E-cigarettes and Lung Health

On May 5, 2016, the Food and Drug Administration (FDA) announced it was extending its authority to include e-cigarettes and other tobacco products. Starting in August 2016, FDA began to apply and enforce key provisions of the Family Smoking Prevention and Tobacco Control Act as it relates to the sales, marketing and manufacturing of e-cigarettes.

The American Lung Association had long called for FDA to bring e-cigarettes and other unregulated tobacco products under its authority. This action was especially important given the rapid rise in youth use of e-cigarettes in the U.S., including a 900 percent increase among high school students from 2011 to 2015.1

The U.S. Surgeon General Issues Report on E-Cigarette Use Among Youth

In December 2016, the U.S. Surgeon General issued a groundbreaking report "E-Cigarette Use Among Youth and Young Adults" that made a number of important conclusions and findings about the use of e-cigarettes among youth. These included that the flavors in e-cigarettes are one of the main reasons youth use them, e-cigarette aerosol is not safe and that e-cigarette use is strongly associated with the use of other tobacco products among youth and young adults.1

Most importantly, the Surgeon General concluded that e-cigarette use among youth is now a significant public health concern and steps must be taken by parents, educators and especially policymakers to discourage use of e-cigarettes.1
How Will FDA Oversee E-cigarettes?

A 2010 ruling from a federal court in a case filed by an e-cigarette manufacturer against the FDA determined that e-cigarettes which do not make therapeutic claims will be regulated as tobacco products.

If a manufacturer does make a therapeutic claim (such as that an e-cigarette can help you quit smoking), then the manufacturer must first prove through a series of clinical trials that their product is safe and effective.

What Are E-cigarettes?

Electronic cigarettes, or e-cigarettes, include e-pens, e-pipes, e-hookah, and e-cigars are known collectively as ENDS – electronic nicotine delivery systems. According to the FDA, e-cigarettes are devices that allow users to inhale an aerosol containing nicotine or other substances.

Unlike traditional cigarettes, e-cigarettes are generally battery-operated and use a heating element to heat e-liquid from a refillable cartridge, releasing a chemical-filled aerosol.

The main component of e-cigarettes is the e-liquid contained in cartridges. To create an e-liquid, nicotine is extracted from tobacco and mixed with a base (usually propylene glycol), and may also include flavorings, colorings and other chemicals.

Following the 2016 announcement allowing FDA oversight of tobacco products, e-cigarette manufacturers must register with FDA by August 8, 2016, and then will have two additional years to submit an application to remain in the marketplace. Until that time, the nearly 500 brands and 7,700 flavors of e-cigarettes will remain on the market – before FDA is able to fully evaluate them. Until FDA's evaluation is done, there are
very few ways for anyone other than the manufacturers to know what chemicals are contained in e-liquids, or how e-cigarette use might affect health, whether in the short term or in the long run.

The U.S. Surgeon General has concluded that e-cigarettes can expose users to several potentially harmful chemicals, including nicotine, carbonyl compounds and volatile organic compounds.¹

**Nicotine**

Nicotine is an addictive substance, and almost all e-cigarettes contain nicotine. Even some products that claim not to have any nicotine in them may still contain it. For instance, initial FDA lab tests conducted in 2009 found that cartridges labeled as nicotine-free had traceable levels of nicotine. A 2014 study found little consistency in the amount of nicotine delivered by e-cigarettes of the same brand and strength.² Similarly, another 2014 study found that the amount of nicotine in e-liquid refills is often substantially different from the amount listed on the package.³ Experienced users learn how to use e-cigarettes in a way that increases their exposure to nicotine. Newer e-cigarette devices, especially "tank" styles, with higher voltage also deliver a greater concentration of nicotine. This matters because the more nicotine used, the greater the potential for addiction.

Nicotine is not safe. The U.S. Surgeon General has found exposure to nicotine during pregnancy harms the developing fetus, and causes lasting consequences for the developing brain and lung function in newborns. Nicotine exposure also affects maternal and fetal health during pregnancy, and can result in low birth weights, preterm delivery and stillbirth. It can also cause sudden infant death syndrome.¹ Nicotine also has a negative impact on adolescent brain development. Human brain development continues far longer than was previously realized, and nicotine use during adolescence and young adulthood has been associated with lasting cognitive and behavioral impairments, including effects on working memory and attention.⁴
*Other chemicals*

We don't presently know what is in e-cigarettes. However, in initial lab tests conducted in 2009 the FDA found detectable levels of toxic cancer-causing chemicals, including an ingredient used in anti-freeze, in two leading brands of e-cigarettes and 18 various cartridges. A review of studies found that levels of toxins in e-cigarette aerosol varied considerably within and between brands. A 2014 study found that aerosol from e-cigarettes with a higher voltage level contains more formaldehyde, another carcinogen with the potential to cause cancer. The findings are alarming, and underscores why the American Lung Association called so urgently for FDA oversight of these products.

