

### **The FDA Should Take Electronic Cigarettes Off The Market Until It Is Satisfied That They Are Safe and Effective.**

There has been a great deal of press interest recently in “electronic (or e-) cigarettes”, devices which apparently contain no tobacco, mimic cigarettes and come in a variety of flavors, many that may be appealing to children and young adults. Several varieties of e-cigarettes are now on the market. Most e-cigarettes claim to deliver nicotine; some claim that they do not.

While e-cigarettes are viewed by some as a less dangerous alternative to cigarettes or a potential smoking cessation aide, there had been no publicly available independent research on the critically important questions of safety and efficacy. With regard to safety, that has now changed with the FDA’s release on July 22, 2009 of extremely troubling laboratory findings regarding the constituents and manufacturing standards of some e-cigarettes now on the market. There continues to be no scientific support for the anecdotal claims that e-cigarettes are an effective smoking cessation aid.

The FDA’s Division of Pharmaceutical Analysis analyzed the ingredients in a small sample of cartridges from two leading brands of electronic cigarettes. In one sample, the FDA detected diethylene glycol, a chemical used in antifreeze that is toxic to humans. In several other samples, the FDA detected carcinogens, including nitrosamines. In other words, these analyses showed that the tested products contained detectable levels of known carcinogens and toxic chemicals.

The FDA’s other important findings include the following:

- The testing suggested that quality control processes used to manufacture these products are inconsistent or non-existent. For example, three different electronic cigarette cartridges with the same label were tested and each cartridge emitted a markedly different amount of nicotine with each puff.
- The electronic cigarette cartridges that were labeled as containing no nicotine had low levels of nicotine present in all cartridges tested, except one.
- In addition to the known carcinogens and toxic chemicals, tobacco-specific impurities suspected of being harmful to humans—anabasine, myosmine, and  $\beta$ -nicotyrine—were detected in a majority of the samples tested.
- One high-nicotine cartridge delivered twice as much nicotine to users when the vapor from that electronic cigarette brand was inhaled than was delivered by a sample of the nicotine inhalation product (used as a control) approved by FDA for use as a smoking cessation aid.

See <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm>.

The American Legacy Foundation shares FDA Commissioner Dr. Margaret A. Hamburg's concern "about the safety of these products and how they are marketed to the public." We also share the FDA's particular concern that these products could increase nicotine addiction and tobacco use among young people, noting that they are easily available on the internet and in shopping malls, contain no health warnings and are available in flavors such as chocolate, strawberry and mint.

Legacy commends the FDA for its work to date on e-cigarettes and its decision to inform the public about the known harms. We encourage the FDA and other researchers to continue this work and also to examine whether these devices actually help smokers quit or instead, delay cessation attempts by providing smokers with a way to continue their smoking behaviors when they cannot smoke a tobacco product. While we remain open to promising products that can help smokers quit smoking, a consideration of all of the available evidence combined with important unanswered questions strongly supports our call on the FDA to prohibit the marketing and sale of e-cigarettes unless and until the FDA is satisfied that they are safe and effective.