

# Researchers Call E-Cigarettes Unsafe as U.S. Court Weakens FDA Regulation

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A federal court has ruled that the Food and Drug Administration (FDA) can only regulate e-cigarettes as tobacco products (*FDA cannot regulate nicotine in "tobacco products"*) and not as drug-delivery devices, even as new research cast doubt on their safety.

The U.S. Court of Appeals for the D.C. Circuit said in its ruling that the Federal Food, Drug, and Cosmetic Act does not give the FDA the authority to regulate e-cigarettes under the same rules as nicotine gum or the nicotine patch, the Associated Press reported Dec. 7.

The ruling prevents the FDA from requiring e-cigarette manufacturers to conduct stringent clinical trials to prove the product's safety and effectiveness as an aid to quit smoking. The court said that the FDA did have the authority to regulate e-cigarettes as tobacco products.

The ruling was criticized by public health groups who have warned that e-cigarettes are unproven as stop-smoking aids, contain hazardous substances, and suffer from haphazard quality control and safety issues.

Matthew L. Myers, president of the Campaign for Tobacco-Free Kids, said the ruling will permit "any manufacturer to put any level of nicotine in any product and sell it to anybody, including children, with no government regulation or oversight at the present time."

## Researchers question e-cigarette safety

Meanwhile, new research suggests the electronic nicotine delivery devices may be unsafe, according to a Legacy Foundation press release published Dec. 7 on PR Newswire.

Investigators at the Schroeder Institute for Tobacco Control and Georgetown University's Lombardi Center lab-tested different brands of e-cigarettes. They found that the amount of nicotine delivered varied greatly, depending upon the maker of the device, the cartridge used, and "even from puff to puff."

"This inconsistency suggests poor quality control measures, which contributes to the list of unknowns about e-cigarettes and adds to the public health community's skepticism surrounding the products," said the study's lead author, Nathan Cobb, MD, Research Investigator at the Schroeder Institute.

Cobb and his colleagues said that although manufacturers claim that e-cigarettes may reduce the harm associated with cigarette smoke, the devices also present risks not associated with tobacco. The researchers found that e-cigarettes delivered three to five times less nicotine than advertised, but the "juice" bottles used to refill them could contain over 1.5 grams of nicotine, a lethal dose, in packages that were not child-resistant.

Cobb said, "The variation in design and poor quality control emphasizes that they should not be on the market until and unless regulation to ensure device safety has been established."

The study, "Novel Nicotine Delivery Systems and Public Health: The Rise of the 'E-Cigarette,'" appeared in the December 2010 issue of the American Journal of Public Health.

Meanwhile, researchers at the University of California conducted a separate study of e-cigarettes and concluded that they are unsafe to sell, HealthDay reported Dec. 7.

The investigators bought six different brands of e-cigarettes online and assessed their safety. Among other findings, they reported that most e-cigarette cartridges leaked nicotine onto users' hands; that cartridge labels rarely included expiration dates, health warnings, or information about what was in them; that cartridges with no nicotine content "looked identical to those that claimed to have higher nicotine content ... once removed from their packs and wrappers"; and that safety features often malfunctioned.

Printed and online marketing material for the devices also made factually inaccurate claims. For example:

"Be careful to avoid inhaling any significant quantity of fluid. Although it gives you a slight tingling sensation, it is not harmful."

"Within two weeks your lung capacity will increase by 30 percent ... Wrinkles in your skin will become less noticeable."

Investigators concluded that "regulators should consider removing electronic cigarettes from the market until design features, quality control, disposal and safety issues have been adequately addressed."

The study, "Electronic nicotine delivery systems: is there a need for regulation?" was released online December 7, 2010 in Tobacco Control.