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Lawmakers Continue E-Cig Regulatory Onslaught

Right from the gate, e-cigarettes have defied categorization. Various jurisdictions nationwide are approaching the innovative products with a wide ranges of sales restrictions. >BY BRYAN M. HAYNES

With the growing popularity of e-cigarettes, federal, state, and local regulators are increasingly restricting the use and sale of these products, and new regulatory restrictions are continually being announced. One trade association has reported that e-cigarette makers have been able to capture approximately 14 percent of the 44 million tobacco users in the United States, and this market is expected to grow further.

WHAT EXACTLY ARE E-CIGARETTES?

Short for “electronic cigarettes,” e-cigarettes are essentially electronic nicotine delivery systems; they are most often shaped like cigarettes—although occasionally like cigars or pipes—and are designed to deliver nicotine to a user in the form of a vapor. Generally, an e-cigarette consists of a lithium battery-powered heating element and replaceable cartridges that contain nicotine or other chemicals, and an atomizer that, when heated, converts the contents of the cartridge into a vapor that a user inhales. E-cigarettes are considered to be non-combustible, given that they emit a vapor rather than smoke.

Sometimes, they can be legally used where traditional tobacco products are banned, and various physician groups have defended the product, based on their opinion that e-cigarettes deliver nicotine without the combustion, tar, and numerous other chemicals found in regular cigarettes.

FEDERAL CHALLENGES TO E-CIGS

The Food and Drug Administration (“FDA”) has, however, expressed concern about the lack of clinical studies on the potential health risks posed by e-

cigarettes and the way these products are sometimes marketed without health warnings or age restrictions. Notably, between 2008 and 2010, the FDA made a determination that certain e-cigarettes were unapproved combination drug/device products. Based on this determination, the FDA detained and effectively prevented the e-cigarettes made by several companies from being imported. One company challenged that determination in court.

The U.S. Court of Appeals for the D.C. Circuit, in *Sottera, Inc. v. Food & Drug Administration*, issued a decision

which discussed the regulatory classification of e-cigarettes and other products “made or derived from tobacco” and the jurisdictional line that should be drawn between “tobacco products” and “drugs,” “devices,” and combination products, as those terms are defined by relevant laws. The court held that e-cigarettes and other products made or derived from tobacco should be regulated as “tobacco products,” and were accordingly not drugs/devices unless they are marketed for therapeutic purposes. The federal government decided not to seek further review of this decision, and the FDA is complying with the jurisdictional lines established by *Sottera*. Notwithstanding, the FDA has recently indicated its intention to issue regulations covering e-cigarettes. Thus, any manufacturer, distributor or retailer of e-cigarettes must keep abreast of any of the FDA’s proposed enactments relating to e-cigarettes to ensure they understand how any changes affect the sale, distribution, and use of e-cigarettes.



>The e-cigarette category is experiencing tremendous growth, both in terms of sales volume, and in brand proliferation. Pioneered by small startups, the market has now been joined by all three of the largest cigarette manufacturers. Specialty tobacco importer and brand developer Kretek Imports, Moorpark, Calif., has developed EZ Cig (above), as well as Cig2o entries.

STATE, LOCAL REGULATORY ENACTMENTS AFFECTING E-CIGARETTES

States and localities have been increasingly enacting regulatory limitations on both the sale and use of e-cigarettes. Various state attorneys general have also brought lawsuits alleging that e-cigarette distributors have violated state law by selling to minors or making unsubstantiated health claims. Several of the state and local regulatory restrictions and administrative pronouncements related to e-cigarettes include:

- Arizona:** State law prohibits minors from buying or possessing e-cigarettes.
- California:** State law prohibits the sale of e-cigarettes to minors.
- Colorado:** E-cigarettes have been classified as a tobacco product by Colorado law, and thus the sale and use of e-cigarettes by minors is prohibited.
- Connecticut:** State law prohibits the use of e-cigarettes by minors. A bill to regulate

smoking of e-cigarettes in certain public places was introduced in 2013, but has not passed.

- Kentucky:** Legislation, which has not yet passed, was introduced in 2013 to regulate smoking of e-cigarettes indoors; however, local bans of indoor smoking of e-cigarettes are already in effect in Bullitt and Madison Counties.
- Massachusetts:** Local ordinances in effect in South Hadley, North Attleboro, and Somerset restrict the indoor use of electronic cigarettes as well as their sale to minors.
- Minnesota:** State laws regulate and tax the sale of e-cigarettes and impose criminal penalties for their sale to minors.
- Missouri:** State law bans e-cigarette use, except in private homes, vehicles, and some hotel rooms.
- New Hampshire:** State law prohibits the sale of e-cigarettes and liquid nicotine to

minors and prohibits the distribution of free samples of such products in a public place. The use of such products is also prohibited on the grounds of any public educational facility.

- New Jersey:** State laws prohibit the use of electronic smoking devices in all enclosed indoor places of public access as well as in workplaces.
- New York:** Local ordinances in Cattaraugus County ban e-cigarette sales to minors and prohibit the use of e-cigarettes in public places and workplaces. Suffolk County has similarly enacted an ordinance which prohibits the sale of e-cigarettes to minors and which prohibits "the use of e-cigarettes and like products in public places where traditional forms of smoking are already disallowed."
- Oregon:** An agreement was reached between the Attorney General and an e-cigarette manufacturer prohibiting the sale and distribution of manufacturer's electronic cigarettes in Oregon.

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New York City Targets E-Cigs with “Defacto Ban”

Despite a May 2, 2013 meeting of the New York City Committee on Health, during which a representative from the NYC Department of Health & Mental Hygiene stated that the department had no intention of trying to regulate e-cigarettes, drafts of three tobacco bills were leaked in August showing that Mayor Michael Bloomberg’s administration was working to explicitly categorize electronic cigarettes as tobacco products and enact a sweeping ban on flavored e-cigs.

One of the bills would raise the legal age to purchase all tobacco products to 21, while another would prohibit the display of any cigarette advertising in stores. A third bill would prohibit the use of tobacco coupons, create a \$10.50 price floor for cigarette packs, and increase the fines against those selling illegal cigarettes. Initially the bills, drafted by the Health Department and introduced into the Council at the request of Mayor Bloomberg, didn’t reveal the city’s position on electronic cigarettes. Menthol and “tobacco flavored” appear to remain unregulated under the bills, but the sale of flavored e-cigs would be relegated to nearly extinct “tobacco bars,” resulting in a defacto ban, says Dr. Michael Siegel, a professor of Community Health Sciences at the Boston University School of Public Health and a supporter of electronic cigarettes as a lower risk smoking alternative.

Washington: *Local ordinances in King County (which includes Seattle) ban the use of e-cigarettes in all public places.*

Given the growing debate regarding e-cigarettes, legislation that seeks to tax and regulate the sale and use of e-cigarettes is predicted to be introduced and enacted in an ever-increasing number of jurisdictions in the future. Manufacturers, distributors, and retailers of e-cigarettes must carefully monitor the laws at the federal, state, and local levels to ensure that they are in compliance. Many laws impose substantial monetary—and in some cases even criminal—penalties for violations. As the category continues to grow, detractors mobilize, often ignoring the inherent differences from combustible tobacco. **S**

Utah: *State laws regulate the sale, gifting, and distribution of e-cigarettes by manufacturers, wholesalers, and retailers.*

Virginia: *The attorney general issued an official opinion that e-cigarette use does*

not fall within the definition of “smoking” for purposes of the Virginia law that prohibits smoking in a variety of locations, including elevators, public school buses, and the interior of public elementary, intermediate and secondary schools.

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