

United States Senate

WASHINGTON, DC 20510

February 2, 2015

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

Dear Commissioner Hamburg:

We are writing to bring your attention to a new study of formaldehyde and e-cigarette vapors, published as a letter in the January 22 issue of the New England Journal of Medicine.¹ The study, conducted by researchers at Portland State University, determined that high levels of a hidden form of formaldehyde can be present in the “vaped” aerosol formed by electronic cigarettes at higher power settings. This study places new urgency on the need for the Food and Drug Administration to finalize its deeming regulations, including how it will exercise authority to regulate e-cigarettes.

The study discusses that formaldehyde formed during vaping can react with the propylene glycol or glycerol that is also present, to form other compounds – the “hemiacetals” that the article references. While they may not be detected as formaldehyde in the vapors that are inhaled, as they enter the lungs, they can break back down and yield formaldehyde.

Formaldehyde is a known carcinogen. The study found that the incremental lifetime cancer risk due to formaldehyde from long-term e-cigarette “vaping” could be between 5 to 15 times higher than the formaldehyde risk from long-term cigarette smoking. Also, although the full health effects of hidden formaldehyde are as yet unknown, it is likely to deposit in the lungs more efficiently than gaseous formaldehyde.

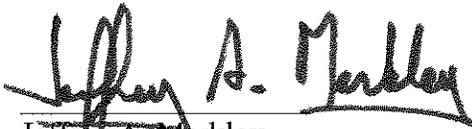
As the electronic cigarette industry moves at breakneck speed to produce products with higher voltages that can deliver higher nicotine dosages at the whim of the user, the dangers of hidden formaldehyde will increase, including cancer risks. Moreover, more research is needed on the short-term and long-term risks associated with exposure to “second-hand” e-cigarette vapors.

This study is part of an emerging body of evidence on the health effects of e-cigarette use, and highlights just how little we still know about the products themselves. Without FDA’s leadership, the products, manufacturing practices, marketing, and labeling will continue to vary in ways that are potentially harmful to users, especially young people whose use has skyrocketed in recent years.

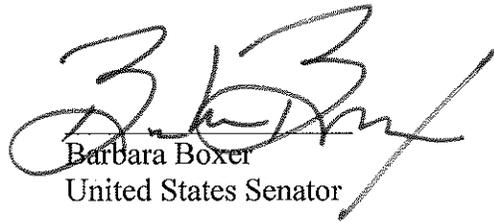
¹ Jensen, R. Paul, et al., “Hidden Formaldehyde in E-Cigarette Aerosols,” *The New England Journal of Medicine*, Vol. 372, No. 4, January 2015.

We would like to request a meeting with you at your earliest convenience to discuss FDA's progress and timeline. In light of new studies such as this one, we again urge you to finalize regulations by April 25, 2015 and to put in place a strong enforcement policy that protects the public health.

Sincerely,



Jeffrey A. Merkley
United States Senator



Barbara Boxer
United States Senator



Richard Blumenthal
United States Senator



Richard Durbin
United States Senator



Sherrod Brown
United States Senator



Edward J. Markey
United States Senator