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September 24, 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,

The undersigned Attorneys General write to 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 (also known as e-cigarettes).

State Attorneys General have long fought to protect their States' citizens, particularly youth, from the dangers of tobacco products. For example, every State Attorney General sued the major cigarette companies for the harm their products caused. With the protection of our States' citizens again in mind, the undersigned Attorneys General write to highlight the need for immediate regulatory oversight of e-cigarettes, an increasingly widespread, addictive product.

As you know, e-cigarettes are battery-operated products designed to deliver nicotine to the user by heating liquid nicotine, derived from tobacco plants, along with flavors and other chemicals, into a vapor that the user inhales. The nicotine found in e-cigarettes is highly addictive, has immediate bio-chemical effects on the brain and body at any dosage, and is toxic in high doses.¹

E-Cigarette Sales are Growing Exponentially Using Marketing that Includes Television

Sales of e-cigarettes have grown rapidly in the United States, and after doubling every year since 2008, sales in 2013 are now accelerating even faster and projected to reach \$1.7 billion.² The cost of e-cigarettes has fallen

¹ U.S. Surgeon General, U.S. Department of Health and Human Services, *The Health Consequences of Smoking: Nicotine Addiction* (1988); Emergency Response Safety and Health Database, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, http://www.cdc.gov/niosh/ershdb/EmergencyResponseCard_29750028.html

² Compare Josh Sanburn, *Can Electronic Cigarettes Challenge Big Tobacco?*, Time.com, Jan. 8, 2013, available at <http://business.time.com/2013/01/08/can-electronic-cigarettes-challenge-big-tobacco/>, (estimating 2013 sales at \$1 billion), with Stuart Elliot, *E-Cigarette Makers' Ads Echo Tobacco's Heyday*, New York Times, Aug. 29, 2013, available at <http://www.nytimes.com/2013/08/30/business/media/e-cigarette-makers-ads-echo-tobacco-heyday.html>, (estimating 2013 sales at \$1.7 billion).

dramatically, as well, making them more affordable, and thus more attractive to young people. Unlike traditional tobacco products, there are no federal age restrictions that would prevent children from obtaining e-cigarettes, nor are there any advertising restrictions.

Along with the growth of e-cigarette sales, there has also been a growth of e-cigarette advertising over the past year. For example, in this year's Super Bowl broadcast, NJOY e-cigarettes purchased a 30-second television advertisement slot which reached at least 10 million viewers in certain markets and reportedly translated into a dramatic 30-40% increase in sales.³ The advertisement depicted an attractive man smoking an e-cigarette that looked just like a real cigarette. Since then, advertisements for e-cigarettes have regularly appeared on primetime television, making it easier for those advertisements to reach children. Moreover, e-cigarettes are not being marketed as smoking cessation devices, but rather as recreational alternatives to real cigarettes. Consumers are led to believe that e-cigarettes are a safe alternative to cigarettes, despite the fact that they are addictive, and there is no regulatory oversight ensuring the safety of the ingredients in e-cigarettes.

E-Cigarettes Appeal to Youth

E-cigarettes contain fruit and candy flavors -- such as cherry, chocolate, gummy bear, and bubble gum -- that are appealing to youth. The FDA has banned such flavors from cigarettes and should take the same action regarding e-cigarettes. E-cigarettes and refills of the liquid nicotine solution used with e-cigarettes can easily be ordered online without age verification. By intentional use or mistaken ingestion from the non-child resistant containers, e-cigarettes and liquid nicotine refills can deliver dangerously high doses of liquid nicotine to youth.

In addition to flavors, e-cigarette manufacturers, such as eJuiceMonkeys.com and Magic Puff City E-cigarettes, use cartoon monkeys to sell e-cigarettes,⁴ even though for many years, the major manufacturers of traditional cigarettes have been banned from using cartoons to advertise. Finally, e-cigarette manufacturers, such as White Cloud Cigarettes, offer reusable e-cigarette "skins" -- known as Vapor Jackets -- that are intended to make the e-cigarette desirable or fashionable and are available in a variety of patterns that appeal to children, one of which uses images from the popular video game, Angry Birds.⁵

Further, data from the 2011 and 2012 National Youth Tobacco Surveys (conducted by the Centers for Disease Control and Prevention) show that e-cigarette use among students doubled in the last year. Specifically, one in 10 high school students reported that they had tried an e-cigarette in the last year -- up from one in 20 in 2011, and 1.8 million middle and high school students said they had tried e-cigarettes in 2012.⁶ The increased usage among young people

³ Benjamin Wallace, *Smoke Without Fire*, New York Magazine, April 28, 2013, available at <http://nymag.com/news/features/e-cigarettes-2013-5/>.

⁴ See <http://ejuicemonkeys.com/> and <http://cityecigarettes.com/>

⁵ See <http://www.whitecloudelectroniccigarettes.com/accessories/vapor-jackets/>

⁶ Catherine Corey, *Notes from the Field: Electronic Cigarette Use Among Middle and High School Students -- United States, 2011-2012*, Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, September 6, 2013, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm?s_cid=mm6235a6_w

echoes the growth among adult users, and researchers indicated that aggressive marketing campaigns, in part, drove the increase.⁷

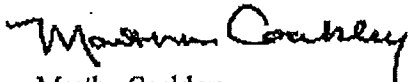
The FDA has Authority to Regulate E-cigarettes and Protect the Public

In the Tobacco Control Act, Congress recognized that nicotine is an addictive drug, and virtually all new users of tobacco products are under the age of eighteen and are therefore too young to legally purchase such products. Congress further found that tobacco advertising and marketing contributes significantly to the teenage use of nicotine-containing tobacco products. To help prevent children from using tobacco products, the Tobacco Control Act imposed restrictions on advertising and marketing to youth. These restrictions should be applied to e-cigarettes, as well, to safeguard children from nicotine addiction and other potential health effects of e-cigarettes.

