

REPORT OF THE CHIEF LEGISLATIVE ANALYST

DATE: December 16, 2013

TO: Honorable Members of the Rules, Elections and Intergovernmental Relations Committee

FROM: Gerry F. Miller *KEV*
Chief Legislative Analyst
Council File No.: 13-0002-S143
Assignment No.: 13-12-1033

SUBJECT: Resolution to SUPPORT and/or SPONSOR legislation and/or administrative action to urge the Food and Drug Administration to assert authority over the ingredients in e-cigarettes and other nicotine delivery devices.

CLA RECOMMENDATION: Adopt attached Resolution to include in the City's 2013-14 Federal Legislative Program SPONSORSHIP and/or SUPPORT of legislation and/or administrative action that would urge the Food and Drug Administration to assert authority over the ingredients in e-cigarettes and other nicotine delivery devices.

SUMMARY

The Resolution (Koretz – O'Farrell - Parks) states that electronic cigarette (e-cigarette) devices contain various chemicals, including nicotine, and notes that the Campaign for Tobacco-Free Kids is calling on the Food and Drug Administration to regulate e-cigarettes to protect public health. According to the Resolution, the U.S. Court of Appeals has determined that e-cigarettes can be regulated by the FDA as a tobacco product and the FDA is currently conducting a public review process to consider asserting authority over the regulation of e-cigarettes. The Motion advises that the federal government, specifically the FDA, is the appropriate jurisdiction to consider the regulation of e-cigarettes and other nicotine delivery devices. The Resolution therefore requests that the City include in its 2013-14 Federal Legislative Program sponsorship and/or support of legislation and/or administrative action that would urge the Food and Drug Administration to assert authority over the ingredients in e-cigarettes and other nicotine delivery devices, and support for any federal legislation or action which would encourage and enable such an assertion of authority by the FDA.

BACKGROUND

Electronic cigarettes, also known as e-cigarettes, are battery-powered devices that provide doses of nicotine and other additives (such as flavorings) which are heated, vaporized, and inhaled by the user. In contrast to traditional cigarettes, e-cigarettes only emit substances when activated by pressing a button or through suction. Flavorings include amaretto, vanilla, and apple, among others.

Publications such as The San Francisco Chronicle and Scientific American have noted that e-cigarettes are growing in popularity and are sometimes used as a method to cease smoking traditional tobacco cigarettes. Various health groups have expressed concerns relative to health effects, marketing strategies of e-cigarette companies, and accessibility to youth.

In its *Morbidity and Mortality Weekly Report* dated September 6, 2013, the Centers for Disease Control and Prevention (CDC) reported that from 2011 to 2012 e-cigarette use doubled among middle and high school students, to 1.78 million students. Among middle school students, the

portion of students who had used e-cigarettes increased from 1.4 percent to 2.8 percent from 2011 to 2012. Among high school students, the rate increased from 4.7 percent to 10 percent.

As reported in the National Geographic Daily News, the director of the Center for Tobacco Control Research and Education at the University of California, San Francisco advised that e-cigarettes contain fewer toxins than traditional cigarettes but also contain nicotine and various chemicals. Organizations such as the Electronic Cigarette Industry Group and the Smoke Free Alternatives Trade Association have stated that regulation of e-cigarettes is unnecessary, as not all e-cigarettes contain nicotine and thus do not pose the same health risks as traditional tobacco cigarettes.

Federal Regulatory Efforts

In accordance with a decision issued by the U.S. Court of Appeals for the D.C. Circuit in the case of *Sottera, Inc. v. U.S. Food and Drug Administration*, the FDA indicated in an April 2011 letter to stakeholders that it intends to regulate e-cigarettes and related products in a manner consistent with its mission of protecting the public health. Potential regulatory activities could include registration, ingredient listing, and user fees. It is our understanding that the FDA has not yet determined when it will consider approving these rules.

On September 24, 2013, the National Association of Attorneys General (NAAG) sent a letter to the FDA which advised that the FDA has the authority to regulate e-cigarettes as a “tobacco product” under the Tobacco Control Act. The letter, signed by over forty attorneys general (including the California Attorney General), notes the growth in e-cigarette sales and the expansion of advertising in primetime television and other venues (attached). According to NAAG, the variety of available flavors and designs of e-cigarette devices are appealing to youth.

State and Local Regulatory Efforts

The State of California and local governments within California have enacted or considered enacting legislation relative to the sale and use of e-cigarettes. On February 22, 2013, state Sen. Ellen M. Corbett introduced Senate Bill (SB) 648 which would extend the restrictions and prohibitions against the smoking of tobacco products to include restrictions or prohibitions against e-cigarettes. SB 648 passed the Senate but not the Assembly. On December 4, 2013, The San Francisco Chronicle reported that two cities within California, Carlsbad and Richmond, have banned the use of e-cigarettes in public places.

