

# United States Senate

WASHINGTON, DC 20510

August 5, 2015

Dr. Stephen Ostroff  
Acting Commissioner  
U.S. Food and Drug Administration  
10901 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Acting Commissioner Ostroff:

As you work to complete a final rule asserting FDA's jurisdiction over e-cigarettes, we urge you to include product standards and appropriate manufacturing processes to eliminate or sharply reduce toxic substances that have been found in e-cigarettes.

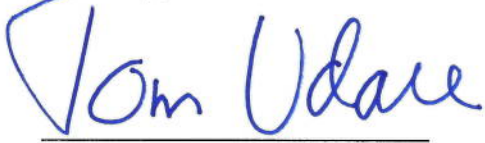
In recent years, the number of people using e-cigarettes has soared, including among young people. The Centers for Disease Control and Prevention recently released their annual survey of youth tobacco use, which estimates that e-cigarette use by high school and middle school students tripled from 2013 to 2014. This growth has occurred in an unregulated marketplace. Manufacturers have introduced a wide variety of e-cigarettes. As of January 2014, an estimated 466 different brands of e-cigarettes were on the market, available in more than 7,000 unique flavors. Because e-cigarettes are not yet regulated by FDA, e-cigarette manufacturers have been able to introduce these products to the market without having to test them for potentially harmful substances, adhere to good manufacturing processes or meet other standards to minimize risk.

Through published studies and presentations at the 2014 FDA workshop on e-cigarettes, we know that carcinogens and other toxins, including formaldehyde, acetaldehyde, acrolein, volatile organic compounds, tobacco-specific nitrosamines, and metals like nickel and lead have been found in the aerosol generated by e-cigarettes. Studies have shown that the level of toxic substances can vary significantly among different e-cigarette products as a result of the content of the e-liquid and the design features of the e-cigarette. For example, the type of solvent used and the voltage of the battery appear to affect the levels of formaldehyde and acetaldehyde that are generated.

Poor manufacturing can also create potential health risks. The majority of e-cigarettes sold in the United States are imported, primarily from China. A *New York Times* investigation found little oversight and quality control standards among some Chinese e-cigarette manufacturers. Metals and other compounds used to construct e-cigarettes can leach into the e-liquid and into the aerosol that is inhaled, and batteries can leak, overheat or explode. Clearly, research and oversight is lacking for e-cigarettes, including a better understanding the long-term health risks of using them and the risks to non-users of breathing in second-hand aerosol emitted from them.

Millions of Americans have used e-cigarettes, and the e-cigarette market continues to grow. We urge you to include product standards and good manufacturing processes to help minimize the health risks of toxins in e-cigarettes in the final rule that will assert FDA's jurisdiction over e-cigarettes. Thank you in advance for your timely response and attention to this important matter.

Sincerely,




Tom Udall  
U.S. Senator



Richard Blumenthal  
U.S. Senator



Amy Klobuchar  
U.S. Senator



Brian Schatz  
U.S. Senator



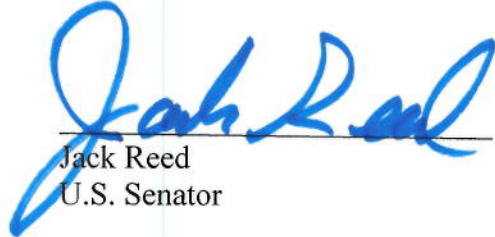
Barbara Boxer  
U.S. Senator



Sherrod Brown  
U.S. Senator



Richard Durbin  
U.S. Senator



Jack Reed  
U.S. Senator