

Synopsis

- E-cigarettes that make health claims or that contain nicotine are prohibited for sale in Canada.
- Despite this, their popularity and global economic investment has grown. In addition, new research is now available that suggests that the original concerns regarding e-cigarettes may not be valid.
- It is recommended that the CPHA reconsider its position on the regulation of e-cigarettes and possibly advocate for more moderate control measures.

Purpose

To re-examine CPHA's position on e-cigarettes in light of recent research

Current Status

Historically, CPHA has supported Health Canada's prohibition on the sale of e-cigarettes despite divided debate on the topic. This prohibition prevents the sale of nicotine containing e-cigarettes, but does not address the sale of e-cigarettes that do not contain nicotine. While some see the product as a "healthier" alternative to smoking and as a promising smoking cessation device, others see e-cigarettes as a potentially dangerous product that could undermine existing tobacco laws. Emerging evidence, however, suggests that e-cigarettes may not be as hazardous to human health as initially thought.

Background

The World Health Organization defines e-cigarettes as "products that contain tobacco-derived substances, but in which tobacco is not necessary for operation... electronic cigarettes are capable of providing inhaled doses of nicotine, but [products] that do not contain nicotine are also available." For a complete definition, see Appendix 1.

A detailed analysis of available literature (see Appendix 2) is summarized here:

- In recent years, e-cigarettes have grown in popularity globally and companies producing them have received an increasing amount of investment, especially from large tobacco companies. Consumers (?) spent an estimated \$2B on e-cigarettes and associated paraphernalia in 2011.
- Studies have shown that e-cigarettes contain fewer toxins than traditional cigarettes, although quality control concerns remain and the long-term effect of usage is unknown.
- Smoking cessation claims remain unproven but new research looks promising.
- There is no international consensus on the regulation of e-cigarettes. Some countries have imposed outright bans, some are regulating them as medicines (e.g. UK), and others are regulating them as tobacco products (e.g. US).

Options and Rationale

Based on available information, CPHA is considering the following policy options:

- 1) **Provide no comment on the current situation** – This option provides *de facto* support for the current situation. This option would also limit the availability of the products for study, making it more difficult to independently evaluate their potential use for smoking cessation and to determine the health effects of long-term use.
- 2) **Advocate for moderation of the current prohibition** - This option would allow some approved products to be sold in Canada under a combination of tobacco/medical product regulations. Such a position should encourage the scientific study of e-cigarette products and ensure that Canadians have access to quality-controlled, approved devices and associated paraphernalia.
- 3) **Support the removal of all controls on the sale of e-cigarettes** – This option provides no protection for the health and safety of Canadians and could encourage the importation, promotion and sale of potentially dangerous products.

Given the new and growing evidence concerning e-cigarettes, CPHA is considering the following changes to its current position and seeks guidance from the Policy Review Group:

CPHA to support the regulation of e-cigarettes as a combination drug/tobacco device:

- All products should be subject to testing required for other smoking cessation products, before public release.
- Impose the same limitations on e-cigarettes that apply to traditional cigarettes in an effort to prevent the re-normalization of tobacco products.
- Since e-cigarette products would be widely available, quality control and labelling standards should be established to mitigate the likelihood of fraud and product mislabelling.
- Due to the presence of trace quantities of toxic contaminants in tested products, additional risk assessments must be undertaken.

CPHA to support rigorous research on long-term safety and efficacy:

- Establish the safety and smoking cessation efficacy of e-cigarettes through appropriately designed and reviewed studies.

CPHA to support the restriction of health and smoking cessation claims made by manufacturers:

- Restrict health and smoking cessation claims until e-cigarettes are proven to be an effective smoking cessation aid.
- Encourage the smoking community to take advantage of currently approved, available treatments.

Appendix 1: Structure of an E-cigarette

E-cigarettes are devices that look and feel like a traditional cigarette but do not require tobacco to function¹. Instead users draw on the mouthpiece of a metal or plastic tube to activate a microelectrical circuit that vaporizes the e-cigarette liquid. This creates a fine mist which can then be inhaled. E-cigarette liquid is contained in a removable cartridge and usually consists of nicotine and/or flavouring agents dissolved in chemicals such as glycerine and propylene glycol.

