ECTA

Electronic Cigarette Trade Association of Canada

To: HESA

House of Commons Standing Committee on Health

Re: Electronic Cigarettes

October, 2014

Contents

ECTA Introduction

The Electronic Cigarette Trade Association of Canada (ECTA) is a self regulatory organization actively implementing stringent, but appropriate consumer product regulations to Electronic Cigarette products in Canada since 2011. As the fastest growing electronic cigarette trade association globally, we currently represent over 25 individual Canadian businesses, each with multiple locations and/or avenues of distribution.

We recognize the need for regulation that exceeds the requirements for consumer products, and have developed a program that addresses these issues. This program includes a 230 page guide with policies and procedures for vendors to ensure quality control, product safety, marketing standards, appropriate labeling, preventing sales to minors and comprehensive laboratory testing, chemical analysis and research.

Information compiled by ECTA on products, clinical and scientific research is invaluable and should be considered when making any recommendation based on public health.

Our goal at this meeting will be to provide information, including numerous scientific studies, research & surveys, and testing that has been conducted by ECTA. The information we will provide will directly correlate to Key Topics comprising areas of concern currently being discussed by public health officials. In addition we will also present a brief summary of the regulations that ECTA members must follow.

It is our hope that this information will form the basis for a working relationship between regulators and the industry for the future. While there are time and topic limitations at this meeting we would like to participate in all future discussion to provide our valuable input and ensure this committee and other parties have all information required to make an educated recommendation/decision on the electronic cigarette industry.

Electronic Cigarette: Defining the Product

Electronic cigarettes comprise 2 separate products which work together to achieve a specific effect.

Hardware:

1) **The body**, commonly referred to as a "Battery", is a rechargeable electronic device. These range from "simple" (on/off, charge indicators, protective circuits) to "complex" (computer based program updates, puff counters, power adjustment, etc).

2) **The top**, commonly referred to as an "atomizer" or "cartridge", is a small heating element with variations on materials used in construction, capacity and coil resistance.

Hardware is manufactured according to FCC or CE standards as well as ROHS (restriction of hazardous substances) standards (required by European nations).

The pace of product development is consistent with technology developments for other similar small electronic devices.

ECTA requires all members have FCC or CE certifications from the manufacturer along with ROHS (when manufactured outside of North America), correct instructions, warnings and warranty information.

3) **The Eliquid** is a "recipe" combination of the ingredients listed below (this is consistent throughout the industry). Eliquid is most often sold in a bottle used to refill atomizers. It can also be pre-filled into cartridges (though this presentation is no longer as common). Ingredients are:

a) propylene glycol (a commonly used chemical in food, medicine, cosmetics, industry)
b) vegetable glycerin (a sugar alcohol also used in food, medicine, cosmetics)
c) food flavoring (artificial, natural and/or organic)
d) optional nicotine (strengths ranging from "0" to 24 mg/ml)

Propylene Glycol and Vegetable Glycerin form the base and are used in various combinations, differing in percentage by manufacturer (100% of either, 70/30, 50/50, etc).

The use of food flavoring is carefully monitored by ECTA to ensure chemical additives that are not recommended for inhalation by OSHA and/or current scientific review are viewed as "preventable risk" elements to be avoided.

Nicotine is the most critical additive for consumer success in successfully switching from tobacco products. The highest commercial strength offered in Canada is 24 mg/ml. This is approximately equivalent to ¾ less than the available nicotine in tobacco cigarettes, based on common daily use.

Nicotine use, as with Tobacco (and all nicotine products) is "self-tritrated", with the consumer determining the amount ingested and used throughout the day. However, UNLIKE tobacco products, eliquid permits the user to select various strengths throughout the day or over time, choosing whether to wean off nicotine without having to simultaneously discontinue use of the product.

ECTA requires that all eliquids sold by members be properly labeled in accordance with CCCR2001, along with specific additions listing in both English and French: ingredients, batch number, date of expiry, nicotine level (including nicotine free), a poison symbol, indications for use, allergen warnings, and wording or symbol indicating the product is not for use by minors.

