



## Are E-Cigarettes Safe?

Even without tobacco, the poorly regulated devices may pose unique dangers

**Television advertisements** for cigarettes have been banned in the U.S. since 1971, but in the past few years supposedly healthier, battery-powered alternatives have landed numerous prime-time appearances. Electronic cigarettes, or e-cigs, as they are known, soaked up the spotlight in recent Super Bowl commercials, on late-night talk shows and in a comedy sketch during the 2014 Golden Globe Awards. Indeed, a recent survey shows that nearly 60 percent of Americans are now familiar with the sleek, smokeless devices.

The concept behind e-cigs is clever: they allegedly offer all the fun of typical cigarettes without any of the dangers. E-cigs use a small, heated coil to vaporize a nicotine-laced solution into an aerosol mist. By inhaling the mist, users enjoy the same satisfaction they would get from an ordinary cigarette but do not expose themselves to tobacco, which turns into cancer-causing tar when it is burned. Such products free smokers from huddling in the cold or rain and, in many places, from ordinances that forbid smoking in public places.

But are e-cigs truly safe? No one knows for sure. Yet there is no question that the nicotine they contain is addictive—which is one reason many public health experts have grown alarmed by their rapidly increasing popularity. Among their concerns: e-cigs might

lure former smokers back to conventional cigarettes, expose users and bystanders alike to unidentified dangers, or become a gateway for teens who might subsequently experiment with tobacco products and other drugs.

The U.S. Food and Drug Administration and the European Union are grappling with these issues as they decide how to regulate the products. Unfortunately, they must act before all the facts are available. Unfettered access could leave people vulnerable to unknown health hazards, but there is also the chance that greater restrictions might hurt folks who are trying to forgo conventional—and more dangerous—tobacco products.

### FIRST PUFFS

THE CURRENT ITERATION of e-cigarettes was invented and popularized by Chinese pharmacist Hon Lik in 2003 and entered the U.S. market some seven years ago. (Earlier attempts at a “smokeless, non-tobacco cigarette,” patented in 1965, never caught on.) Initially the FDA tried to regulate them as drug-delivery devices, defined under federal law as items “intended to affect the structure or any function of the body.” E-cigarette company NJOY sued the agency, however, arguing that nicotine-containing devices were

similar to tobacco products—which the FDA had also previously tried and failed to have declared drug-delivery systems. A federal appeals court ruled in December 2010 that the agency lacked authority over e-cigs because they offer only the recreational benefits of a regular cigarette. That legal decision allowed sales of e-cigarettes to proceed but left many questions about their safety unaddressed.

In lieu of carcinogenic tobacco, e-cigarettes typically contain three main ingredients: nicotine, a flavoring of some kind and propylene glycol—a syrupy synthetic liquid added to food, cosmetics, and certain medicines to absorb water and help them stay moist. The primary established danger of nicotine is that the stimulant is highly addictive, although emerging science also links it to an impaired immune system. Propylene glycol has been “generally recognized as safe,” or GRAS (an official FDA designation), since 1997. Yet more needs to be understood before e-cigarettes can be given a clean bill of health.

Propylene glycol, for example, is usually eaten (in cupcakes, soft drinks and salad dressings) or slathered onto the body (in soaps, shampoos and antiperspirants)—not breathed into the lungs. Many things that can be safely eaten—such as flour—can damage the lungs when inhaled. No one knows whether propyl-

ene glycol falls into that category. “We have little information about what happens to propylene glycol in the air,” the federal Agency for Toxic Substances and Disease Registry says on its Web site. An assessment from the agency, issued in 2008, references only a couple of studies that cover inhalation exposures—all with laboratory animals rather than people.

Beyond the three main ingredients, some researchers worry about by-products from heating electronic cigarettes and the solution inside them. Various studies suggest the vapors from e-cigarettes contain several cancer-causing substances, as well as incredibly tiny particles of tin, chromium, nickel and other heavy metals, which, in large enough concentrations, can damage the lungs. These particles likely fleck off the solder joints or metal coil in the devices when heated. Because they are so small, the tiniest bits of metal, known as nanoparticles, can travel deep into the lungs. There they could exacerbate asthma, bronchitis—an inflammation of the tubes that carry air to and from the lungs—and emphysema—a disease in which the lungs’ many air sacs are destroyed, leaving patients short of breath. So far there are not enough data to say with certainty whether e-cigs worsen these disorders.