On December 4, 2013 the Los Angeles City Council approved an Ordinance to regulate the sale of e-cigarettes. The Ordinance requires retailers to obtain a Tobacco Retailer Permit and prohibits the self-service display of e-cigarettes (C.F. 13-1204). During the December 4, 2013 City Council meeting, Motion (Koretz – O’Farrell – Parks) was introduced which requested the City Attorney to prepare an Ordinance to regulate the use of e-cigarettes where smoking is prohibited by law (C.F. 13-1204-S1). According to the City Attorney, state and local law prohibits smoking in the following locations: outdoor dining areas; City-permitted farmer’s markets; City parks and beaches; indoor workplaces; 20 feet from the entryway of a government building; and, vehicles when a minor is present.

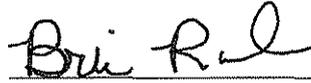
Conclusion

While the City is taking various actions relative to the sale and use of e-cigarettes, action is needed on the federal level to make a final determination on safety and health effects for these devices. Therefore, we recommend support of legislation and/or administrative action that would

urge the Food and Drug Administration to assert authority over the ingredients in e-cigarettes and other nicotine delivery devices.

Departments Notified

City Attorney

A handwritten signature in black ink, appearing to read "Brian Randol", written over a horizontal line.

Brian Randol

Analyst

- Attachments:
1. Resolution (Koretz – O’Farrell - Parks).
 2. Letter from National Association of Attorneys General dated September 24, 2013 concerning FDA regulation of e-cigarettes.

RESOLUTION

WHEREAS, any official position of the City of Los Angeles with respect to legislation, rules, regulations or policies proposed to or pending before a local, state or federal governmental body or agency must have first been adopted in the form of a Resolution by the City Council with the concurrence of the Mayor; and

WHEREAS, many electronic cigarette (e-cigarette) devices contain many chemicals, along with nicotine, including volatile organic compounds, such as benzene and toluene; heavy metals, such as nickel and arsenic; tobacco specific carcinogens; and carbon compounds such as formaldehyde and acrolein; and

WHEREAS, The Campaign for Tobacco-Free Kids is calling on the Food and Drug Administration (FDA) to regulate e-cigarettes to protect public health, including through further research on the contents, and through the setting of standards on said content, of e-cigarettes; and

WHEREAS, the U.S. Court of Appeals has determined that e-cigarettes can be regulated by the FDA as a tobacco product, and the FDA is undertaking a process of public review while considering such a potential assertion of authority; and

WHEREAS, a municipality, county or state may take some actions and assert some authority, but the federal government and specifically the FDA is the appropriate jurisdiction for many matters pertaining to e-cigarettes and other nicotine delivery devices:

NOW, THEREFORE, BE IT RESOLVED, with the concurrence of the Mayor, that by the adoption of this Resolution, the City of Los Angeles hereby includes in its 2013-2014 Federal Legislative Program a call for action urging the Food and Drug Administration (FDA) to assert authority over the ingredients in e-cigarettes and other nicotine delivery devices, and support for any federal legislation or action which would encourage and enable such an assertion of authority by the FDA.

PRESENTED BY: Paul Koretz

PAUL KORETZ
Councilmember, 5th District

Mitch O'Farrell
MITCH O'FARRELL
Councilmember, 13th District

Bernard C. Parks
SECONDED BY
BERNARD PARKS
Councilmember, 8th District

[Signature]
DEC 4 2013



National Association
of Attorneys General

PRESIDENT

J.B. Van Hollen
Wisconsin Attorney General

PRESIDENT-ELECT

Jim Hood
Mississippi Attorney General

VICE PRESIDENT

Marty Jackley
South Dakota Attorney General

IMMEDIATE PAST PRESIDENT

Douglas Gansler
Maryland Attorney General

EXECUTIVE DIRECTOR

James McPherson

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://citycigarettes.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

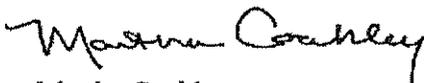
The FDA has Authority to Regulate E-cigarettes and Protect the Public

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.

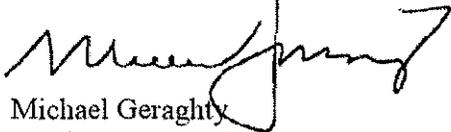
The FDA has authority to regulate electronic cigarettes as “tobacco products” under the Tobacco Control Act, as they are products “made or derived from tobacco” that are not a “drug,” “device,” or combination product. Case law, such as *Sottera, Inc. v. Food & Drug Administration*, 627 F.3d 891 (D.C. 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.

