



Ray Yates

Comment from Ray

Site Data

Regulatory
AgendaAgency
ReportComment Period (Required
by Statute
Aug 8 2014, at 11:59

This is a Comment on the **Food and Drug Administration (FDA) Proposed Rule: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Extension of Comment Period**

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ID: FDA-2014-N-0189-77173

Tracking Number: 1jy-8dnz-nbz2

Document Information

Date Posted:

Aug 27, 2014

RIN:

0910-AG38

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Submitter Information

Category:

Individual Consumer

Comment

Hi, my name is Ray and I am a former smoker. I'm 65 years old and have smoked at least a pack of cigarettes a day since I was 19 years old. January 2013 I was hospitalized and diagnosed with advanced emphysema complicated with pneumonia. Fortunately I left the hospital 6 days later with 3 puffers (one includes steroids) and the full knowledge my lungs were full of holes and breathing was only going to get worse as there is no cure for the damage done. I tried to stop smoking but lasted only 5 more days and started to smoke again. I don't know why and I could only provide a guess if I were to try providing a reason. In June I was belatedly (they said they had no up to date phone number for me) contacted by the hospital who informed me to visit a lung specialist a week later. I did and was shown x-rays of my lungs which also showed I had a spot growing one of my lungs which had increased in size since January. Of course it was assumed to be cancerous by the doctor. I was given 3 choices of , chemo, radiation or remove the lung. I turned all 3 down and was therefore given and estimated 3-6 months to life if I do nothing about this. Well I did plenty actually on my own knowledge, research and informed decision making logic. I'm past the 3-6 months and still going strong. I chose natural remedies in diet, exercise, activity and even though I still have to use the puffers (including the steroid) I do not depend on them as much as I initially did.

I also stopped smoking cigarettes by simply opening my mind to one of these fake cigarettes (electronic) with fake smoke (vapour) after lengthy research on them. I am one of the stakeholders because of this. I had assumed for a few years it was Tobacco companies making them and they were just targeting kids. I was wrong. Tobacco never did want to see then until the realization they were slowly but surly helping smokers quit entirely. I have personally been through the patch gum, lozenges and even tried the mist just after my hospital stay. I couldn't do it. I bought my first electronic device from a company now owned by Tobacco. Greensmoke. I bought it in August 2013 and it arrived on the 30 of August. I fired it up on September 1st with the same though in mine as my other attempts. Give it a fair chance. I have not had a cigarette since. To me this is ingenious. A simple mechanical device emitting vapour (with or without nicotine) I still use mine. I still use nicotine in mine. I did research on nicotine also and propylene glycol . My documented research indicated both have health benefits in other forms of use, such as nicotine use for aiding in schizophrenia and nicotine therapy in epilepsy. A recent discovery from the Florida hospital provides a young 5 year old (Karen Machon) relief from seizures. Nicotine also is not as deadly as many have come to believe. In fact other studies on nicotine including one from the FDA that the risk of overuse or addiction from u top 4mg is not as concerning as once thought. Propylene Glycol as has been used for years in medical inhalers and even in hospital to rid possible bacteria in the atmosphere. This was and still is very important to me with my limited lung functions. I cannot afford to contact pneumonia again nor can I risk inhaling chemicals that may cause more damage. I do use flavors as my sense of taste has effectively returned to my surprise and I love it. The tobacco flavors or e-liquid is of no interest to me any longer because they remind me of when I first started and cigarettes were still fresh in my memory. I presently use 1.8mg nicotine strength without flavoring (as suggested by Hon Lik's -the originator of marketing this ingenious device.) facebook page. It's not bad at all but most importantly still keeping me away from smoke.

In conclusion I wish to believe the FDA, Health Care, Cancer Societies, Lung Associations, Hearth Associations truly do have mine and the other estimated 6,000,000 deaths that will occur over the next 12 months. I do agree Harm Reduction is in need of more data but for now the Research is what brought me beyond the time I was given to live. Giving up and giving in was not part of my moral beliefs and never will be. In a moral sense I believe denying other smokers of the possible Harm Reduction of this device is nothing short of neglect. Neglect that we have an answer even if it's not the perfect one millions of smokers cannot or would rather not achieve. It's more important to offer this option legally and without strident regulation. Quality control is all that is really need here. Like I did.....give it a fair chance. It's worked and I am PROOF and testament to this. I have included a couple of files with research on the behalf of the other 5999,999 other smokers out there who will surely die of smoking related disease and neglect if the FDA does not respond sensibly to the real stakeholders in this world wide decision. Thank you for listening..