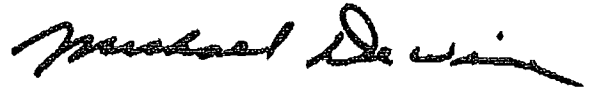
The FDA has authority to regulate electronic cigarettes as "tobacco products" under the Tobacco Control Act, as they are products "made or derived from tobacco" that are not a "drug," "device," or combination product. Case law, such as *Sottera, Inc. v. Food & Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010), further 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 ask the FDA to move quickly to ensure that all tobacco products are tested and regulated to ensure that companies do not continue to sell or advertise to our nation's youth.

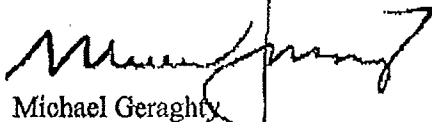
Very respectfully yours,




Martha Coakley
Massachusetts Attorney General



Mike DeWine
Ohio Attorney General



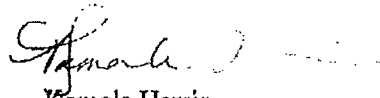
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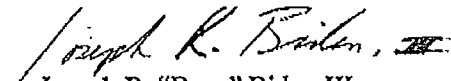


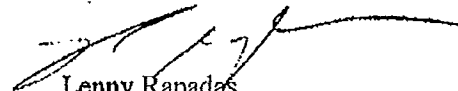
Kamala Harris
California Attorney General

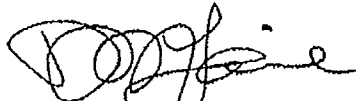
⁷ Sabrina Tavernise, *Rise Is Seen in Students Who Use E-Cigarettes*, New York Times, September 5, 2013, available at <http://www.nytimes.com/2013/09/06/health/e-cigarette-use-doubles-among-students-survey-shows.html>

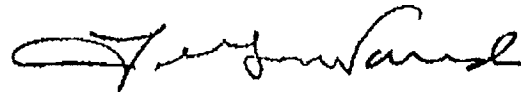

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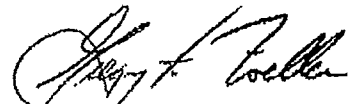

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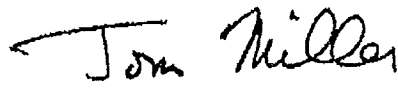

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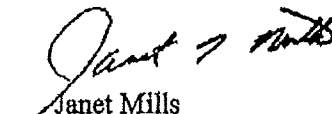

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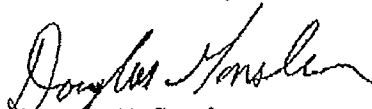

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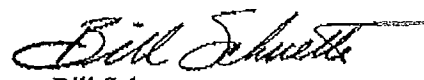

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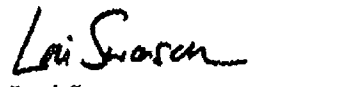

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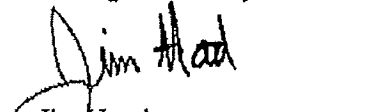

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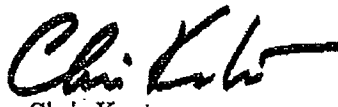

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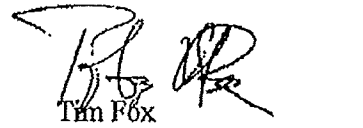

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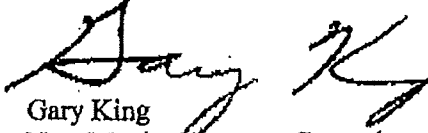

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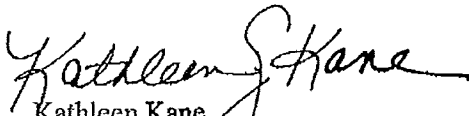
Catherine Cortez Masto
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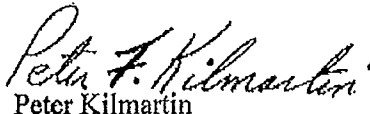
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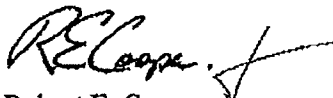
Roy Cooper
North Carolina Attorney General



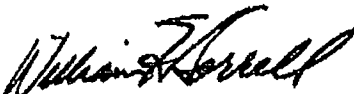
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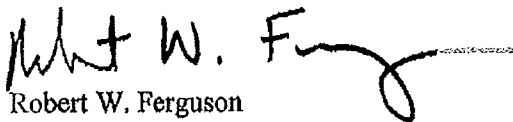
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Tennessee Attorney General



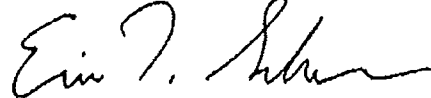
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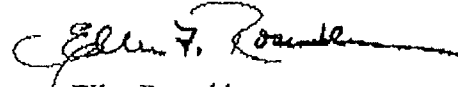
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Joseph Foster
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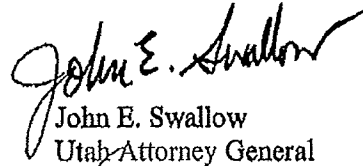
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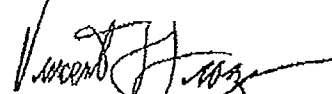
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Vincent Frazer
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