The devices consist of several components (See Figure 1):

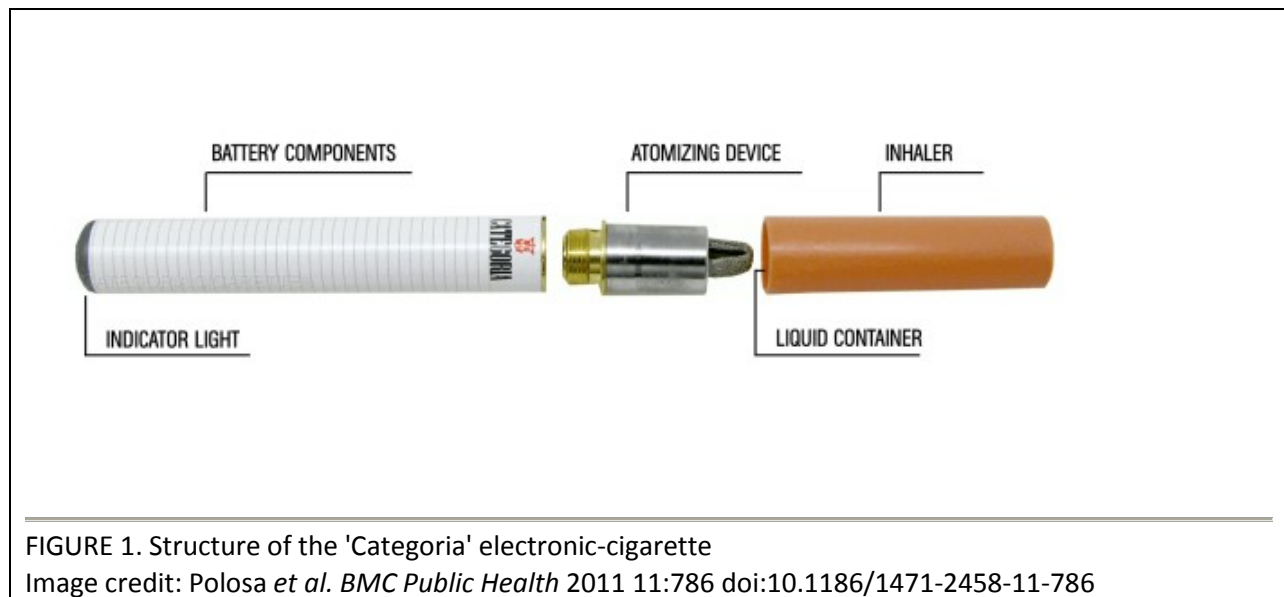


FIGURE 1. Structure of the 'Categoria' electronic-cigarette

Image credit: Polosa *et al.* *BMC Public Health* 2011 11:786 doi:10.1186/1471-2458-11-786

1. A cartridge filled with liquid, sometimes containing various concentrations of nicotine dissolved in a chemical matrix (usually propylene glycol) sometimes containing no nicotine at all.
2. A micro-electrical circuit, which is activated when the user draws on the mouthpiece. The atomizing device warms the liquid causing it to vaporize into a fine mist that can be inhaled.
3. A rechargeable battery or one-time-use battery.
4. An indicator light, which illuminates when the device is being used.

Appendix 2: E-cigarette Background and Literature Analysis

Brief Economic Background

A Chinese company, Ruyan, is largely credited with the invention of the e-cigarette, which was released on the Asian market in 2004.² The first documented cases of e-cigarettes on the American market occurred in 2007.³ Since then the product's popularity has grown substantially. In the United Kingdom, the market grew from 700,000 users in 2012 to 1.3 million users in 2013,⁴ while the Union Bank of Switzerland reported that the US market for e-cigarettes has doubled every year since 2008.⁵ A recent survey indicates that 1 in 5 current smokers in America have used e-cigarettes.⁶

Euromonitor International claimed that (consumers? spent) \$2B on e-cigarettes and associated paraphernalia in 2011,⁷ while analysts at Wells Fargo & Co. in New York project the US market for e-cigarettes will reach \$10B by 2017.⁸ These speculations may be largely fueled by the recent investment in the industry by large tobacco companies. For example, in 2012 Lorillard bought Blu e-cigarettes for \$135 million. Other companies that have a stake in the e-cigarette industry include Altria (parent company of Phillip Morris), British American Tobacco, Imperial Tobacco and Reynold's American.

Health Claims

Many e-cigarette companies claim that "vaping" (the act of using an e-cigarette) is healthier than smoking because the electronic cigarette does not produce smoke or contain the toxic compounds present in a traditional cigarette. Advocates also promote the use of e-cigarettes as a harm reduction strategy for current smokers.

