



Ronald S. Mistein
Executive Vice President,
Legal and External Affairs,
General Counsel and Secretary

(336) 335-7718
Fax (336) 335-7707

October 23, 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 Lorillard Inc., the owner of blu eCigs, the leading electronic cigarette company in the United States, I am writing to express our agreement with many of the principles expressed by state Attorneys General who urged the Food and Drug Administration (FDA) on September 24, 2013¹, to assert its authority to regulate electronic cigarettes under the Tobacco Control Act.

Lorillard agrees that FDA is authorized to regulate e-cigarettes. Since acquiring blu eCigs in April 2012, Lorillard repeatedly has stated that it stands ready to work with FDA to develop regulations for e-cigarettes. Lorillard has reiterated this publicly and in private meetings with FDA.

E-cigarettes are a product that has the potential to play a critical role in the national harm reduction discussion. For too many years, tobacco policy has been mired in an all-or-nothing philosophy. Under this approach, smokers are presented with just one alternative: quit. This mindset has prevented the implementation of a comprehensive public health strategy designed to reduce tobacco-related disease.

E-cigarettes are distinctly different from combustible tobacco cigarettes in that e-cigarettes have no tobacco smoke, no ash, no odor and no combustion, resulting in virtually none of the chemicals present in cigarette smoke. On the other hand, e-cigarettes are similar to combustion cigarettes, in that they mimic the behavior of traditional smoking.

¹ National Association of Attorneys General. FDA Regulation of E-Cigarettes. Sept. 24, 2013. Letter to The Honorable Margaret Hamburg. <http://www.naag.org/ags-urge-fda-to-regulate-sale-and-advertising-of-e-cigarettes.php>

Making less harmful products available to smokers as soon as possible should be a top priority for policy makers. We should arrive at a place where regulations mirror the continuum of risk. Regulation should promote the development of products that significantly reduce exposure to harm in the users of tobacco products. These and other regulatory actions by the FDA should encourage cigarette smokers to switch to e-cigarettes.

FDA rules should ensure the adoption of quality standards and good manufacturing practices, accompanied by a regulatory framework that ensures sales and marketing to youth is prohibited. In the meantime, absent regulations, blu eCigs has voluntarily implemented many responsible measures concerning the conduct of our business, while pressing state governments for sales restrictions that prevent youth access.

To be clear: We agree that electronic cigarettes are not a product for youth. Any usage of electronic cigarettes by youth is unacceptable; electronic cigarettes are intended to be used as an alternative to combustion cigarettes by smokers of legal age, and should not be sold or used by anyone under age 18.

However, it is disturbing that the Attorneys General and others in the public health community are relying on their 1990's tobacco playbook and raising the specter of youth usage of electronic cigarettes as a reason for FDA to ban or adopt draconian restrictions on the marketing and sale of these tobacco alternatives. In fact, concerns that youth are using electronic cigarettes at alarming rates are not supported by evidence.

In their letter the state Attorneys General cite a recent report by the Centers for Disease Control and Prevention (CDC) as proof that youth are taking up the use of e-cigarettes at alarming rates. The CDC study claimed that electronic cigarette use had more than doubled among middle and high school students from 2011 to 2012. This report's "conclusion" has led many to call for the ban on the sale of electronic cigarettes, or at the least the imposition of drastic marketing and sales restrictions that may cause adult smokers to forgo the opportunity to switch from smoking to vaping. Yet the CDC study did not offer evidence, nor are we aware of any such evidence, of an epidemic of youth usage of electronic cigarettes at all.

The CDC survey showed that 2.1 percent of the youth had experimented with e-cigarettes. It did not report daily or regular use statistics for e-cigarettes. In other words, the statistic reported by CDC includes youth who took only so much as one puff from an e-cigarette and may not have used the product ever again. This means that the CDC's claim that electronic cigarette use has doubled among underage youth is likely dramatically overstated. As far as we know from that survey, none of them are using e-cigarettes daily, in contrast with the unfortunate fact that many more youth continue to regularly smoke combustible cigarettes.

Unfortunately, the CDC has claimed that its survey shows that kids are starting with e-cigarettes and then progressing to smoke combustion cigarettes. This is not supported by the scientific evidence. Dr. Michael Siegel, professor in the Department of Community Health Sciences, Boston University School of Public Health, has said the statement is a "fabrication" and that "the study did not document any examples of youth starting to smoke as a result of first trying electronic cigarettes." Furthermore, Siegel notes that the "among youth who experimented with electronic cigarettes in 2012, the overwhelming majority - 90.6% - were smokers."