Ray and Family

Attachments (1)



THRA

Tobacco Harm Reduction Association of Canada

The Tobacco Harm Reduction Association of Canada (THRA) is a Not-For-Profit advocacy group. Our mission is to promote the availability of effective, affordable and reduced harm alternatives to smoking by increasing public awareness and to encourage the testing and development of products to achieve acceptable safety standards and reasonable regulation; and to promote the benefits of reduced harm alternatives

Use of electronic cigarettes and the act of vaping is not smoking. Use of nicotine outside of tobacco, has never been considered "smoking". Vapour is not smoke and not any source of second-hand smoke.

Tobacco Harm Reduction Association of Canada

Position Statement Brief on Electronic Cigarettes

Background

Electronic cigarettes (electronic cigarettes) are designed to deliver nicotine and mimic the appearance, use, and - occasionally - taste of a cigarette. A typical electronic cigarette consists of a battery, an atomizer that heats e-liquid into a vapour, and a cartridge/tank that contains flavouring in a base of propylene glycol or vegetable glycerin and water. The e-liquid may also contain nicotine.

There are three types of electronic cigarettes:

- **Cig-Alikes** look like traditional cigarettes and have a cartridge. Many of these devices have been purchased by tobacco companies, who market them.
- **Second Generation** electronic cigarettes are refillable tank systems.
- **Third Generation** electronic cigarettes are called mods. These are also refillable tank systems and can be built and rebuilt into many configurations.

The Tobacco Industry recently requested the United States FDA ban second and third generation systems. It appears that they cannot compete and have lost market share to these newer evolving and better systems (1). These Second and Third Generation systems are sold by local entrepreneurs who provide jobs and pay taxes.

The number of Electronic cigarette users has climbed to several million worldwide. Electronic cigarettes have become the center of an industry that has grown in the last four years approximately from \$82 million to \$2.5 billion in annual sales. It is estimated that sales of electronic cigarettes will surpass and supplant tobacco cigarettes by 2024. It should be noted that tobacco companies have only recently entered into the electronic cigarette market, (since 2012) by purchasing some larger electronic cigarette companies. Many of those companies manufactured devices that were reaching the end of their market viability.

The majority of Electronic cigarette sales are by small business -- brick and mortar stores and internet online shops. Studies show that many new vapers start with cig-alikes but quickly move on to better tank systems.

There is tremendous public confusion over the legal status of these products which appear to be in a legal grey zone. Federal, Provincial (and territorial) and city tobacco control legislation is under pressure to act on this new technology that is neither tobacco nor a medicine.

The municipalities of Vancouver and Toronto have or are considering categorizing electronic cigarettes under smoke free bylaws. Decisions are being made using faulty, misleading and erroneous studies with minimal or no input from the public. We believe that before any bill is tabled, there needs to be a meaningful interaction between the

legislators and the Vaping community. At present, legislators have summarily disregarded current scientific and medical studies.

The current proposals and methodologies to regulate electronic cigarettes are not acceptable. Regulations covering standardization, testing, promotion, sale, and use of electronic cigarettes (with and without nicotine) are urgently needed. Many studies have been completed or are under way in the US and United Kingdom, demonstrating that electronic cigarettes are a promising Tobacco Harm Reduction strategy (2). We await the results of further research, including several clinical trials in process. With available data, a number of conclusions can be drawn:

- Vapers use electronic cigarettes because they want a safer alternative to smoking. Electronic cigarette mimic the process of smoking without the thousands of chemicals and known carcinogens in tobacco smokes. Vapers are using a Tobacco Harm Reduction strategy that costs tax payers nothing yet supports Public Health goals of reducing smoking levels and quite possibly contribute to many smokers quitting.
- Electronic cigarettes are much safer than tobacco cigarettes. To date there is no evidence of harm from electronic cigarettes. (3)
- Electronic cigarettes have great potential to help smokers reduce cigarette consumption and possibly quit smoking altogether. However, electronic cigarettes are not a smoking cessation product but can be used for that purpose if the vaper chooses (much the same way a smoker might use a carrot or regular chewing gum). Although propylene glycol is generally considered safe for oral consumption, the long-term health impact of inhaling propylene glycol into lungs many times daily over a period of months or years needs to be assessed. It must be noted, though, that propylene glycol is used in asthma inhalers and the Nicotine Replacement Therapy (NRT) product "Nicorette Inhaler".

