

DEPARTMENT OF THE ATTORNEY GENERAL

News Release

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ATTORNEY GENERAL DAVID M. LOUIE CALLS ON FDA TO REGULATE E-CIGARETTES AND PROHIBIT SALES TO MINORS

HONOLULU – Emphasizing the need for immediate regulatory oversight of electronic cigarettes ("e-cigarettes"), Attorney General Louie today urged the U.S. Food and Drug Administration ("FDA") to place restrictions on the advertising and ingredients of the popular, highly-addictive product, and to prohibit its sale to minors.

In a bipartisan letter co-sponsored by Massachusetts Attorney General Martha Coakley and Ohio Attorney General Mike DeWine, and joined by 38 other Attorneys General, AG Louie urges the FDA to take all available measures to regulate e-cigarettes as "tobacco products" under the Tobacco Control Act. E-cigarettes, an increasingly widespread product that is growing rapidly among both youth and adults, are battery operated products that heat liquid nicotine derived from tobacco plants, into a vapor that is inhaled by the user.

State Attorneys General have fought for years to protect people from the dangers of tobacco products. In 1998, the Attorneys General of 52 states and territories signed a landmark agreement with the four largest tobacco companies in the United States to recover billions of dollars in costs associated with smoking-related illnesses and to restrict cigarette advertising to prevent youth smoking.

Unlike traditional tobacco products, there are no federal age restrictions that would prevent children from obtaining e-cigarettes. Noting the growing use of e-cigarettes and the growing prevalence of advertising, the letter highlights the need to protect youth from becoming addicted to nicotine through these new products.

A survey conducted by the Center for Disease Control and Prevention shows that from 2011 to 2012, the percentages of youth who have tried or currently use e-cigarettes have roughly doubled. The survey estimates that nearly 1.8 million middle and high school students tried e-cigarettes in 2012.

According to the U.S. Surgeon General, nicotine is highly addictive, has immediate bio-chemical effects on the brain and body at any dosage, and is toxic in high doses. The lack of regulation of e-cigarettes puts youth at risk of developing a lifelong addiction to a potentially dangerous product that could also act as a gateway to using other tobacco products.

E-cigarette manufacturers are using marketing tactics similar to those big tobacco used in the last 50 to 100 years to attract new smokers. Celebrity endorsements, television advertising, cartoons, fruit flavors, attractive packaging and cheap prices all serve to encourage youth consumption of these dangerous products.

Additionally, some manufacturers' marketing campaigns claim that these products do not contain the same level of toxins and carcinogens found in traditional cigarettes, cigars, and other tobacco products. These claims imply that e-cigarettes are a safe alternative to smoking, when in fact nicotine is highly addictive, the health effects of e-cigarettes have not been adequately studied, the ingredients are not regulated, and may still contain carcinogens. The lack of regulation puts the public at risk because users of e-cigarettes are inhaling unknown chemicals with unknown effects.

Hawaii has taken an active role in the fight against tobacco use by its youth. In 2013, the Hawaii State Legislature passed Act 227, which expressly prohibits the sale of e-cigarettes to persons under the age of 18 years. Notwithstanding Hawaii's proactive approach, Attorney General Louie believes that participating in the nationwide effort to regulate e-cigarettes is critical to ensuring that Hawaii's youth are protected from manufacturers' efforts to make e-cigarettes attractive and easily accessible.

The letter was co-sponsored by Attorney General Louie, along with Massachusetts Attorney General Martha Coakley and Ohio Attorney General Mike DeWine. The other states joining the letter to the FDA are Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Guam, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virgin Islands, Washington, and Wyoming. The letter to the FDA can be found here: <u>http://www.naag.org/sign-on_archive.php</u>.

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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 <u>Compare</u> 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), <u>with</u> 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-tobaccos-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

Michael Geraghty Alaska Attorney General

Dustin McDaniel ⁷ Arkansas Attorney General

Mike DeWine Ohio Attorney General

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Tom Horne Arizona Attorney General

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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