

E-cigarette or drug delivery device?

July 20 2011

Devices marketed as "electronic cigarettes" are in reality crude drug delivery systems for refined nicotine, posing unknown risks with little new benefits to smokers, according to tobacco control experts.

In a "Perspective" published today in the [New England Journal of Medicine](#), researchers from the Legacy's Steven A. Schroeder National Institute for Tobacco Research and Policy Studies explore the current regulatory climate around electronic cigarettes ("e-cigarettes") and their safety. The authors, Nathan K. Cobb, MD, a pulmonologist and assistant professor at Georgetown University Medical Center, and David B. Abrams, PhD, executive director of the Schroeder Institute, also question future implications for physicians, policy makers and e-cigarette users.

E-cigarettes are constructed to mimic real cigarettes in size and appearance, but contain no tobacco and are not cigarettes at all. In reality they are delivery devices for refined [nicotine](#), having more in common with inhalers used to treat asthma or other delivery devices for both approved and [illicit drugs](#). Though individual brands vary in construction, the products generally produce a propylene glycol mist containing nicotine along with flavorings and other chemicals.

Currently, three interrelated products are being sold: the delivery device itself; cartridges that can contain up to 20 mg of nicotine; and refill kits that allow consumers to fill used cartridges with replacement nicotine solution. Some refill bottles, easily obtained over the Internet, contain enough nicotine to kill an adult if accidentally ingested.

The U.S. [Food and Drug Administration](#) (FDA) announced April 25, 2011, that it would regulate e-cigarettes as "tobacco products" and not as "drug-delivery devices." That action came after federal courts blocked the agency from regulating the products as drug-delivery devices. The courts maintained that, under the 2009 Family [Smoking Prevention and Tobacco Control Act](#) (FSPTCA), the FDA must regulate as tobacco products any product that contains nicotine from tobacco and that makes no claims to be therapeutic. These decisions together, the authors note, "upend[ed] the status quo" by having the effect of allowing the sale of unregulated refined nicotine directly to consumers, unless and until the FDA takes further action.

"The court's decision that e-cigarettes should be regulated as tobacco products and not as drug-delivery devices has substantially delayed the FDA regulatory process that normally protects the public health. It has the practical effect of allowing manufacturers to sell potentially dangerous refined nicotine products directly to consumers," said Cobb. "It is entirely possible that future modifications to the products will improve the efficiency of nicotine delivery and could dramatically increase the risks of addiction, abuse and serious overdose."

While most devices and nicotine fluids are produced by small manufacturers, Cobb and Abrams note that the fact that leading cigarette manufacturers Philip Morris International and British American Tobacco recently purchased sophisticated nicotine inhaler technologies may be an indication that both companies are developing next generation nicotine delivery devices of their own.

Abrams, a professor at Johns Hopkins Bloomberg School of Public Health added "Any refined nicotine product, whether used for smoking cessation and tested and approved by the FDA (like the Nicotrol inhaler) or a new product designed for 'reduced or modified' risk, can and must be tested and strictly regulated before being introduced to the market".

The authors argue that a comprehensive approach to regulating products containing refined nicotine is needed to protect the public's health and should involve Congress, the courts and the FDA.

In this piece, Cobb and Abrams discuss several safety concerns:

- Testing of cartridges reveals poor quality control, variability in nicotine content among brands, and deviations between label claims and cartridge content.
- The devices do not reliably deliver nicotine, and have not been sufficiently evaluated in scientific studies the way the FDA requires of other drugs and devices used for smoking cessation. Smokers attempting to use e-cigarettes as quitting aids will most likely find them ineffective due to the fluctuating nicotine content and unpredictable delivery.
- Manufacturers sell cartridges with a range of up to 20 milligrams of nicotine. However, refill kits allow consumers to fill used cartridges with replacement solutions at much higher doses. In fact, the devices are not limited to delivering nicotine. The paper notes that instructions for filling cartridges with marijuana hash oil can be easily accessed on the Internet.
- The safety of inhaling [propylene glycol](#) over an extended period of time has not been studied in humans.
- E-cigarettes may serve as a "bridge product" that smokers use in places where traditional tobacco smoking is prohibited, thus perpetuating their addiction and use of real cigarettes. Additionally, they may be used as a 'starter' product for young people considering smoking, especially since the cartridges can

be purchased over the Internet with tempting flavoring like grape and chocolate.

In their conclusion, Cobb and Abrams counter the argument made by e-cigarette advocates that taking the devices off the market could mean current users would be forced to return to traditional [tobacco products](#). Instead, the two researchers point to the multiple pharmaceutical-grade nicotine products on the market that have been regulated, approved and deemed safe and effective by the FDA, including patches, gums, lozenges, nasal sprays and even an FDA-approved inhaler. The two researchers also state that current users should pursue research-proven effective cessation tools, such as nicotine replacement products, telephone quit lines, and Web-based cessation services, as well as non-nicotine pharmacotherapies like bupropion and varenicline.

More information: For Legacy's e-cigarettes fact sheet, please visit the following page: [www.legacyforhealth.org/PDFPub ...ARETTE_0909 temp.pdf](http://www.legacyforhealth.org/PDFPub...ARETTE_0909_temp.pdf)

Provided by Georgetown University Medical Center

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