

## Letter

# FDA Summary of Adverse Events on Electronic Cigarettes

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The Center for Tobacco Products (CTP), Food and Drug Administration (FDA), oversees the implementation of the Family Smoking Prevention and Tobacco Control Act (TCA). As part of its responsibility in implementing the TCA, CTP receives and reviews voluntary communications from consumers, health care professionals, and concerned members of the public regarding a variety of tobacco products. Surveillance of adverse event (AE) reports allows regulatory agencies (1) to identify previously undetected safety concerns and take appropriate action to prevent further adverse events and (2) or to educate consumers about health and safety risks. Since the late 1980s, over 100 AE reports on tobacco products have been submitted to FDA (electronic cigarettes,  $n = 47$ ; cigarettes,  $n = 36$ ; smokeless tobacco,  $n = 14$ ; other tobacco,  $n = 5$ ). Notably, approximately half of all tobacco-related AE reports concern electronic cigarettes, the first of which was submitted in 2008.

Electronic cigarettes, also known as e-cigarettes, are battery-operated products designed to deliver nicotine and other chemicals such as flavors. An internal heat source turns nicotine and other chemicals into a vapor that is inhaled by the user. Most e-cigarettes are manufactured to look like conventional cigarettes, cigars, or pipes. Some resemble everyday items such as pens and USB memory sticks. Despite limited short-term and long-term health effects data for e-cigarettes, the popularity of e-cigarettes has been increasing. Currently, there are estimated to be more than 400 brands of e-cigarettes available ([Food and Drug Administration, 2011](#); Kesmodel & Yadron, 2010). Results from a survey conducted by the Centers for Disease Control and Prevention indicate that awareness of e-cigarettes doubled from 16.4% in 2009 to 32.2% in 2010 and the number of people reporting ever using e-cigarette more than quadrupled between 2009 and 2010 ([Regan, Promoff, Dube, & Arrazola, 2011](#)). E-cigarettes continue to be extensively promoted, primarily via the internet, shopping mall kiosks, and viral marketing, so it is likely that consumer awareness and use of e-cigarettes will continue to increase.

The numbers of AE reports received by CTP pertaining to e-cigarettes are summarized as follows: 2008 and earlier (1 of 18 total tobacco product reports), 2009 (10 of 16), 2010 (16 of 27), 2011 (11 of 30), and first-quarter 2012 (9 of 11). Of the 47 reports on e-cigarettes, 8 reported serious adverse events. A summary of serious e-cigarette complaints include hospitalization for illnesses such as pneumonia, congestive heart failure,

disorientation, seizure, hypotension, possible aspiration pneumonia, second-degree burns to the face (product exploded in consumer's mouth while driving and during routine use), chest pain and rapid heartbeat, possible infant death secondary to choking on e-cig cartridge, and loss of vision requiring surgery.

In addition to these serious adverse events, other e-cigarette complaints include concerns about false advertising, headache/migraine, chest pain, cough/sputum, nausea/vomiting, dizziness, feeling sick, confusion/stupor, sore throat, shortness of breath, abdominal pain, pleurisy, blurry vision, and sleepy/tired. Of note, there is not necessarily a causal relationship between AEs reported and e-cigarette use, as some AEs could be related to pre-existing conditions or due to other causes not reported.

There are aggressive marketing and a substantial increase in the number of unregulated e-cigarette products available in the United States. There is concern about the apparent absence of adequate quality control oversight during the manufacturing of e-cigarettes ([Riker, Lee, Darville, & Hahn, 2012](#)). Research by CTP reviewers found e-cigarette companies marketing flavored cartridges containing nicotine levels ranging from 0 mg to upwards of 24 mg. E-cigarettes are available online and in retail stores and are relatively inexpensive (approximately \$10/disposable). There are few barriers to access, including to youth.

More complete information about the toxicity and public health impact of e-cigarettes would help better educate FDA and consumers about e-cigarettes concerning

- whether e-cigarettes to be marketed for therapeutic purposes would be safe and effective for their intended use,
- whether marketing of e-cigarettes as tobacco products is appropriate for the protection of public health, and
- what types or concentrations of harmful and potentially harmful chemicals, including nicotine, are delivered to the consumer and found in the vapor emissions.

Research will inform our understanding of the design and composition of all varieties of e-cigarettes on the market and the health effects on the consumer as well as for those exposed to the vapor. When FDA regulates e-cigarettes marketed as tobacco products, the resulting quality control measures and product standards for this class of products may help to decrease adverse

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health events. CTP is currently developing a tobacco-specific adverse event reporting system. In the meantime, concerned consumers or the public can report adverse events for any tobacco products to MedWatch Online Voluntary Reporting, <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>

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### Declaration of Interests

*None declared.*

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