

A Healthier Perspective on Public Health and e-Cigarettes: A Response To Carney

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Let's get this out of the way: e-cigarettes are not an FDA approved smoking cessation product. Let us examine why. Current estimates put the cost to gain FDA approval for a new drug at \$500 million dollars or more.¹ Due to FDA rules, any change in flavorings used or concentration of active ingredients requires a new approval. This creates an immense cost. Take the company I work for, Vermont Vapor, Inc., in Castleton, Vermont. Vermont Vapor manufactures 26 flavors of e-liquid (the liquid that is heated to create a vapor in an electronic cigarette). All of those flavors are available in one of five strengths ranging from no nicotine whatsoever to 35 mg/ml. Thus, the total FDA approvals Vermont Vapor would need to obtain to be approved would be one hundred and thirty. The cost for gaining approval for 130 new drugs? 65 billion dollars.² Now, I don't believe I'm giving away any corporate secrets by disclosing that my company doesn't have a spare 65 billion dollars. But don't feel too bad for it: the GSP/GDP of Vermont is less than 30 billion.³

The FDA also does not allow e-cigarettes to be marketed as safer than combustible cigarettes. Again, this needs explanation. If you make (almost any) health claim about a product, under FDA rules that product is treated as a drug or device requiring FDA approval.⁴ Indeed, the FDA has threatened walnut producers who made health claims because those claims – that omega-3 fatty acids found in walnuts may help lower cholesterol – transformed the walnuts into drugs.⁵ So, for example, if a farmer sold carrots at the farmers' market and said that munching on carrots was safer than smoking, she would be in violation of federal law by selling unapproved drugs. Now, most reasonably sane people can agree that eating carrots is healthier than smoking cigarettes. Likewise, most experts agree that vaping (using an e-cigarette) is healthier than smoking⁶, most likely 95-99.99% healthier.⁷ But the law precludes sellers (of e-cigarettes or of carrots) from using that information in marketing.

Professor Jan Carney recently claimed in her commentary on vtdigger.org that it is a myth that e-cigarettes help people quit smoking.⁸ Without getting out a dictionary, I think it is fair to say that a myth is something believed without evidence. Unfortunately for Ms. Carney, there is evidence that e-cigarettes are as effective if not much more effective than FDA approved smoking cessation methods. A peer reviewed study published in 2011 found 22.5% of smokers who were “unwilling to quit” that used e-cigarettes were able to quit smoking.⁹ This is equivalent to the quit rate for FDA approved smoking cessation products when used by smokers who wanted to quit. Another study published in the American Journal of Preventative Medicine found a 70% quit rate among those who used e-cigarettes more than 20 times per day.¹⁰ And, finally, a recent survey¹¹ of 88 e-cigarette users conducted in Castleton, Vermont, found that of those surveyed, 96.6% had quit smoking and the average time since quitting smoking was 3 years. The average time they had smoked cigarettes prior to quitting was 25 years. Only 3 of the

1 http://www.medscape.com/viewarticle/405869_4

2 Note: It is possible that costs could be lowered by using the 505(b)(2) pathway. If the FDA approved that pathway, the cost for each subsequent NDA could drop to as low as \$3 million. However, even at that level, the total cost would be \$1.88 billion or more

3 https://en.wikipedia.org/wiki/List_of_U.S._states_by_GDP

4 See e.g. <http://www.thompson.com/public/newsbrief.jsp?id=2145>

5 <http://www.fda.gov/iceci/enforcementactions/warningletters/ucm202825.htm>

6 CDC: <http://www.cdc.gov/tobacco/stateandcommunity/pdfs/cdc-osh-information-on-e-cigarettes-november-2015.pdf>

FDA: <http://motherboard.vice.com/read/the-fda-says-e-cigarettes-are-less-harmful-than-smoking>

NHS: <http://www.nhs.uk/news/2013/06/June/Pages/e-cigarettes-and-vaping.aspx>

AHA: <http://circ.ahajournals.org/content/early/2014/08/22/CIR.000000000000107.full.pdf>