Key Topics

Questions around renormalization of tobacco use

An oft repeated fear in Public Health circles is that electronic cigarettes will re-normalize smoking and use of tobacco products, following years of "gains" in de-normalizing.

Electronic cigarettes do the polar opposite. They act in direct contradiction to ongoing tobacco use by providing a cleaner, safer product that is replacing the use of tobacco for millions, worldwide.

The basis of the argument may appear reasonable in general. When examined more closely, from a well thought out and logical perspective, there are specific reasons renormalization should not be an issue of significant concern.

1) The vast majority of electronic cigarettes sold in Canada physically appear very different from tobacco cigarettes. They are 5-20x larger, come in various shapes and colours, and are made of metal. While they mimic the physical procedure of smoking, when in use, they do not taste the same, nor deposit smoke in the air, nor produce a passive discharge, and length of use is at the discretion of the consumer (ie: no requirement to complete as with a cigarette). Users do not confuse these products with tobacco and understand them as tobacco free, reduced harm alternatives.

2) Smoking Tobacco has been de-normalized at a social level for very real and significant reasons:
a) The public is now acutely aware of the damaging and deadly health effects of passive, first and second hand smoke.
b) The smell of tobacco smoke is generally repulsive to most people, stains surfaces, produces a passive smoke that is instantly identifiable and generally considered gross or dirty.
c) Although less obvious, smoking tobacco is a fire hazard and is the number 1 cause of fire related fatalities in Canada.

3) After 10 years on the market and hundreds of clinical and laboratory studies, there is no evidence, or reasonable fear, that vapor from, or the use of electronic cigarettes causes deadly or harmful health effects to its users nor to bystanders.
Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. *BMC Public Health. 14(18)*

"Current state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to contaminants of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. However, the aerosol generated during vaping as a whole (contaminants plus declared ingredients) creates personal exposures that would justify surveillance of health among exposed persons in conjunction with investigation of means to keep any adverse health effects as low as reasonably achievable. Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern."

4) Vapor produced from e-cigarettes dissipates in seconds, and has none of the characteristically offensive odor produced by tobacco smoke. E-cigarettes are powered by small batteries which present no more fire risk than other battery powered devices.

5) Electronic Cigarettes are sold as a less harmful alternative to smoking and by their very nature provide users an effective mechanism for weaning off nicotine by controlling the exact concentration in e-liquid. This does not mean it should be considered a smoking cessation product when it is not sold as such. Many non cessation products may be used as a tool for cessation, yet they are not sold with that claim. A person that chooses to chew on a pen to help relieve cravings does not turn that pen into a cessation product.

De-normalization of smoking is in danger of crossing the line into de-normalizing and devaluing the rights of individuals who smoke. Individuals should not be prevented from pursuing a safer alternative, when that alternative clearly exists, nor viewed as an unimportant element in the discussion. Electronic cigarettes hold real potential to further de-normalize tobacco use, and thus further the march against preventable death and disease from tobacco use in Canada.

Indentifying an Appropriate Regulatory Framework

Most countries are encountering difficulties classifying e-cigarettes into existing regulatory frameworks. Three product classifications attempted are: **Tobacco products**, **Pharmaceutical/medical products**, and **Consumer products**. Issues have arisen within each category. Medicinal product regulation has resulted in high profile (and successful) court challenges. Tobacco regulation is also under court challenge in the European Union. In the US it is facing ongoing resistance from the industry and consumers. General consumer product regulation remains inadequate to address the unique needs of this product and its presentation in the market. These issues are contributing to confusion, misinformation, lack of communication and the rise of unregulated and/or semi-regulated industry globally.

1) **Tobacco Regulation**: Regulating electronic cigarettes as Tobacco would result in them being understood by the public as "part of the problem", rather than a potential solution. Tobacco regulation was designed to discourage use by any means possible, due to negative health effects. This is completely inappropriate for a competing product with no proven harmful effect, no tobacco element and no smoke. Regulation in this category will result in
   a) Increasing the involvement of tobacco corporations in this industry, who do not have the same incentive of seeing the product as a means of reducing and eventually replacing tobacco use.
   b) Stifling innovation, improvement and change. Electronics, which are in constant states of change cannot be regulated as an organic crop.
   c) Further entrenching incorrect information that electronic cigarettes are a tobacco product, for those unfamiliar with the product. Electronic cigarettes should stand or fall on their own merits alone, solely within the context of their own unique make-up.