Public Health concerns over electronic cigarettes have prompted studies on the possible risks associated with vaping. These studies demonstrate that risks are of minimal concern. Despite these results, the risks should still be monitored on an on-going basis:

Youth Gateway

Youth "gateway use of electronic cigarettes to smoking" has largely been discounted as minimal to non-existent. US, UK and Canadian (4) Youth Tobacco surveys as recent as 2013 show cigarette use at their lowest levels ever recorded with steady declines over the past three years. The UK ASH survey shows that Youth using electronic cigarettes were already smokers and uptake of non smoking youth using electronic cigarettes to smoking was negligible (5);

Renormalization

Recent studies show that electronic cigarettes do not re-normalize smoking, rather it replaces tobacco and normalizes vaping; In the United States, FDA Director Dr Zeller is quoted as saying that if all smokers quit smoking and switched to electronic cigarettes it would be a boon for Public Health; (6)

Flavours

Flavours are a primary feature for smokers who choose electronic cigarettes as an alternative to smoking tobacco products. As smokers switch they start to regain their sense of taste and gravitate from tobacco-like flavours to fruit and other sweet flavours. NRT's, used as smoking cessation products, also feature flavours. Some public health officials have cautioned that sweet and fruit flavours target minors. This is an unacceptable idea, as the exact same flavours are also enjoyed in alcohol and energy boost drinks. (7)

Dual Usage

Dual usage (tobacco and electronic cigarettes) is common among new vapers. The transition from smoking to vaping is individual and often tailored by the individual to their own tastes and needs. Where dual usage is a factor, studies conclude that users smoke less tobacco products. This same issue is also part of NRT usage, and noted by the FDA as permissible (8).

Nicotine

Nicotine is the ingredient smokers crave from tobacco smokes. People "smoke for the nicotine but die from the smoke and tar". Vapers use nicotine in varying strengths and can gradually decrease levels to zero nicotine. Nicotine when stripped from cigarettes is no more addictive than caffeine... Nicotine is also used in all smoking cessation products. It is also resident in many everyday vegetables, such as tomatoes, egg plant and green peppers (over 100 vegetables are noted as containing nicotine) (9).

Nicotine Poisonings

Nicotine poisonings are recently emphasized and sensationalized in the news, and have become attributed almost entirely to electronic cigarettes, in spite of a number of other far more common nicotine products on the market. Nicotine used in e-liquid for electronic cigarettes is not pure or concentrated; it is a highly-diluted pharmaceutical grade nicotine, comprising not more than 2.4% of any e-liquid used for vaping.

As these products are relatively new, usage is increasing. Reports of possible poisoning may increase. To our knowledge, there is not a single confirmed report of a death attributed to e-liquid poisoning.

There are 14 possible nicotine exposures in Canada (reported in BC) over the past three years. In the US there were 2700 possible nicotine exposures out of 2.2 million poisoning calls in 2013. Statistics show that over-the-counter medications left out for children are the leading cause of poisoning fatalities (10).

Vapers using e-liquid should be safety conscious, treating the product the same way as alcohol, medical drugs and household hazardous products - properly sealed and out of reach of children.

Vapour Emissions

Vapour emissions have become a concern of non-vapers due, in large part, to publicity campaigns. Studies show that exhaled vapor contains nicotine and nitrosamines (11) but at such low levels that there is no discernible harm to the user or bystanders (12), and measurable amounts are similar to nicotine ingestion from common vegetable consumption. On-going studies should continue and evaluate health effects on vapers and non-vapers (13).

Advertising

Electronic cigarette advertising in Canada is very limited and aimed exclusively to adult smokers and not youth. The UK has recently instituted advertising standards for electronic cigarettes, to prevent inadvertently swaying youth to the product (14). Adult advertising will ensure that smokers will know there is a safer alternative to smoking available.

Public Vaping

Public vaping is a controversial subject. Some anti-smoking organizations have lumped vaping in with tobacco and become "anti-vaping" without recognizing significant differences. They are campaigning to restrict vaping in public areas for the fear that it "may" promote smoking. An "out of sight out of mind" theory. Electronic cigarettes, however, provide individuals who smoke a safer alternative. In the United States, New York City recently restricted electronic cigarettes in public spaces. The result: smoking rates rose by 2% (15).