While these claims have not been conclusively proven, there is some evidence to support them. Studies have shown that e-cigarette cartridges contain fewer harmful chemicals than traditional cigarettes.^{9,10} One study found that the vapour from e-cigarettes had a significantly lower cytotoxic effect on mammalian cells than tobacco smoke extract, though investigators suggested more research at the clinical level to determine the effect on humans.¹¹ Despite this evidence, e-cigarettes cannot be considered harmless. In 2009, the US Food and Drug Administration (FDA) conducted an analysis of two brands of e-cigarette cartridges. The analysis yielded trace levels of carcinogenic nitrosamines in over half of the samples. The analysis also found potentially harmful compounds such as anabasine, myosmine and β -nicotyrine in most of the tested samples.¹² These compounds are also present in tobacco smoke, though in concentrations that are 100-1000 times higher than in e-cigarettes. A Korean study published in 2013 confirmed the trace presence of nitrosamines in 105 replacement liquid brands from 11 different companies were at levels 10x higher than originally reported by Ruyan e-cigarettes.¹³

E-cigarette manufacturers maintain that the concentrations of harmful compounds found in their products will not affect human health and are comparable to the concentrations found in approved smoking-cessation products such as patches, gums, lozenges, and inhalers.

E-cigarettes, Lung Function and Second-hand "Vaping"

Propylene glycol, the main ingredient in most e-cigarette cartridges, has been approved for use in food products in Canada.¹⁴ It is widely used as a humectant, as a food preservative and in theatrical fog machines. It is also used in medical devices such as asthma inhalers and other nebulised medications. Despite this, as Thomas Glyn, Director of Cancer Science Trends for the American Cancer Society points out, "little is known about the long-term effects of inhaling it"¹⁵ and existing evidence is contradictory. A study published in *Toxicology* found no significant short-term effects of lung function from first- and second-hand e-cigarette mist.¹⁶ This work was contradicted by a similar study published in *Chest*, finding

that e-cigarette use led to adverse physiologic effects in the short-term.¹⁷ These results were indirectly supported by yet another study, which examined the occupational hazards of employees in the entertainment industry who suffered long-term exposure to fog machine mist containing glycols. Investigators found that, in comparison to a control population, the entertainment workers experienced more nasal symptoms, shortness of breath, work-related chest tightness, and decreased lung function.¹⁸

E-cigarettes and Smoking Cessation

When e-cigarettes first appeared in the North American market, many companies advertised them as a tool for smoking cessation (see Appendix 3 for examples). At the time, however, the only evidence that e-cigarettes could be used as an effective tool came from anecdotal evidence and industry-funded, small-scale studies. As a result, the FDA issued several warnings¹⁹ to companies to stop them from making unfounded claims. While these companies have removed such statements from their websites and their advertisements, a few continue to advertise these claims via social media and online advocacy groups.²⁰

While scientists have begun investigating whether e-cigarettes are an effective tool for smoking cessation, the evidence that supports this premise is still weak. E-cigarette advocates often invoke the Italian ECLAT study²¹ which found that 11% of the smokers in their study who received e-cigarettes containing nicotine reported that they had abstained from smoking traditional cigarettes at the last follow-up visit. These findings are hopeful even though critics argue that the study methodology is flawed and the statistical analysis inappropriate.²²

While other studies have come to similar conclusions,^{23,24} most of these have been funded by industry and may be subject to bias

Quality Control

There are no mandated quality control standards for the manufacturing of e-cigarettes and their associated paraphernalia. This has raised concerns about the quality of nicotine (medical-grade vs. pesticide-grade),²⁵ manufacturing competence,²⁶ bacteriological contamination,²⁷ and faulty product design.²⁸ Also, analyses have shown that cartridges contain widely varying amounts of nicotine per puff^{29,30,31} and no standard concentrations for cartridges labelled “none”, “low”, “medium” and “high”. A 2009 FDA analysis found trace amounts of nicotine in some cartridges labelled “no nicotine”, while in one of the tested products, analysts found trace amounts diethylene, a toxic contaminant and a common component in antifreeze. There also has been at least one documented case of an exploding e-cigarette, probably due to a faulty battery.

Complicating this situation is the fact that many e-cigarette users purchase materials online from international sources. It is, therefore, important that international efforts be put in place to establish quality control standards that protect the health and safety of consumers.

Regulatory Considerations

E-cigarettes in Canada are currently regulated under the *Food and Drugs Act and Regulations*. Health Canada issued an advisory against e-cigarettes in 2009.³² The department argued that there is insufficient evidence to support the safety of the devices. Products containing nicotine or that make health claims are not approved for manufacture, importation or sale in Canada, while nicotine-free products remain unregulated. Health Canada has been criticized for these regulatory inconsistencies the Non-Smokers’ Rights Association has recommended more comprehensive regulation.

E-cigarettes containing nicotine are widely available in the US. The FDA initially attempted to ban their importation by regulating them as a combination drug/medical device under the *Federal Food, Drug and Cosmetic Act*. This decision was overturned by the US Court of Appeals in 2010.* The Court ruled that any product containing nicotine from tobacco should be considered a tobacco product unless marketed for therapeutic purposes.