Craig Weiss, president and CEO of NJOY, went on NPR during the summer and espoused the safety of e-cigarettes, pointing to “clinical trial” data he said would soon be published in peer-reviewed literature. When *SCIENTIFIC AMERICAN* requested that study, it received a draft of a small study looking at the use of e-cigs for short-term smoking reduction, not the kind of large, long-term, rigorously conducted trial that has become the gold standard in medicine. “It is not a study that would lead to drug approval,” admits Joshua Rabinowitz, NJOY’s chief scientist, but a clinical trial “is defined as a test of biological response in a human in a clinical setting, and that is exactly what was done.”

The few scientists actively trying to fill the gap in the research literature are running into obstacles. When studying tobacco cigarettes, researchers rely on smoking machines that simulate how frequently a typical smoker takes a puff and how much smoke is inhaled with each breath. No one has yet determined how much e-cig vapor the typical user breathes in, so different studies assume different amounts of vapor as their standard, making it difficult to compare their results. Tracing what happens to that vapor once it is inhaled is equally problematic. When the human body breaks down a foreign substance, one can typically find chemical by-products in hair or urine that provide clues about how it has interacted with cells. This is true for nicotine, but in the case of propylene glycol, no one has established what the relevant by-product is or how to best detect it.

#### WILD WEST

AS SCIENTISTS STRUGGLE to test the safety of e-cigarettes, the devices are becoming more and more popular among teens and preteens. E-cigarette use among U.S. high school students more

than doubled from 4.7 percent in 2011 to 10 percent in 2012, according to recent data from the Centers for Disease Control and Prevention’s National Youth Tobacco Survey. At least 160,000 students who had never tried conventional cigarettes puffed on e-cigs. Yet another analysis linked e-cig use with greater odds of trying tobacco. They come in kid-friendly flavors, including chocolate, bubble gum and gummy bear. Sold online and in the mall, e-cigarettes are also easy for minors to acquire.

Federal legislative milestones that protect youngsters from conventional cigarettes—such as blocking sales to minors and preventing commercials targeted at adolescents—do not exist for e-cigarettes. In an attempt to remedy the situation, 40 state attorneys general signed a letter last September urging the FDA to assume “immediate regulatory oversight of e-cigarettes, an increasingly widespread, addictive product.”

Yet there has been hardly any definitive legislation regarding the sale and consumption of e-cigs in the U.S. Meanwhile Canada has made it illegal to sell e-cigarettes preloaded with nicotine in stores, but the regulation is not well enforced, and customers can buy vials of nicotine online. Things are slightly better across the pond. At press time, the European Parliament had approved a ban on e-cigarette advertising starting in mid-2016, and the ban seemed likely to get approval from the E.U.’s member states.

Without regulations, it is the “Wild West” for e-cigarette companies, says Stanton Glantz, director of the Center for Tobacco Control Research and Education at the University of California, San Francisco, and a self-described e-cigarette pessimist. He argues that given the paucity of health data, current indoor smoking bans should apply to e-cigs as well. “One of the real problems [with] these things is that because of the low quality control, you never quite know what you are getting,” he says. Those who support minimal regulation contend that limiting the use of e-cigarettes would encourage more people to smoke conventional cigarettes.

As the debate blazes, deep-pocketed big tobacco investors are buying up e-cig companies, injecting millions of dollars into the market and banking on a bright future for the devices. More than 100 e-cigarette companies are now jockeying for the business of smokers and nonsmokers alike. The success of all these enterprises hinges on the claim that e-cigarettes are healthier than traditional cigarettes. Companies like to paint a black-and-white picture of a new era of safe smoking. “Cigarettes, you’ve met your match,” NJOY proudly proclaims in its Super Bowl ads. Whether e-cigs are genuinely safe is far hazier. ■

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