2) **Pharmaceutical & Medicinal regulation**: Regulating electronic cigarettes as a medicinal or alternative health product is the most devastating and harmful option to consider. Such attempts have been successfully challenged in the courts in the US, Norway, Germany and Eastonia – and challenged within the system (not via courts) in a number of other jurisdictions, globally.

   Medicinal regulations are created to address specific needs and requirements for treatments in medical therapy intended to address existing diseases and conditions. Individuals choosing to consume alternative products to increase their health and prevent the potential of disease is not considered "medical therapy" for any existing product.

   Electronic cigarettes are not a therapy. They have no medicinal or treatment value. They are a harm reduction product intended to replace the desire and need for tobacco

cigarettes, cigars and other smoked tobacco products.

The process for medicinal approval, either as a natural / alternative health product or a medicine contains requirements that this product, in all its presentations, are unable to meet. These would include: a prescribable period of use, proof of efficacy, medical device license, and strict dosage control. Electronic cigarettes were not invented, nor patented in any way that would support this process.

Calls to apply for medicinal approval have resulted in a stifled domestic industry, lack of correct information to the public, lack of communication between regulators and industry, and the continued forward march of tobacco related death and disease amongst Canadians who may have otherwise chosen to try an alternative.

3) **Consumer Product Regulation**: Regulating electronic cigarettes as general consumer products provides the most appropriate regulatory fit. However blindly adopting this regulation without modification presents some challenges. Consumer regulation does not usually require age restrictions, laboratory testing guidelines and ongoing investigation into the safety profile of elements in eliquid that are inhaled, (a slightly different use than is common to the ingredients) and should be monitored.

4) **Custom electronic cigarette regulation**: A new and unique regulatory structure for electronic cigarettes is the most preferable structure. Custom regulations would permit the industry, science and public health to collaborate information on an on-going basis, to ensure that, should any element of the product pose issues, it can be immediately and properly addressed and applied to the product consistently.

   Consumers are better served when this industry is working smoothly within a shared and cooperative environment.

   While tobacco is an organic crop product, and very different than electronic cigarette products, that shared cooperative environment may have mitigated much of the damage tobacco has visited on the world.

Realizing Benefits and Addressing Risks

52 of the world's leading medical and clinical research scientists have very clearly recognized, and spoken to, the benefits of electronic cigarette use for smokers.
http://nicotinepolicy.net/documents/letters/MargaretChan.pdf

Smoking tobacco is a serious health concern. The very process of burning any organic material

and inhaling the smoke a health risk, and tobacco smoking is well proven as the leading cause of preventable death and disease, world-wide. Smokers who are unable or unwilling to quit and new smokers who would choose an alternative, if it were readily available, will benefit from electronic cigarettes.

Vaporizing a liquid does not involve combustion, nor combustion related toxicants. E-liquid is made up of 4 primary ingredients, all of which have been independently approved for human use.

Should science discover, at some time in the near or distant future, that an element used in eliquid is harmful for inhaling, unlike an organic crop, the eliquid recipe can be altered for increased safety. This is the same process of harm reduction employed in most consumer products. *It's simply not possible to apply this same method to tobacco, as it is an organic crop whose elements cannot be changed, and inhaling smoke of any kind contains inherent, non-mitigatable risks.*

This underscores the need for an industry regulated in such a way that invites cooperation between science and industry, and standardizes manufacturing industry-wide. A cooperation ECTA actively pursues and supports.

ECTA members are currently required to submit samples of all eliquids to a comprehensive laboratory test that measures constituents and properties of the liquid and checks for contaminates. Our testing protocol has been lauded as the most advanced in the world and was created with scientific consultation from PhD's in Chemistry and Research Doctors with experience in clinical research on electronic cigarettes. While our members voluntarily submit to this process, and many non-member businesses also participate, regulations can ensure consistency in these processes for the entire industry.