The Medicines and Healthcare Products Agency (MHRA) in the UK performed a lengthy public consultation[†] about the regulation of e-cigarettes. Based on the results of that consultation, the MHRA announced that from 2016, e-cigarettes will be considered as medicines, which will subject manufacturers to stricter regulations and quality standards.³³ The MHRA advises citizens to avoid the use of e-cigarettes until quality control measures are in place for safety reasons.

Several countries including Norway, Brazil, the Seychelles, and Singapore have implemented outright bans for e-cigarettes and associated products. France has implemented a public smoking ban for e-cigarettes.³⁴ Others attempt to regulate them as either medical devices[‡] or as tobacco products.[§] Some countries have not implemented any regulations at all.

Unintended Consequences of E-cigarettes

In a 2012 report, WHO expressed concern that the use of e-cigarettes would undermine gains in tobacco control. First and foremost, WHO believes that due to loopholes in public smoking bans, the public use of e-cigarettes could re-normalize the use of tobacco products. This sentiment is echoed by the British Medical Association.³⁵ In addition, the NSRA and WHO argue that the availability of flavoured nicotine cartridges such as “Bubblegum”, “Snickerdoodle” and “Sweet Tarts” have an obvious appeal to youth, which may serve as a gateway to developing a harmful nicotine addiction. Finally, by making nicotine consumption more convenient and potentially allowing e-cigarettes in closed environments, smokers might have less incentive to quit smoking.

These products are made even more enticing though celebrity endorsement, either paid or spontaneous. Celebrities such as Stephen Dorff** and Courtney Love†† have appeared in commercials for e-cigarettes, while actress Katherine Heigl famously promoted e-cigarettes on David Letterman’s Late Night Show,^{‡‡} informing the audience that the products are a safe, healthy alternative to smoking.

* Case Detail: Sottera, Inc. v. FDA. Accessed: July 12, 2013. Available at: http://www.wlf.org/litigating/case_detail.asp?id=629

† Public consultation (MLX 364): The regulation of nicotine containing products (NCPs) Accessed: July 12, 2013. Available at: <http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617>

‡ Hungary, Australia, Germany, New Zealand, Turkey, Canada, Norway

§ Belgium, Republic of Korea, Bhutan, Uruguay

** Stephen Dorff, Blu e-cigarettes ad, available at: http://www.youtube.com/watch?v=VZishwAt_RM

†† Courtney Love, NJOY e-cigarettes ad, available at: <http://www.youtube.com/watch?v=SFs761eEFk>

‡‡ Katherine Heigl, David Letterman Appearance e-cigarette promotion, Available at: <http://www.youtube.com/watch?v=ysGyflwvrr1s>

Appendix 3: E-cigarette Smoking Cessation Advertisements

TRY E-CIGARETTES
QUIT SMOKING & SATISFY YOUR CRAVING!

No Tar or Carbon Monoxide
No Ash, Stub or Terrible Smell
No Yellow Teeth or Bad Breath

Virtually Odorless
Same Nicotine Fix, Real Vapor
Less Harmful To Yourself & Others

CLICK HERE...
GET YOURS TODAY!

E-Cigs

FOR A HEALTHY LIFESTYLE
E-Cigs
Satisfying Nicotine

The advertisement features a close-up of an e-cigarette with a red tip and a clear reservoir. Below it, a list of benefits is presented with red 'X' and green checkmark icons. To the right, there is a pack of 'E-Cigs' and a single e-cigarette.

Source: <http://freeelectroniccigarettekit.com/> Accessed: July 15, 2013

NO IFS, ANDS OR BUTTS
MAKE THURSDAY SMOKE-FREE

Smokers, on November 17th switch to Camel SNUS and enjoy smoke-free, spit-free, great-tasting tobacco packed in a pouch. Camel SNUS—it just might change the way you enjoy tobacco.

camelsnus.com*
*WEBSITE RESTRICTED TO AGE 21+ TOBACCO CONSUMERS.

BREAK FREE

The advertisement shows a hand holding a silver Camel Snus pouch. The background is dark blue with faint 'CIGARETTES' text. A 'BREAK FREE' logo is in the top right corner.

QUIT SMOKING NOW!

Compare the top brands and see why V2 is America's #1 eCigarette ([click here](#))

Best Vapor!
Best Technology!

v2cigs

The advertisement features a woman with dark hair holding a V2 e-cigarette. The background is dark with a glowing 'v2cigs' logo at the bottom.

Source. Advertisement for Camel Snus. November 7, 2011. Available at: <http://www.trinketsandtrash.org/detail.php?artifactid=7037&page=1>. Accessed April 3, 2012; Top Electronic Cigarettes

Web site. Available at: <http://topelectroniccigarettes.com/reviews/332-v2-e-cigarettes-review-break-the-addiction-to-gain-better-health-and-lifestyle>. Accessed April 3, 2012

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