7 See NHS supra at 6; see also <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4154473/> (vaping up to 450 times safer than smoking);

8 <http://vtdigger.org/2016/03/07/jan-k-carney-the-myths-and-facts-about-e-cigarettes/>

9 <https://bmcpubhealth.biomedcentral.com/articles/10.1186/1471-2458-11-786>

10 [http://www.ajpmonline.org/article/S0749-3797\(10\)00792-0/](http://www.ajpmonline.org/article/S0749-3797(10)00792-0/)

11 “e-Cigarette Questionnaire” See attached.

respondents (3.4%) still smoked (“dual users”). Only one of the respondents had never smoked cigarettes; note, however, that the survey did not inquire about other prior nicotine product use (snuff, snus, chew, patch, gum, etc.).

Of particular concern to Ms. Carney is the fact that “high school students who used e-cigs were actually more likely to use other tobacco products in the next year.”¹² While this may, indeed, appear concerning at first glance, it should be noted that minors are currently forbidden under state law from possessing e-cigarettes. The students who are using e-cigarettes are in violation of state law (the technical term for this is juvenile delinquency).¹³ It should, therefore, come as no great surprise that those minors who are currently violating one law would be more willing to break another law.

I would also like to take a more in depth look at Ms. Carney's claims regarding the safety of e-cigarettes. First, Ms. Carney states that “e-cigarette vapor *may* contain nicotine, heavy metals and ultrafine particles, lung irritants, and *potentially* cancer causing substances” [emphasis mine].¹⁴ Nowhere, however, does she talk about the amount of the substances present in e-cigarette vapor or whether that amount is sufficient to cause any risk. Municipal water *may* contain arsenic and mercury – indeed, it is quite common.¹⁵ The question isn't whether a particular substance is present, but whether a dangerous amount of that substance is present. In fact, this question was answered by researchers in 2014, finding “[t]here was no evidence of potential for exposures of e-cigarette users to contaminants that are associated with risk to health at a level that would warrant attention if it were an involuntary workplace exposures. . . . Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.”¹⁶

Second, Ms. Carney cites a widely discredited letter¹⁷ to the editor of the New England Journal of Medicine on the presence of formaldehyde. However, the results produced by those researchers were the result of e-cigarettes being used by a machine in an improper manner that caused incomplete combustion.¹⁸ One byproduct of incomplete combustion is formaldehyde. E-cigarettes are designed to heat the liquid inside (a type of alcohol) to it's boiling point; not to set it on fire. No human could withstand the burning and acrid taste produced by this, yet with no humans involved in the study, the machine just kept puffing. This should be common sense. Indeed, it is analogous to maple sap: heated to the right temperature, it is quite tasty and reasonably healthy. But if you let it boil too long it will light on fire and smoke and dangerous byproducts like formaldehyde are produced. Used properly, studies have found e-cigarette vapor to contain less formaldehyde than plain human breath.¹⁹

Far from “supporting adults' decisions to quit smoking,” as Ms. Carney claims, H.171 would force e-cigarette users who have quit smoking years ago to breathe in secondhand smoke – something even Ms. Carney must admit, is bad for their health.

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Author's Note: The opinions and views expressed herein are those of the author, individually, and do not necessarily represent the views of Vermont Vapor, Inc., where the author is employed.

12 Supra at 8.

13 7 V.S.A. § 1005.

14 Supra at 8.

15 <http://www.epa.gov/dwreginfo/chemical-contaminant-rules>.

16 <http://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-14-18>.

17 <http://www.nejm.org/doi/full/10.1056/NEJMc1413069>.

18 <http://onlinelibrary.wiley.com/doi/10.1111/add.12942/>.

19 http://www.acvoda.nl/wp-content/uploads/2013/11/Therapeutic_Advances_in_Drug_Safety-2014-Farsalinos-2042098614524430.pdf