Flavors in e-cigarettes are also a cause for concern. Not only are flavors used to target kids, but they may be harmful on their own. E-cigarette and flavor manufacturers and marketers may suggest that the flavor ingredients used in e-cigarettes are safe because they have FEMA GRASTM status for use in food, but such statements are false and misleading. The reality is that FEMA GRASTM status only applies to food, meaning it's safe to eat, and does not apply to inhaling through e-cigarettes.

The U.S. Surgeon General has concluded that flavoring/taste is one of the main reasons youth and young adults use e-cigarettes and according to data from the 2013-2014 wave of FDA’s PATH study, among youth who have ever tried an e-cigarette, 81 percent used a flavored product the first time they tried one.

Diacetyl, a buttery flavored chemical often added to food products such as popcorn, caramel, and dairy products, has also been found in some e-cigarettes with flavors. Diacetyl can cause a serious and irreversible lung disease commonly known as "popcorn lung."

*Poisoning concern*

Aside from concerns about e-cigarette use and emissions alone, data released by the Centers for Disease Control and Prevention (CDC) shows that calls to the nation's poison centers for e-cigarette exposure poisonings are rapidly increasing. One study
found that while most calls involving e-cigarette liquid poisoning came from accidental ingestion of the e-cigarette or its liquid, about one-sixth of the calls related to someone inhaling these items. Exposure through the eye and the skin were also reported.

Large doses of nicotine have a potential for poisoning, with symptoms beginning with nausea and vomiting in cases of acute toxicity and progressing to seizures and respiratory depression in cases of severe nicotine poisoning. The U.S. Surgeon General has concluded that ingestion of e-cigarette liquids containing nicotine can cause acute toxicity and possibly death.\(^1\) This is particularly true in children as calls to poison control centers have increased nationwide. Tragically, one child died from acute e-cigarette poisoning in 2014, attributed to the ingestion of liquid nicotine from an e-cigarette.

**Secondhand Emissions from E-cigarettes?**

As public spaces increasingly become smokefree, anecdotal reports show some people are attempting to use e-cigarettes indoors and in public spaces which are smokefree, like bars, restaurants and even public transit.

While e-cigarettes do not contain smoke, they do expose others to secondhand emissions. Two studies have found formaldehyde, benzene and tobacco-specific nitrosamines (all carcinogens) coming from those secondhand emissions. Other studies have shown that chemicals in the emissions contain formaldehyde, acetaldehyde and other potential toxins. The U.S. Surgeon General has concluded that e-cigarette aerosol is not harmless, and can contain harmful and potentially harmful chemicals, including nicotine.\(^1\)

The American Lung Association supports prohibiting the use of e-cigarettes in worksites and public places, and including e-cigarettes under smokefree laws with other tobacco products. Currently, nine states, the District of Columbia and hundreds
of communities have prohibited e-cigarette use in the same places where smoking is already prohibited.

Can E-cigarettes Help Someone Quit Smoking?

Many e-cigarette companies market their product as a tool to help smokers quit. However, the FDA’s Center for Drug Evaluation and Research has not approved any e-cigarette as a safe or effective method to help smokers quit.

Instead of quitting, many e-cigarette users are continuing to use e-cigarettes while still using conventional cigarettes. In 2015, 58.8 percent of the people who recently used e-cigarettes also currently smoked conventional cigarettes. The U.S. Surgeon General has found that even smoking a few cigarettes a day is dangerous to your health. The U.S. Public Health Service has found that the seven therapies approved by the U.S. Food and Drug Administration in combination with individual, group or phone cessation counseling are the most effective way to help smokers quit. Until and unless the FDA approves a specific electronic nicotine delivery system or e-cigarette as safe and effective for use as a tobacco cessation aid, the American Lung Association does not support their use for cessation or any direct or implied claims that e-cigarettes help smokers quit.

Youth and E-cigarettes

Youth are using e-cigarettes at increasing and alarming rates. Between 2011 and 2015, the U.S. Surgeon General found e-cigarette use among high school students increased by 900 percent, with more teens now using e-cigarettes than cigarettes. The tobacco industry aggressively markets e-cigarettes to youth, glamorizing e-cigarette use in advertisements and offering e-cigarettes in candy flavors like bubble
gum and gummy bears. Kids can also easily buy e-cigarettes online, according to a March 2015 study published in *JAMA Pediatrics*. Learn more about youth e-cigarette use. FDA oversight, which would include youth access restrictions, must be maintained to protect kids from becoming the next generation hooked on nicotine.

**Bottom Line**

E-cigarettes are a tobacco product. The American Lung Association remains concerned about their impact on the public health, given the dramatic increase in use among youth. As FDA begins its oversight of these products, we will learn more about them and more safeguards will be put in place to protect the public health.

Smokers who wish to quit can learn more about ways that have been proven safe and effective in helping smokers quit at [Lung.org/stop-smoking](http://Lung.org/stop-smoking).