If and when risks are identified, a healthy regulatory relationship will further the rights of individuals (consumers) by ensuring that risks can be properly addressed, while also permitting the Canadian industry to grow. This in turn, permits Canadian regulators to better control the product and its presentation in our Country.

Current risks include unfortunate sales to minors. This occurs mainly with 3rd party retailers. The lack of any specific legislation preventing sales to minors has created confusion in the market. With dedicated retailers openly ID'ing and refusing minor sales, while 3rd party retailers source products not clearly marked as "adult", freely and openly selling to minors in the absence of any rules saying otherwise. Regulation can easily address and remove this risk.

Other avoidable risks involve a lack of manufacturing oversight and a potential lack of

consistency in supply of raw materials. Manufacturers require open access to raw materials and the ability to select suppliers according to the standards they employ, as well as a framework of rules to operate within. Regulatory confusion has interfered considerably with this process, specifically in Canada, though also to some extent in the United States. Canadian consumer rights are thus overlooked.

The greatest risk remains a lack of oversight, a lack of consistent information and the replacement of science with ideologies often based on a questionable past relationship with tobacco corporations, or general fear and unwillingness to look at the product honestly.

SUMMATION

ECTA is willing and able to work with governing bodies and policy makers, to open and conduct discussions and investigations into the wealth of information currently available, including clinical, medical and laboratory studies. We recognize electronic cigarettes are a unique consumer product which bears a higher level of scrutiny due to its positioning as a replacement for a deadly, but commonly available tobacco, used daily by, and harming, over 5 million Canadians.

We are confused by the lack of real dialogue and the circulation of incorrect and incomplete information, the proliferation of “review” studies based on ideology holding preference over clinical investigations.

ECTA has commissioned an independent review by medical researchers of publications circulating among Canadian policy makers (at a regional and municipal level). Unfortunately, that review will not be completed in time for this meeting of HESA. We would be happy to submit it after the fact.

Meanwhile, we stand ready to open up and continue the conversation.

Appendix

Selection of Peer Reviewed Clinical and Laboratory Research

1. Polosa R, Morjaria J, Caponnetto P , Caruso M, Strano S , Battaglia E & Russo C. (2014). Effect of Smoking Abstinence and Reduction in Asthmatic Smokers Switching to Electronic Cigarettes: Evidence for Harm Reversal. *International Journal of Environmental Research and Health. 11(5), 4965-4977*
"Conclusion: The e-cig may help smokers with asthma to reduce their cigarette consumption or remain abstinent and hence reduce the burden of smoking-related asthma symptoms. The positive findings observed with e-cigs allows us to advance the hypothesis that these products may be valuable for smoking cessation and/or tobacco harm reduction also in asthma patients who smoke. Large randomized controlled trials are now needed to confirm and expand these preliminary observations."

2. Farsalinos K & Polosa R. (2014). Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Sage Journals: Therapeutic Advances in Drug Safety. 5 (2), 67-86*
"Abstract: Electronic cigarettes are a recent development in tobacco harm reduction. They are marketed as less harmful alternatives to smoking. Awareness and use of these devices has grown exponentially in recent years, with millions of people currently using them. This systematic review appraises existing laboratory and clinical research on the potential risks from electronic cigarette use, compared with the well-established devastating effects of smoking tobacco cigarettes. Currently available evidence indicates that electronic cigarettes are by far a less harmful alternative to smoking and significant health benefits are expected in smokers who switch from tobacco to electronic cigarettes. Research will help make electronic cigarettes more effective as smoking substitutes and will better define and further reduce residual risks from use to as low as possible, by establishing appropriate quality control and standards."

3. Burstyn I. (2014). Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. *BMC Public Health. 14(18)*
"Conclusion: Current state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to*contaminants* of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. However, the aerosol generated during vaping as a whole (contaminants *plus declared ingredients*) creates personal exposures that would justify surveillance of health among exposed persons in conjunction with investigation of means to keep any adverse health effects as low as reasonably achievable. Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern."

