



October 22, 2013

The Honorable Margaret Hamburg, Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD 20993

Re: FDA Regulation of E-Cigarettes

Dear Commissioner Hamburg:

On behalf of the Association of State and Territorial Health Officials (ASTHO), we urge the Food and Drug Administration (FDA) to take all available measures to meet the FDA's stated deadline of October 31, 2013, to issue proposed regulations that will address the advertising, ingredients, and sale to minors of electronic cigarettes (known as e-cigarettes).

We believe that the FDA should have the authority to regulate the manufacturing, marketing, labeling, distribution, and sale of all tobacco products because it is the only agency with both the scientific expertise and regulatory authority to accomplish this mission. The FDA has the authority to regulate electronic cigarettes as "tobacco products" under the Tobacco Control Act, as they are products "made or derived from tobacco" that are not a "drug," "device," or combination product. Furthermore, case law, such as *Sottera, Inc. v. Food & Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010), supports the contention that e-cigarettes are "made or derived from tobacco" and can be regulated as "tobacco products" under the Tobacco Control Act. We urge the FDA to act quickly to ensure that all tobacco products are tested and regulated.

Considerable controversy has arisen over the contents of e-cigarette cartridges. Evidence suggests that e-cigarettes contain lower levels of some common tobacco-related toxicants than traditional cigarettes,¹ but an analysis by your agency identified concentrations of several impurities harmful to human health in e-cigarette cartridges.² E-cigarettes are also produced by a number of different manufacturers, and the level of exposure to nicotine and toxins can vary widely between products, some of which contain nicotine levels that approach fatal doses.³ The amount of nicotine and other substances delivered in an e-cigarette often fluctuates between puffs taken by the same user.^{4,5} The labeling of e-cigarettes may also be misleading. Your agency also found that e-cigarettes claiming to be nicotine-free actually contain small amounts of nicotine.⁶ Research confirms that smoking e-cigarettes has many of the same immediate adverse effects on lung functions



as traditional cigarettes.⁷ As a relatively new and understudied product, however, any long-term health effects of e-cigarettes remain unknown.

E-cigarette users are most likely to be current smokers.^{8,9} Research of tobacco consumers demonstrates that e-cigarettes may be used as a smoking cessation device or harm-reduction tool when substituted for cigarettes.^{10,11} Your agency does not, however, formally recognize e-cigarettes as a form of nicotine replacement therapy.¹² Some tobacco experts have also cited concerns that instead of being used as a quit aid, e-cigarettes may be a gateway that entices more consumers—particularly youth—to initiate using tobacco products and become addicted to nicotine.¹³

High school students' use of e-cigarettes has doubled over the course of one year according to the data from the CDC's 2011 and 2012 National Youth Tobacco Surveys. In addition, 1.8 million middle and high school students said they had tried e-cigarettes in 2012.¹⁴ This increased use is likely facilitated by the availability of these products at an affordable price. Consumers overwhelmingly believe that e-cigarettes are effective for cessation and purchase these products despite the fact that e-cigarettes are not FDA-approved cessation devices.¹⁵ Furthermore, e-cigarette manufacturers are developing products and using marketing techniques--such as different flavors and visually appealing cartoons or ad placements--to entice youth into using e-cigarettes, demonstrating that cessation and individual harm reduction are not the manufacturers' goals. These trends only exaggerate the urgent need for quick action.

ASTHO's members, the chief health officials of the 57 state and territorial jurisdictions, are dedicated to formulating and influencing sound public health policy and ensuring excellence in state-based public health practice. Therefore, we urge that the FDA meet the October 31, 2013 deadline to issue regulations regarding e-cigarettes. We support the FDA's mission to reduce tobacco use and decrease the morbidity and mortality associated with tobacco consumption.

Because tobacco use is a major driver in causing chronic disease, ASTHO's members are concerned with its public health implications. Tobacco use is the single most preventable cause of disease, disability, and death in the United States. An estimated 443,000 people die prematurely each year from smoking or exposure to second-hand smoke, and another 8.6 million have a serious illness caused by tobacco use.¹⁶ The emergence of novel tobacco products like e-cigarettes presents new challenges to state public health agencies and the public. Some key considerations for our membership include the inclusion of e-cigarettes into clean indoor air laws, youth marketing, and taxation laws. Until we understand more about the long-term health effects of e-cigarettes, these products should be tested and regulated as rigorously as conventional tobacco products.



Sincerely,

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¹ Goniewicz ML, Knysak J, Benowitz N, *et al.* “Levels of selected carcinogens and toxicants in vapour from electronic cigarettes.” *Tobacco Control*. March 6, 2013. Available at <http://tobaccocontrol.bmj.com/content/early/2013/03/05/tobaccocontrol-2012-050859.abstract>. Accessed 10-11-2013.

