FDA Study Doubting Safety of Electronic Cigarettes 'Narrow in Scope,' Spokesman Says
By Melissa Attias, CQ Staff

Representatives of electronic cigarette companies say safety concerns about their products expressed by the Food and Drug Administration are based on a study that is extremely narrow in scope.

The FDA study examined 19 varieties of electronic cigarettes from two popular brands: "Smoking Everywhere," based in Florida, and "Njoy," based in Scottsdale, Ariz. It found that some of the products contained carcinogens and toxic chemicals, including a chemical used in antifreeze, FDA announced Wednesday. Electronic cigarettes, also called "e-cigarettes," generally use batteries to turn cartridges containing nicotine, flavoring and other chemicals into a vapor that is then inhaled by the user.

"There are over 100 companies in this country who do business with electronic cigarettes," said Matt Salmon, president of the Electronic Cigarette Association (ECA) and former Arizona congressman, in an interview. "My biggest concern is that it seems to be more about a public relations opportunity [for FDA]. And if it is so important, why did they sit on it for two months?" Salmon said, referring to the May 4 date on the FDA lab report.

FDA officials said that additional testing needs to be conducted to confirm the findings in their report.

Many brands of electronic cigarettes have been marketed as a healthy alternative to smoking and a smoking cessation product, but the ECA only accepts electronic cigarette companies that do not make cessation or health claims in their marketing materials or sell their products to those younger than the legal smoking age, Salmon said. The group currently has approximately 12 members, Salmon added, including Njoy.

Health experts say little is known about the content of electronic cigarettes or their effects on the body.

"These are devices delivering nicotine of unknown magnitude into the body with no proven benefit for cessation and some indication of risk," said Jonathan Samet, director of the Institute for Global Health at the University of Southern California, during a telephone news conference.

During its analysis, FDA detected diethylene glycol, an ingredient in antifreeze that is toxic to humans, at approximately 1 percent in one Smoking Everywhere cartridge. They also found tobacco-specific nitrosamines, which are human carcinogens, in half of the samples tested and tobacco-specific impurities in a majority of samples tested, according to the lab report.
In addition, FDA says that some electronic cigarette cartridges labeled as containing no nicotine actually contained nicotine. Other cartridges labeled as containing the same level of nicotine, however, emitted distinctly different amounts, FDA said.

Njoy released a separate statement defending the safety of their products which said the company has not received any reports of significant adverse health consequences since the products entered the market in April 2007.

"Njoy has been tested by an independent third-party laboratory, Exponent," they wrote. "This testing, as well as our consultation with medical experts, gives us confidence that our products are appropriate alternatives for traditional cigarettes for the committed smoker. We are therefore surprised the FDA's testing has resulted in the agency suggesting that our products represent a health risk on par with conventional cigarettes."

Smoking Everywhere, which is not a member of the ECA, declined to comment on the FDA analysis.

Public health experts have long been concerned that electronic cigarettes could increase nicotine addiction and increase tobacco use among young people, especially because they come in flavors like chocolate, bubblegum and mint. Jonathan Winickoff, chairman of the American Academy of Pediatrics Tobacco Consortium, says tobacco research has shown that regular flavored cigarettes increase the social acceptance of smoking and young people's curiosity to try a cigarette.

In addition, experts say electronic cigarettes are easily accessible by youth in stores, online and at mall kiosks because they are not subject to the same regulation as tobacco products. One company is even claiming to put vitamins in their electronic cigarettes, Winickoff said, which could cause young people to believe that they are good for their health.

"It is very important that parents be extremely clear with their children that these are not safe products," Winickoff said at the telephone news conference.

Since last summer, FDA has detained 50 shipments of electronic cigarettes at the border and they are currently considering further enforcement options, FDA said. The agency believes they have the authority to regulate electronic cigarettes because they meet the definition of a drug and a device. Nevertheless, manufacturers are currently challenging FDA's authority to regulate electronic cigarettes in federal court.

. FDA Lab Report (pdf)

Source: CQ HealthBeat News
Same-day coverage of the people and events shaping health care policy from Washington.
© 2009 Congressional Quarterly Inc. All Rights Reserved