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Federal, State and Local Lawmakers Take Aim at E-Cigarettes

With the growing popularity of e-cigarettes, federal, state and local regulators are continuing to look at these products with a careful eye. The Tobacco Vapor Electronic Cigarette Association has predicted that the market for e-cigarettes may quadruple between now and 2014.

What exactly are e-cigarettes?

E-cigarettes, also known as “electronic cigarettes,” are essentially electronic nicotine delivery systems; they are most often shaped like cigarettes, cigars or pipes and are designed to deliver nicotine or other substances to a user in the form of a vapor. Generally, an e-cigarette consists of a battery-powered heating element and a 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 secondhand smoke. Often, 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 tar and myriad other chemicals found in regular cigarettes.

Federal challenges to e-cigarettes

The Food and Drug Administration 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 legal age restrictions. Notably, between 2008 and 2010, the FDA made a determination that certain e-cigarettes were unapproved drug/device combination products and detained and effectively prevented the e-cigarettes made by Sottera, Inc. from being imported. Sottera challenged that determination in court.

The U.S. Court of Appeals for the D.C. Circuit, in *Sottera, Inc. v. Food & Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010), issued its 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 thus 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*. The FDA has, however, recently stated its intention to issue regulations covering e-cigarettes. Any retailer or distributor of e-cigarettes must keep abreast of all of FDA’s proposed enactments relating to e-cigarettes to ensure they understand how the changes affect them.

State and locality regulatory enactments affecting e-cigarettes

States and localities have also been involved in enacting regulatory limitations regarding both the sale and use of e-cigarettes. Several of the recent State and local limitations are set forth below:

- Minnesota has enacted laws which regulate the sale of e-cigarettes and impose criminal penalties for the sale of e-cigarettes to minors.
- New Hampshire has enacted laws which prohibit the sale of e-cigarettes and liquid nicotine to minors and which also prohibit the distribution of free samples of such products in a public place. The State also prohibits the use of such products on the grounds of any public educational facility.
- New Jersey has enacted laws which prohibit the use of electronic smoking devices in all enclosed indoor places of public access as well as in workplaces.
- Utah has enacted laws which regulate the sale, gift and distribution of e-cigarettes by manufacturers, wholesalers and retailers.
- King County, Washington has enacted an ordinance which bans the smoking of e-cigarettes in public places.

Given the debate regarding e-cigarettes, legislation regulating the sale and use of cigarettes is predicted to be introduced and enacted in an ever-increasing number of jurisdictions. Retailers and users of cigarettes must carefully monitor the laws at the federal, state and local levels to ensure that they are in compliance given that many laws impose substantial monetary, and in some cases criminal, penalties. ^{TR}