² FDA. “Evaluation of E-cigarettes.” May 4, 2009. Available at <http://www.fda.gov/downloads/drugs/scienceresearch/ucm173250.pdf>. Accessed 10-11-2013.

³ Cameron JM, Howell DN, White JR, *et al.* “Variable and potentially fatal amounts of nicotine in e-cigarette nicotine solutions.” *Tobacco Control*. Feb. 13, 2013. Available at <http://tobaccocontrol.bmj.com/content/early/2013/02/12/tobaccocontrol-2012-050604.extract>. Accessed 10-11-2013.

⁴ *Ibid.*

⁵ FDA. “Evaluation of E-cigarettes.” May 4, 2009. Available at <http://www.fda.gov/downloads/drugs/scienceresearch/ucm173250.pdf>. Accessed 10-11-2013.

⁶ *Ibid.*

⁷ Vardavas C, Anagnostopoulos N, Kougias M, *et al.* Short-term Pulmonary Effects of Using an Electronic Cigarette: Impact on Respiratory Flow Resistance, Impedance, and Exhaled Nitric Oxide. *Chest*. June 2012.141(6):1400-6. Available at <http://www.ncbi.nlm.nih.gov/pubmed/22194587>. Accessed 10-11-2013.

⁸ Pearson J, Richardson A, Niaura R, *et al.* “e-Cigarette Awareness, Use, and Harm Perceptions in US Adults.” *American Journal of Public Health*. September 2012. 102(9):1758-66. Available at <http://www.ncbi.nlm.nih.gov/pubmed/22813087>. Accessed 10-11-2013.

⁹ Regan AK, Promoff G, Dube SR, Arrazola R. “Electronic nicotine delivery systems: adult use and awareness of the 'e-cigarette' in the USA.” *Tobacco Control*. January 2013. 22(1):19-23. Available at <http://tobaccocontrol.bmj.com/content/early/2011/10/27/tobaccocontrol-2011-050044.abstract>. Accessed 10-11-2013.

¹⁰ Bullen C, Howe C, Walker N, *et al.* “Electronic cigarettes for smoking cessation: a randomised controlled trial.” *Lancet*. Sept. 9, 2013. Available at [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)61842-5/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)61842-5/abstract). Accessed 10-11-2013.

¹¹ Caponnetto P, Campagna D, Polosa R, *et al.* “Efficiency and Safety of an eElectronic cigarette (ECLAT) as Tobacco Cigarettes Substitute: A Prospective 12-Month Randomized Control Design Study.”

Plos ONE. June 2013. 8(6):1-12. Available at <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0066317>. Accessed 10-11-2013.

¹² FDA. "FDA 101: Smoking Cessation Products." Update Sept. 24, 2013. Available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm198176.htm>. Accessed on 10-11-2013.

¹³ CDC. "Notes from the Field: Electronic Cigarette Use Among Middle and High School Students –United States, 2011-2012." *Morbidity and Mortality Weekly Report*. Sept. 6, 2013. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm?s_cid=mm6235a6_w. Accessed 10-11-2013.

¹⁴ *Ibid*.

¹⁵ For examples, see comments made in response to a petition filed by the American Association of Public Health Physicians (AAHP) to the FDA, "Citizen Petition: Reclassify Nicotine Vaporizers (E-cigarettes) from 'Drug-Device Combination' to 'Tobacco Product'" (docket no. FDA-2010-P-0095 (Feb. 23, 2010), available at <http://www.regulations.gov#!docketDetail;D=FDA-2010-P-0095>, accessed 10-11-2013). Examples of comments from the public on the petition include: (1) "Electronic cigarettes have helped me to quit smoking. I have been tobacco free for over 6 weeks now after being a smoker of over 20yrs"; (2) "E-cigarettes have help me quit smoking real cigarettes"; (3) "I was able to quit smoking using the vaping method and have not smoked in over 2 months." *Id*. Indeed, there are many websites on which e-cigarette users claim to have quit smoking by using e-cigarettes. For example, on PuffWeb.com's "How to Quit Smoking in 30 Days Using Electronic Cigarettes," the page author writes, "The following is an account of my (successful) attempt at quitting smoking using Electronic Cigarettes. I was able to become smoke free in 30 days" (available at <http://www.puffweb.com/how-to-quit-smoking-in-90-days-using-electronic-cigarettes/>, accessed 10-11-2013).

¹⁶ CDC. "Tobacco Use – Targeting the Nation's Leading Killer." 2010. Available at http://www.cdc.gov/chronicdisease/resources/publications/aag/pdf/2010/tobacco_2010.pdf. Accessed 10-11-2013.