda, Chair, Senator Ronald D. Kouchi, Vice Chair, and Members of the Ways and Means Committee

Re: Opposition to SB1220

Hearing: WAM, Friday, February 27, 2015 1:00 PM

I oppose bill SB1220. An additional 80% tax is outrageous, and would make typical e-liquid bottles go from $18 retail for a 30ml bottle to $32 retail.

This bill would put local businesses at a huge disadvantage and drive business out of state, along with discouraging the use of e-cigarettes which are proven to be far less harmful than smoking and shown to help quitting smoking.

This bill could create a black market for e-liquid and vapor products, with people turning to Craigslist, Facebook groups and Reddit to distribute their products. Most shops currently carry higher quality e-liquid that is made in labs with quality controls and child-safe packaging.

These products are already more expensive than standard tobacco products. They are already illegal to purchase for under 18. And nicotine does not cause cancer.

Please defer this bill for more discussion. Let the FDA come out with their ruling on the products before making decisions that can affect everyone. In addition, please AUDIT the cancer research center. They are already getting a lot of money, but apparently they are not managing it correctly.

Thank you for your time and consideration.

Alika Spahn Naihe
Kalihi, Hawaii

To: Senator Jill N. Tokuda, Chair, Senator Ronald D. Kouchi, Vice Chair, and Members of the Ways and Means Committee

Re: Opposition to SB1220

Hearing: WAM, Friday, February 27, 2015 1:00 PM

I oppose bill SB1220. An additional 80% tax is outrageous, and would make typical e-liquid bottles go from $18 retail for a 30ml bottle to $32 retail.

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are already getting a lot of money, but apparently they are not managing it correctly.

Thank you for your time and consideration.

michael Locey
Kauai Hi

To: Senator Jill N. Tokuda, Chair, Senator Ronald D. Kouchi, Vice Chair, and Members of the Ways and Means Committee

Re: Opposition to SB1220

Hearing: WAM, Friday, February 27, 2015 1:00 PM

I oppose bill SB1220.

Thank you for your time and consideration.

Cynthia Howder

SB1220
Submitted on: 2/26/2015
Testimony for WAM on Feb 27, 2015 13:00PM in Conference Room 211

Submitted By	Organization	Testifier Position	Present at Hearing
Jake J. Watkins	Individual	Oppose	No

Comments:

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SB1220
Submitted on: 2/26/2015
Testimony for WAM on Feb 27, 2015 13:00PM in Conference Room 211

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

Comments: Strongly Oppose SB1220.

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Testimony for WAM on Feb 27, 2015 13:00PM in Conference Room 211

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

Comments:

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SB1220
Submitted on: 2/26/2015
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Submitted By	Organization	Testifier Position	Present at Hearing
Oakwood Hirata	Individual	Oppose	No

Comments:

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