4. McAuley T, Hopke P, Zhao J & Babaian S. (2012). Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality. *Inhalation Toxicology. 24 (12). 850-857*
"Conclusions: For all by-products measured, electronic cigarettes produce very small exposures relative to tobacco cigarettes. The study indicates no apparent risk to human health from e-cigarette emissions based on the compounds analyzed."
5. Cahn Z & Seigal M. (2011). Electronic cigarettes as a harm reduction strategy for tobacco control: A

step forward or a repeat of past mistakes? *Journal of Public Health Policy. 32. 16-31*
"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."

6. Caponnetto P, Auditore R, Russo C, Cappello GC & Polosa R. (2013). Impact of an electronic cigarette on smoking reduction and cessation in schizophrenic smokers: a prospective 12-month pilot study. International J of Environ Res Public Health. 28;10(2). 446-61
"Conclusions: We have shown for the first time that the use of e-cigarette substantially decreased cigarette consumption without causing significant side effects in chronic schizophrenic patients who smoke not intending to quit. This was achieved without negative impacts on the symptoms of schizophrenia as assessed by SAPS and SANS symptoms scales."

7. Dawkins L, Turner J, Hasna S & Soar K. (2012). The electronic-cigarette: Effects on desire to smoke, withdrawal symptoms and cognition. Addict Behav. 37(8). 970-973.
"Abstract: Electronic cigarettes (e-cigarettes) are battery operated devices that deliver nicotine via inhaled vapour. Few studies have evaluated acute effects on craving and mood, and none have explored effects on cognition. This study aimed to explore the effects of the White Super e-cigarette on desire to smoke, nicotine withdrawal symptoms, attention and working memory. Eighty-six smokers were randomly allocated to either: 18 mg nicotine e-cigarette (nicotine), 0 mg e-cigarette (placebo), or just hold the e-cigarette (just hold) conditions. Participants rated their desire to smoke and withdrawal symptoms at baseline (T1), and five (T2) and twenty (T3) minutes after using the e-cigarette *ad libitum* for 5 min. A subset of participants completed the Letter Cancellation and Brown–Peterson Working Memory Tasks. After 20 min, compared with the just hold group, desire to smoke and some aspects of nicotine withdrawal were significantly reduced in the nicotine and placebo group; the nicotine e-cigarette was superior to placebo in males but not in females. The nicotine e-cigarette also improved working memory performance compared with placebo at the longer interference intervals. There was no effect of nicotine on Letter Cancellation performance. To conclude, the White Super e-cigarette alleviated desire to smoke and withdrawal symptoms 20 min after use although the nicotine content was more important for males. This study also demonstrated for the first time that the nicotine e-cigarette can enhance working memory performance. Further evaluation of the cognitive effects of the e-cigarette and its efficacy as a cessation tool is merited."

Selection of ECTA regulations:

1. Mandatory age restrictions – this prevents minors from purchasing electronic cigarette products. All retail venues require specific signage informing consumers that minors are not permitted to purchase.

2. Mandatory and continuous e-liquid testing – e-liquid from every member is sent to a Health Canada accredited lab for chemical analysis and to ensure nicotine content is accurate and contaminates are not present.

3. Standards for the detection of potentially harmful e-liquid contaminants – ECTA leads the world in setting contaminant limits based on accepted OSHA exposure limits. Products that fail testing cannot be sold.

4. Hardware quality control – All devices must be tested to meet the minimum FCC or CE standard for quality, and bear a quality mark. Optional ROHS certification is also preferred, to ensure that harmful substances are not carried over from the manufacturing process. As Canada does not require ROHS certification, this remains optional – but is generally available for most imported products, and thus preferable.

5. Retail Display standards – Products that may contain nicotine are not accessible from the retail floor.

6. E-liquid standards – E-liquid must have CCCR2001 compliant labels with appropriate warning symbols and information, including product specific additions such as a “no minors” designation. E-liquid must be sold in child resistant containers.