

Congress of the United States
Washington, DC 20510

August 1, 2014

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

Dear Commissioner Hamburg,

On April 25, 2014 – five years after enactment of the Family Smoking Prevention and Tobacco Control Act – the Food and Drug Administration (FDA) published its first proposed rule on how it plans to exercise authority to regulate e-cigarettes. We commend the FDA on many of the provisions included in these proposed rules, including prohibitions on sales to minors, prohibitions on vending machine sales and samples, and requirements to list product ingredients. However, the draft regulation fails to explicitly prohibit the marketing of these products to children, the use of flavorings, and online sales.

E-cigarettes are being aggressively marketed to children today, and, not surprisingly, the use of e-cigarettes has skyrocketed in recent years. The Centers for Disease Control and Prevention reports that, between 2011 and 2012, the percentage of middle and high school students who have tried e-cigarettes more than doubled.¹ What's even more troubling is that these products serve as a gateway to traditional tobacco products. A recent *JAMA Pediatrics* study found that middle and high-school students who used e-cigarettes were *more likely* to smoke traditional cigarettes and less likely to quit smoking.²

It is not a coincidence that the increase in e-cigarette use by children coincides with a dramatic escalation in e-cigarette companies' advertising efforts. According to the journal *Pediatrics*, exposure to e-cigarette marketing by children aged 12 to 17 increased by 256 percent between 2011 and 2013, with Blu ECigs accounting for more than 80 percent of the advertising.³ Moreover, a Congressional investigation led by our offices, found that in just two years, from 2012 to 2013, six of the surveyed companies sponsored or provided free samples at 348 events, many of which were music festivals and

1 Centers for Disease Control and Prevention, *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).

2 Dutra, Lauren and Stanton Glanz. *Electronic Cigarettes and Conventional Cigarette Use Among US Adolescents*. *JAMA Pediatrics*. 2014; 168(7):610-617.

3 Duke, Jennifer, Youn O. Lee, Annice E. Kim, et al. *Exposure to Electronic Cigarette Advertisements Among Youth and Young Adults*. *Pediatrics*. June 2014; 134 (1):1-8.

motorsport events geared toward young people—including Grand Prix auto racing events.⁴

E-cigarette companies are employing the same tactics used by big tobacco decades ago: showcasing glamorous celebrities, creating cool cartoons, and pushing their brands through sexy television and print advertisements. Congress dramatically curtailed the use of these tactics to market traditional cigarettes through the Family Smoking Prevention and Tobacco Control Act, and we urge the FDA to extend these same restrictions to e-cigarettes.

The second area of grave concern is the FDA's failure to address flavorings in e-cigarettes. Fruit and candy based flavors are clearly meant to attract children, and we similarly urge FDA to regulate a halt to the use of such flavors. In the proposed regulation, the FDA cites evidence showing that young people are the most likely to use flavored tobacco products. That is likely why e-cigarettes and liquid nicotine manufacturers are marketing products that use popular candy and drink flavors, like those used in Jolly Rancher candies and Kool-Aid mix. Authors of a recent *New England Journal of Medicine* study contend that the use of these specific candy flavors exploits the association children have between these familiar flavors and the candies kids enjoy.⁵

Finally, we are disappointed that despite the importance of preventing online sales of e-cigarettes, the proposed rule does not include such a restriction. Age verification is very difficult to perform accurately for online purchases. As a result, this loophole could undermine the FDA's ability to keep e-cigarettes out of the hands of children.

While FDA's proposed rule sets the stage for future regulations, strong regulatory actions on marketing to children, e-cigarette flavors, and online sales cannot wait. FDA has an existing mechanism to protect children now—without waiting years to implement new regulations to accomplish these goals. The Family Smoking Prevention and Tobacco Control Act makes marketing new tobacco products illegal without prior FDA authorization. The law also gives FDA the authority to place restrictions on the sale and marketing of newly deemed tobacco products, especially those that pose a risk to children, as a condition of FDA authorization. Instead of exercising this authority to limit children's exposure to tobacco products, the FDA is *proposing* a two-year "compliance policy" that allows addictive e-cigarettes to remain on the market as manufacturers submit new product applications.

We recommend that FDA use its enforcement discretion to allow newly deemed tobacco products to remain on the market only if their manufacturers apply the restrictions imposed on traditional tobacco products to limit youth access, including a ban

4 Sen. Richard Durbin, Rep. Henry A. Waxman, Sen. Tom Harkin, et al., *Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth* (Apr. 14, 2014) (online at <http://democrats.energycommerce.house.gov/sites/default/files/documents/Report-E-Cigarettes-Youth-Marketing-Gateway-To-Addiction-2014-4-14.pdf>)

5 Brown, Jessica, Wentai Luo, Lorne Isabelle, et al. *Candy Flavorings in Tobacco*. *New England Journal of Medicine*. June 2014; 370: 2250-2252.


on flavorings, prohibition of tobacco brand-name sponsorships, and limits on advertising. Allowing e-cigarette products to remain on the market without these restrictions would amount to an abdication of FDA's responsibility to protect our children.

We urge you to finalize this proposed regulation within a year of its release and to adopt an enforcement policy that protects our nation's youth from predatory marketing, flavors that lure youth to toxic nicotine, and easy online access.


Sincerely,



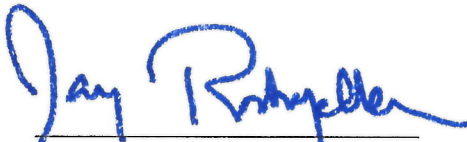
Richard J. Durbin
United States Senator



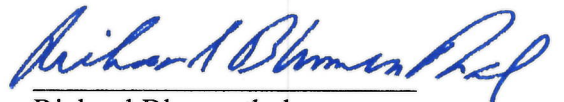
Henry A. Waxman
United States Representative



Tom Harkin
United States Senator



John D. Rockefeller
United States Senator



Richard Blumenthal
United States Senator



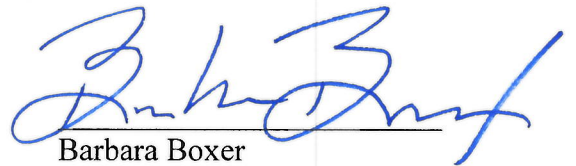
Edward J. Markey
United States Senator



Sherrod Brown
United States Senator



Jack Reed
United States Senator



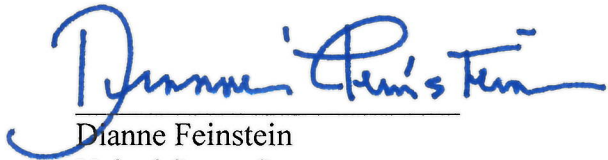
Barbara Boxer
United States Senator



Jeff Merkley
United States Senator



Frank Pallone, Jr.
United States Representative

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Dianne Feinstein
United States Senator

Handwritten signature of Diana DeGette in blue ink, written in a cursive style.

Diana DeGette
United States Representative