We believe individual business owners should be permitted to make decisions on vaping for their own establishments. No harm has been demonstrated from the use of electronic cigarettes to vapers or bystanders. We agree that some venues should restrict vaping: schools, libraries, court houses and facilities with safety/health requirements (oxygen etc).

Vapers are, in general, aware that vaping may make non-vapers uncomfortable and permission should be asked until vaping is better understood by the public. There is a growing understanding among most vaping users about being courteous to non-vapers.

Taxes

Taxes, other than the standard sales tax, should not be levied on electronic cigarettes or liquid. Electronic cigarettes are not tobacco products and do not have the same health or medical profile as tobacco products. Special taxes are levied on tobacco products for a reason. There is no similarity to electronic cigarettes as these help in combating smoking and support public health goals.

Age Restrictions

We support age restrictions according to each jurisdiction's definition of a "minor". Legislation should be enacted for all electronic cigarette liquids that contain nicotine.

Recommendations

1. Because of the limited effectiveness of smoking cessation aids and the potential of electronic cigarettes for smokers to reduce their health risks, the sale of electronic cigarettes must not be banned or restricted.
2. Health Canada along with Federal, Provincial (and Territorial) governments should finance ongoing research — on a priority basis — to determine: usage of electronic cigarettes, reasons, and circumstances, as well as continues to examine health effects.
3. Electronic cigarette devices, parts, and cartridges must be required to meet the same minimum manufacturing standards as other products under Canadian consumer protection law. These provisions should be actively enforced.
4. The sale of bottled e-liquid to consumers must be allowed with defined regulations in place, addressing manufacturing and labeling to provide a safe and secure product. Standards should include child-proof caps and tamper-proof caps (or seals) as well as product information and all applicable warnings and alerts.
5. Flavours must be allowed in e-liquids. Adults enjoy them and flavors assist in maintaining use of electronic cigarettes as an alternative to tobacco products.
6. Canada must establish and actively enforce consumer safety standards

for electronic cigarettes, cartridges and tanks, and e-liquids -- including ensuring manufacturing consistency, testing and regulating the quality and strength of nicotine contained in e-liquid.

7. The packaging of Electronic cigarette cartridges, e-liquid containers and disposable electronic cigarettes must include a list of all ingredients, including nicotine strength. All nicotine containers should all have child-proof caps and tamper-proof caps (or seals).
8. Electronic cigarettes must not be sold to minors (federal and provincial tobacco control legislation).
9. Electronic cigarettes must be promoted only to smoking adults and a guideline for advertising be provided similar to the UK CAP advertising code that will be implemented 10 November 2014.
10. Electronic cigarette use in indoor public places and workplaces should be left up to the discretion of the business owner. Government owned facilities and policy will be decided by the applicable government department.
11. Electronic cigarettes must be banned on school grounds (provincial).
12. Claims that electronic cigarettes are safer than tobacco products must be allowed. Many studies from respected scientific and health organizations (such as the American Heart Association, Heart and Stroke, and NSRA) have determined that electronic cigarettes are safer than tobacco products. Any cessation claims including their effectiveness in helping smokers quit, should continue to be avoided —Health Canada should actively enforce this provision — until there is adequate scientific evidence to support such claims.
13. Health Canada should set up a smoking tool kit, similar to those used in the UK, to monitor monthly smoking and Electronic cigarette usage (16).
14. Electronic cigarettes are not a smoking cessation product, but may be used for cessation if desired by the vaper. Electronic cigarettes are not tobacco or pharmaceuticals and should not be classified under tobacco or pharmaceutical legislation. A third option, for vaping, must be developed with all political levels in consultation with Public Health, Industry and vaper user involvement to provide a balanced and fair legislation that protects all Canadians (17).

Conclusion

Electronic cigarettes and vaping should be endorsed as a Tobacco Harm Reduction strategy that can minimize or alleviate over 37,000 Canadian smoking and related deaths each year. Regulations governing this consumer product should be balanced and fair to protecting vapers and non-vapers.

Science and logic should be the guides for public health policy, rather than applying anti tobacco ideology and rhetoric to electronic cigarette products that are free of tobacco. Such policies and outcomes will save Canadians' lives, now and into the future (18).

“Nothing about us without us (19)”

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