



E-Cigarettes

Are they safe? Will they help smokers quit?

Electronic cigarettes or “e-cigarettes” are battery-operated devices that allow the user to inhale a vapor produced from cartridges filled with nicotine, flavor and other chemicals. E-cigarette companies promote them as healthier, convenient, and more socially acceptable alternatives to traditional cigarettes.

There is no scientific evidence that e-cigarettes are safe or that they can help smokers quit.

What are E-Cigarettes?

- According to the U.S. Food and Drug Administration (FDA), e-cigarettes are combination drug-device products designed to deliver nicotine or other substances to a user in the form of a vapor.¹ FDA does not consider e-cigarettes to be tobacco products.
- Despite FDA’s view on these products, a federal appeals court has ruled that e-cigarettes are tobacco products rather than drug-devices. Unless manufacturers make therapeutic claims, e-cigarettes may only be regulated as tobacco products under the court’s current decision. While the court denied a subsequent request for appeal from FDA and public health advocates, the case may still be appealed to the U.S. Supreme Court.
- E-cigarettes are not traditional cigarettes. They are typically composed of a rechargeable, battery-operated heating element, a replaceable cartridge that may contain nicotine or other chemicals, and an atomizer that uses heat to convert the contents of the cartridge into a vapor, which is then inhaled by the user.²
- Some e-cigarettes contain nicotine, a highly addictive drug³.

Safety and Cessation Concerns

- There is currently no scientific evidence about the safety of e-cigarettes. In initial lab tests, FDA found detectable levels of carcinogens (nitrosamines) and toxic chemicals, including an ingredient used in anti-freeze, in two brands of e-cigarettes and numerous cartridges. FDA determined that users could potentially be exposed to these chemicals.⁴ This contradicts manufacturers’ claims^{5,6,7} that their products are safe alternatives to tobacco.
- E-cigarettes have not been approved by the FDA for use in smoking cessation. No evidence exists to show they help people quit smoking.⁸
- More research on e-cigarettes is needed to determine what ingredients they contain, how they are being used, and what effect they have on users.

Marketing and Youth Access Concerns

- Despite the fact that e-cigarettes have not been shown to be effective tobacco cessation tools, some distributors are marketing them either directly or indirectly for that purpose.⁹
- In one study, FDA found that some e-cigarette cartridges claiming not to contain nicotine actually did.¹⁰
- Government agencies and medical organizations, such as the FDA, the Centers for Disease Control and Prevention, and the American Academy of Pediatrics have also expressed concern that e-cigarettes could increase nicotine addiction and tobacco use in youth.¹¹
- E-cigarettes are often made to resemble traditional cigarettes and can be available in flavors appealing to youth. E-cigarettes may also lead youth to try traditional cigarettes or other tobacco products, which are known to cause disease and premature death.¹²
- Many nicotine refill bottles or cartridges are not adequately packaged to prevent children’s access or accidental ingestion of toxic amounts of nicotine.

Recent Court Ruling on E-Cigarettes

In December 2010, the DC Circuit Court of Appeals struck down FDA's authority to regulate e-cigarettes as drug-delivery devices unless manufacturers make health or cessation claims for their products. FDA wanted to use more stringent "drug" and "device" regulations to determine whether the products should even be permitted on the market. Unfortunately, the court held that e-cigarettes would more appropriately be classified as "tobacco products," now that FDA has the authority to regulate tobacco products under the Family Smoking Prevention and Tobacco Control Act (FSPTCA). This decision means that with respect to e-cigarettes, as with tobacco products, no state or locality can require something different or in addition to the FDA's tobacco product standards, pre-market review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk claims. However, states and localities CAN enact laws/standards that are more stringent with respect to prohibition of sales, distribution, exposure to, access to, advertising or promotion of, or use of tobacco products.

ACS CAN's Current Views

- ACS CAN believes that because nicotine is a drug, e-cigarettes are drug-delivery devices, rather than tobacco products, and should be regulated under FDA's drug and device authority and not available for sale until FDA determines they are safe.
- The DC Circuit Court's December 2010 ruling (explained at left) is problematic because the laws governing tobacco products allow them to be on the market under different product and marketing standards than the safety and efficacy standards applicable to drugs and medical devices. Allowing the FDA to regulate e-cigarettes as drug-delivery devices would give them the authority to study the products, as well as take greater action to protect and advance the public health.
- ACS CAN supports including e-cigarettes in new smoke-free laws or amendments to existing laws. However, due to the legal action surrounding the regulation of e-cigarettes, they should clearly be defined as different from tobacco products and addressed separately in the law.
- Regardless of the marketing tactics that e-cigarette companies use, ACS CAN supports restricting the sale of e-cigarettes until evidence shows that these products are not harmful.
- Laws that only prohibit sales to minors do not go far enough to protect public health.

References

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- ⁴ U.S. Food and Drug Administration. Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA. July 22, 2009. Available online at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm>.
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- ¹¹ U.S. Food and Drug Administration. FDA and Public Health Experts Warn About Electronic Cigarettes.
- ¹² U.S. Food and Drug Administration. FDA Warns of Health Risks Posed by E-Cigarettes. July 23, 2009. Available online at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm173401.htm>.