



# New FDA Rule Classifies and Regulates e-Cigarettes as "Tobacco" Products

By Dominic B. Sanginiti, Jr.

A new FDA rule has sent economic shivers through the unregulated e-cigarette industry because players will now have to follow U.S. health and safety rules in manufacturing and distribution of the products. In ten short years, the completely unregulated e-cigarette industry has gone from \$0 to more than \$3.5 billion in revenue and is still reporting exponential growth. The new regulation, which will take at least two years to implement, classifies and regulates e-cigarettes as "tobacco" products. Restrictions include a ban on selling e-cigarettes to children; advertising restrictions; and a requirement to apply for FDA approval before distributing the products to the U.S. marketplace. FDA approval applications cost upwards of \$1 million each.

The health and safety benefits to consumers are expected to outweigh the financial impact to e-cigarette manufacturers and vendors—just as they did with the traditional tobacco industry. In this unregulated marketplace and much like in the pre-regulation days of cigarettes, companies do not have to reveal what is in the product they are selling, how dangerous it may be, or what safety standards, if any, are being applied to the delivery system. As a result, consumers don't know what is actually in the vapor they are inhaling. A rash of devastating injuries caused by e-cigarette use has brought this issue to the forefront resulting in a number of lawsuits and the new FDA rule.

## What Is an e-Cigarette?

According to the FDA, e-cigarettes are battery-operated Electronic Nicotine Delivery Systems (ENDS) that are used to heat cartridges of liquid containing nicotine. When heated, the units create a vapor that users then inhale. The liquids contain a base (generally some type of glycol component), the nicotine, flavoring, and possibly other unknown elements.

## Who Uses e-Cigarettes?

The Campaign for Tobacco-Free Kids estimates show that three million of the U.S. e-cigarette users are middle school and high school students—most of whom have never smoked traditional cigarettes. Statistics also show that over 50% of adult users have switched to e-cigs in an attempt to quit smoking. "Switchers" appear to be smoking less with e-cigarettes. However even light smoking is risky because "smoking just 1-4 cigarettes a day doubles the risk of dying from heart diseases." Preliminary data does not support that the switch to e-cigarettes results in smoking cessation.

## What Is in the Vapor?

The composition of the liquid is the key component to an e-cigarette—it contains nicotine which is a poisonous substance that comes from the tobacco plant and is addictive, and the liquid base which may have unknown composition. Most people don't realize that many vaping shops mix their own liquids and package them onsite. This is a completely unregulated process that results in chemical inconsistencies and limited information on the composition of the liquids being heated and inhaled. The liquid components, including the nicotine, can be purchased directly off the Internet.

## Why Are e-Cigarettes Unsafe?

Nicotine, Liquids and Vapor

The FDA reported finding toxic cancer-causing chemicals (including formaldehyde) in the aerosols along with a disturbing inconsistency in the levels of chemicals in different cartridges. There are also inconsistent levels of nicotine in liquids. A recent study by the Salt Lake City health department showed disparities of up to 10%—up or down—on 61% of labeled products at vaping stores. As early as 2009,



FDA lab tests reported that some liquids sold as “nicotine free” contained “traceable levels of nicotine.”

The nicotine in the liquids also poses a serious risk to children and to users who suffer skin exposure. In the first five months of 2016, the American Association of Poison Control Centers (AAPCC) reported “770 e-cigarette poison exposures” a high percentage of which occurred in children under age six.

Perhaps the most dangerous additive to these liquids comes from the food flavorings that are used to improve the taste of “vaping.” Flavors are approved by the FDA for “ingestion,” not “inhalation.” The American Lung Association warns that a “buttery” food flavoring used in popcorn and dairy products contains diacetyl, a compound that when inhaled causes “popcorn lung,” an irreversible lung disease. An e-cigarette study published in the National Health Institute’s (NIH) Environmental Health Perspectives journal showed that diacetyl was present in 75% of 51 different e-cigarette compounds tested by scientists working with the World Health Organization (WHO).

## Explosions

The lithium batteries in e-cigarettes are known to explode during charging and during use. At least one exploded while in transport on a plane. The injuries caused by these incidents can be devastating including severe burns, broken jaws/bones, and disfiguring skin, face, and limb injuries. A study released in 2014 by FEMA showed that 80% of the explosions occur during charging. Currently there are no regulations to compel battery testing as may be required with other products (i.e., UL ratings), nor will the FDA rule

address this. Moreover, contrary to the number of incidents with e-cigarettes, lithium batteries typically have a low rate of failure or explosion. The FEMA report suggests that the high incidence in e-cigarettes may be due to a design failure related to the battery shape and/or failure to incorporate measures to prevent the battery from “rocketing” outward during an explosion.

Without regulation of the product design and battery performance, the incidence of explosions and injuries are likely to continue. The unfortunate results of laissez faire product construction are devastating injuries to both adults and minors. Product liability cases are often filed to get remedies for injuries suffered during defective product use—in these cases for use of e-cigarettes.

## Market Players

Even though the new FDA ruling won’t have any effect on battery explosion injuries, it is the first step in bringing much needed regulation to the industry. While there is a great outcry that the new regulations are going to seriously harm small businesses, the truth is that the big tobacco companies have already cornered a large part of the market. According to Reuters, Reynolds Tobacco’s Vuse brand had 36 percent of the U.S. market by June 2015. It then acquired the second highest selling brand, Blue eCigs from Lorillard Tobacco. Interestingly, Reynolds has a sordid history of targeting its products to children—in the 1990s it was sued by the FTC for targeting its Joe Camel cigarette ads to children—a suit that ended in a \$10 million settlement. Big tobacco companies put large amounts of money into advertising—including advertising to prevent regulation of their new revenue stream in the e-cigarette industry.

## More Injuries on the Horizon

The FDA rule will take two years before it is in full effect to protect minors and other users from the dangers of vaping liquids. E-cigarette manufacturers are required to file for FDA reviews sometime late in 2016. During this period, we are likely to see more young people starting to vape, more poisonings, and a rise in medical side effects from use. Unfortunately, the FDA requirements won’t address what may be a defective product issue that results in explosions. The idea of preventing explosions with charging alternatives, i.e., using a different power supplies, has not been tested and carries no guarantee of positive effect. That solution also doesn’t address USB chargers incorporated in the design of e-cigarettes. A solution to the problem has yet to be proposed by the manufacturers because the number of explosions hasn’t reached what they consider to be serious levels.

Right now, nearly all e-cigarette users are at risk for an explosion. Until design changes are made, the growing number of consumers buying e-cigarette systems will result in a rising number of incidents. It’s possible this issue won’t be addressed until product liability lawsuits are settled in court—leaving a large number of consumers with life-changing injuries and questioning how this was allowed to happen.

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