"E-CIGARETTE OR DRUG DELIVERY DEVICE?"

Schroeder Institute Researchers Raise Questions About Safety, Usage and Future Implications of New Nicotine Delivery Products

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Washington, D.C. - 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. For Legacy's e-cigarettes fact sheet, please visit the following page: **http://www.legacyforhealth.org/PDFPublications/ECIGARETTE_0909_temp.**
Legacy is dedicated to building a world where young people reject tobacco and anyone can quit. Located in Washington, D.C., the national public health organization helps Americans live longer, healthier lives. Legacy develops programs that address the health effects of tobacco use, especially among vulnerable populations disproportionately affected by the toll of tobacco, through grants, technical assistance and training, partnerships, youth activism, and counter-marketing and grassroots marketing campaigns. The foundation's programs include truth, a national youth smoking prevention campaign that has been cited as having contributed to significant declines in youth smoking; EX, an innovative public health program designed to speak to smokers in their own language and change the way they approach quitting; and research initiatives exploring the causes, consequences and approaches to reducing tobacco use. The American Legacy Foundation was created as a result of the November 1998 Master Settlement Agreement (MSA) reached between attorneys general from 46 states, five U.S. territories and the tobacco industry. Visit http://www.legacyforhealth.org/.

Legacy is equipped with a VideoLink ReadyCam,,¢ television studio system, providing journalists with faster, easier access to the nation's leading tobacco prevention and cessation experts. From this in-house broadcast studio, Legacy can offer immediate access to its experts to comment on breaking news, new research publications, or any news related to youth smoking prevention, adult quit smoking programs, or any issue related to smoking. The studio is connected directly to the Vyvx fiber network and is always available for live or pre-taped interviews. To arrange an interview, please contact Julia Cartwright at 202-454-5596.
About Georgetown University Medical Center
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-- or "care of the whole person." The Medical Center includes the School of Medicine and the School of Nursing & Health Studies, both nationally ranked; Georgetown Lombardi Comprehensive Cancer Center, designated as a comprehensive cancer center by the National Cancer Institute; and the Biomedical Graduate Research Organization (BGRO), which accounts for the majority of externally funded research at GUMC including a Clinical Translation and Science Award from the National Institutes of Health. In fiscal year 2009-2010, GUMC accounted for nearly 80 percent of Georgetown University's extramural research funding.

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The American Legacy Foundation is a national, independent, public health foundation located in Washington, D.C. It was created as a result of the November 1998 Master Settlement Agreement. The American Legacy Foundation collaborates with organizations interested in decreasing tobacco consumption among all ages and populations nationwide and has established goals to reduce youth tobacco use, decrease exposure to secondhand smoke, increase successful quit rates, and reduce disparities in access to prevention and cessation services and in exposure to secondhand smoke. For more information about the American Legacy Foundation, visit **www.americanlegacy.org** .

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