Lorillard supports reasonable, science based regulations of e-cigarettes. However, that regulation must not have the effect of denying the harm reduction benefits of electronic cigarettes to smokers looking for an alternative. We think there is an opportunity to enact sensible regulation to accomplish this.

After its acquisition of blu eCigs, Lorillard made a commitment to take a leadership role in shaping how manufacturers in this emerging category can be responsible. We agree that e-cigarettes should not be marketed, sold, or used by anyone younger than 18 years of age, and have demonstrated our commitment to this in the following ways:

1. *Two-Step Age Screening Process on blu eCigs Website.*

blu eCigs prohibits the sale of e-cigarettes to anyone younger than 18 years of age through strict age-verification and third party certification procedures on websites or through vendor verification in stores.

Since its acquisition by Lorillard, blu eCigs has implemented a two-step age screening process on its website. The website screening process begins with a self-certification of age. Before being allowed access to the website, the person is asked to certify that he or she is 18 years of age or over. Only individuals certifying they are 18 years of age or older are permitted entry. To purchase any product from the website, a consumer must first provide personal information, including first and last name, address and date of birth. Then two third-party age verification systems compare this information to public records to verify the consumer's identity and that the consumer is 18 years of age or older. If either system verifies the consumer's identity and that the consumer is 18 years of age or older, the transaction is completed. If neither system can verify these facts, the transaction is terminated. This rigorous screening process established by blu eCigs prevents persons under 18 years of age from purchasing blu products on its website.

However, the sale of e-cigarettes to persons under 18 years of age in a face to face transaction at retail stores is still possible in several states that do not make it illegal for retailers to sell, furnish and distribute electronic cigarettes to minors. As a result, Lorillard

has strongly advocated and worked for state legislation to prevent the sale or distribution of electronic cigarettes to minors. It is an important step that states can and should take, and we urge the Attorneys General to support these statutes.

2. *Marketing Targeted at Consumers of Legal Age*

Responsible e-cigarette manufacturers, including blu eCigs, do not market to youth. Lorillard understands the sensitivity associated with advertising and marketing campaigns and their potential influence on minors. For this reason, blu eCigs is actively and effectively ensuring that its advertising is directed at adult smokers.

blu has run two advertisements on television. The advertisements were placed on television shows whose content is directed to viewers who are 18 years of age or older and shown during time slots when at least 85% of the target audience is 18 years of age or older. The advertisements were designed primarily to educate smokers regarding e-cigarettes and included two celebrities. Both celebrities are over 40 years old and have an adult target audience well beyond 18 years of age.

The Attorneys General also assert that flavored electronic cigarettes attract youth to these products. However, it is commonplace for products marketed to adults to be offered in a variety of flavors. Beer and alcohol are available in numerous types of flavors enjoyed by adults, as are many types of coffee and tea. Most notably, nicotine therapy products are also sold in a variety of flavors. For example, flavors of Nicorette gums and lozenges include White Ice Mint, Fruit Chill, Cinnamon Surge and Cherry. While Congress did ban cigarettes with a characterizing flavor other than tobacco or menthol through the Family Smoking Prevention and Tobacco Control Act, Congress did not ban characterizing flavors for other tobacco products, and FDA should not do so with electronic cigarettes. We believe we can and do market and advertise blu eCigs in a responsible manner to adult consumers so that all adults who prefer these flavors may continue enjoying them. Depriving adults the right to use flavored electronic cigarettes may very likely prevent traditional smokers from switching away from combustible cigarettes, resulting in many continuing on a lifelong path of using the most harmful of nicotine products.

We believe strongly that responsible marketing parameters that prohibit marketing and sales to youth can be achieved without suppressing adult access to what may be the most significant harm reduction opportunity ever for traditional smokers.

October 23, 2013
Page 5

Lorillard again welcomes the voices of the 40 state Attorneys General in urging FDA to issue proposed regulations to assert regulatory oversight of e-cigarettes.

Lorillard encourages the FDA to ensure appropriate and reasonable regulation of e-cigarettes through policies developed by the FDA and industry in partnership. Like the Attorneys General, Lorillard looks forward to working collaboratively with the FDA to devise a reasonable, scientifically based regulatory framework covering e-cigarettes that does not stifle what may be the most significant harm reduction opportunity ever for traditional smokers.

Sincerely,



Ronald S. Milstein

cc: James McPherson, Executive Director, National Association of Attorneys General
~~All States' Attorneys-General~~