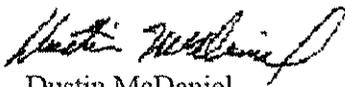
Very respectfully yours,



Martha Coakley
Massachusetts Attorney General



Michael Geraghty
Alaska Attorney General



Dustin McDaniel
Arkansas Attorney General



Mike DeWine
Ohio Attorney General

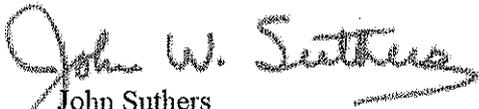


Tom Horne
Arizona Attorney General

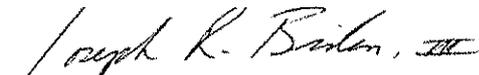


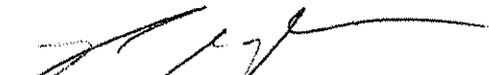
Kamala Harris
California Attorney General

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>

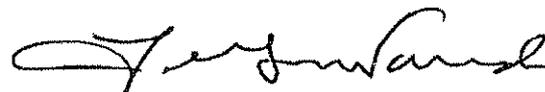

John Suthers
Colorado Attorney General


George Jepsen
Connecticut Attorney General

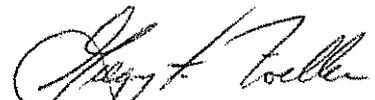

Joseph R. "Beau" Biden III
Delaware Attorney General


Lenny Rapadas
Guam Attorney General


David Louie
Hawaii Attorney General


Lawrence Wasden
Idaho Attorney General

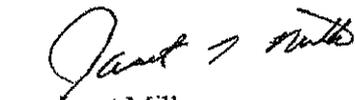

Lisa Madigan
Illinois Attorney General

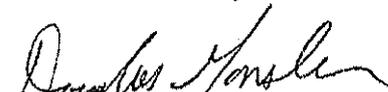

Greg Zoeller
Indiana Attorney General


Tom Miller
Iowa Attorney General

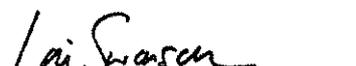

Jack Conway
Kentucky Attorney General


James "Buddy" Caldwell
Louisiana Attorney General


Janet Mills
Maine Attorney General


Douglas F. Gansler
Maryland Attorney General


Bill Schuette
Michigan Attorney General


Lori Swanson
Minnesota Attorney General

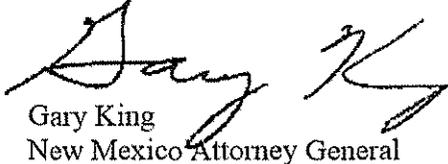

Jim Hood
Mississippi Attorney General


Chris Koster
Missouri Attorney General


Tim Fox
Montana Attorney General



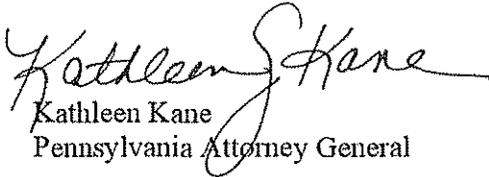
Catherine Cortez Masto
Nevada Attorney General



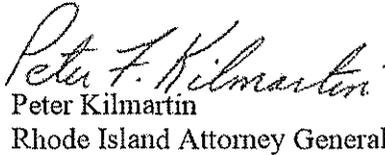
Gary King
New Mexico Attorney General



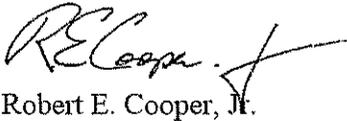
Roy Cooper
North Carolina Attorney General



Kathleen Kane
Pennsylvania Attorney General



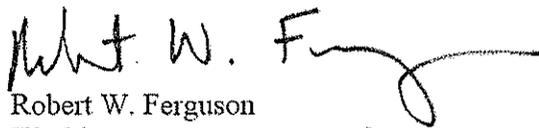
Peter F. Kilmartin
Rhode Island Attorney General



Robert E. Cooper, Jr.
Tennessee Attorney General



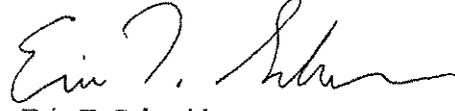
William H. Sorrell
Vermont Attorney General



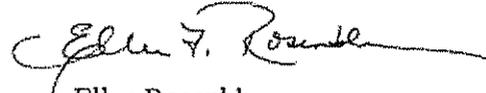
Robert W. Ferguson
Washington Attorney General



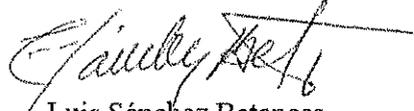
Joseph Foster
New Hampshire Attorney General



Eric T. Schneiderman
New York Attorney General



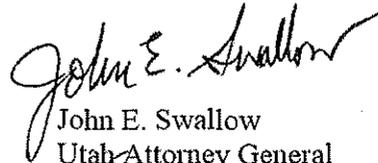
Ellen Rosenblum
Oregon Attorney General



Luis Sánchez Betances
Puerto Rico Attorney General



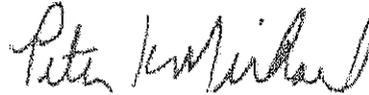
Marty J. Jackley
South Dakota Attorney General



John E. Swallow
Utah Attorney General



Vincent Frazer
Virgin Islands Attorney General



Peter K. Michael
Wyoming Attorney General