

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
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September 16, 2013

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

Earlier this month, the Centers for Disease Control and Prevention (CDC) released new data showing that the percentage of adolescents who use electronic cigarettes, or “e-cigarettes,” is growing rapidly.¹ According to the CDC report, over 1.7 million U.S. middle and high school students tried e-cigarettes last year. We are writing to urge the Food and Drug Administration (FDA) to act quickly to appropriately regulate these products.

The authors of the CDC’s report — who are all from either the FDA’s Center for Tobacco Products or the CDC’s Office on Smoking and Health — cite serious concerns about the health effects of the use of e-cigarettes. For instance, they indicate that e-cigarettes may contain potentially harmful constituents, including irritants and animal carcinogens.² They also raise concerns about the potential negative effects “on adolescent brain development, as well as the risk for nicotine addiction.”³ In an earlier study, FDA found that e-cigarette vapor samples contained toxic chemicals “such as diethylene glycol, an ingredient used in antifreeze.”⁴

¹ Centers for Disease Control and Prevention, *Notes from the Field: Electronic Cigarette Use Among Middle and High School Students – United States, 2011-2012* (Sept. 6, 2013) (online at www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm?s_cid=mm6235a6_w).

² *Id.*

³ *Id.*

⁴ Food and Drug Administration, *FDA and Public Health Experts Warn About Electronic Cigarettes* (July 22, 2009) (online at www.fda.gov/NewsEvents/Newsroom/%20PressAnnouncements/ucm173222.htm).

Despite these health concerns, e-cigarettes are currently completely unregulated. Manufacturers of e-cigarettes are taking advantage of this regulatory loophole to target children. Manufacturers of traditional cigarettes are banned from introducing flavoring into their products to attract children, but this prohibition does not apply to e-cigarettes. As a result, some e-cigarette makers are producing products with kid-friendly flavors such as “Cherry Crush” and “Cookies & Cream Milkshake.”⁵

Unlike traditional cigarettes, e-cigarettes are also not subject to the federal ban on television advertising. Advertising spending on products like e-cigarettes has skyrocketed from \$2.7 million in 2010 to \$20.8 million last year, using tactics like celebrity endorsements and sports sponsorships to glamorize smoking. According to the American Lung Association, these products are being directly marketed to kids, “which could result in a lifelong addiction to nicotine.”⁶

The new CDC report shows the dangerous impacts these practices are having. Use of e-cigarettes by youth doubled in just one year from 2011 to 2012.⁷ Moreover, the CDC data suggest that e-cigarettes could be serving as a gateway product to nicotine addiction. Over 20% of the middle school students who reported using e-cigarettes said they had never tried traditional cigarettes.⁸ According to the authors of the CDC report, “This raises concern that there may be young people for whom e-cigarettes could be an entry point to use of conventional tobacco products, including cigarettes.”⁹ As CDC Director Tom Frieden stated when the report was

⁵ *E-cigarettes may have a place – just not with minors*, Boston Globe (July 12, 2013) (online at www.bostonglobe.com/opinion/editorials/2013/07/11/cigarettes-may-have-place-just-not-with-minors/aIjcHjP5LJZL6k7cLjQ8OK/story.html).

⁶ *Rise Is Seen in Students Who Use E-Cigarettes*, New York Times (Sept. 5, 2013) (online at www.nytimes.com/2013/09/06/health/e-cigarette-use-doubles-among-students-survey-shows.html?pagewanted=print); *FDA Oversight Badly Needed*, New York Times (Aug. 20, 2013) (online at www.nytimes.com/roomfordebate/2013/08/20/the-ambiguous-allure-of-the-e-cig/fda-oversight-of-e-cigs-badly-needed); *Electronic cigarettes growing in popularity with teens*, Los Angeles Times (Sept. 6, 2013) (online at www.latimes.com/science/la-sci-e-cigarettes-20130906,0,2387959.story); *State of Tobacco Control 2013*, American Lung Association (Jan. 16, 2013) (online at www.stateoftobaccocontrol.org/sotc-2013-report.pdf).

⁷ Centers for Disease Control and Prevention, *Notes from the Field: Electronic Cigarette Use Among Middle and High School Students – United States, 2011-2012* (Sept. 6, 2013) (online at www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm?s_cid=mm6235a6_w).

⁸ *Id.*

⁹ Centers for Disease Control and Prevention, *E-cigarette use more than doubles among U.S. middle and high school students from 2011 to 2012* (Sept. 5, 2013) (online at www.cdc.gov/media/releases/2013/p0905-ecigarette-use.html).

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released, “Many teens who start with e-cigarettes may be condemned to struggling with a lifelong addiction to nicotine and conventional cigarettes.”¹⁰

We recognize that some believe e-cigarettes could advance public health if addicted smokers switch to e-cigarettes from traditional cigarettes. Others advance the idea that e-cigarettes could help provide a pathway to smoking cessation. We do not dismiss these ideas, but they need to be proven. In 2009, Congress enacted the Family Prevention and Tobacco Control Act to give FDA the authority to make science-based decisions about products like e-cigarettes.¹¹ Certainly, these dangerous products should not be marketed to children.

As a first step, FDA needs to assert jurisdiction over e-cigarettes. We know you have been working on these “deeming” regulations for years. But as the new CDC report makes clear, continued delay comes with a large public health cost. That is why we are writing to urge you to accelerate your efforts. With over a million youth now using e-cigarettes, FDA needs to act without further delay to protect public health.

Sincerely,

Henry A. Waxman
Ranking Member
Committee on Energy and
Commerce

Diana DeGette
Ranking Member
Subcommittee on Oversight and
Investigations

Frank Pallone, Jr.
Ranking Member
Subcommittee on Health

John D. Dingell
Member
Committee on Energy and
Commerce

¹⁰ *Id.*

¹¹ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31.