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E-Cigarettes: An Issue for Employers Worldwide

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Background. The U. S. District of Columbia Circuit Court of Appeals, on December 7, 2010, decided in favor of manufacturers of certain electronic cigarettes ("e-cigarettes") in the landmark case, *Sottera, Inc., Doing Business as NJOY v. FDA* (No.10-5032). In this decision, the Court held that the U. S Food and Drug Administration ("the FDA"): 1) cannot regulate e-cigarettes labeled for "smoking pleasure" purposes, as opposed to therapeutic purposes, under the Food Drug and Cosmetic Act's (FDCA) drug and device provisions; and 2) such products, unless marketed for smoking cessation or other therapeutic purposes, can only be regulated as customarily-marketed products under The Family Smoking Prevention and Tobacco Control Act, a 2009 law allowing state and local governments to regulate the sale or use of tobacco products. This decision means that e-cigarettes marketed for smoking pleasure purposes only may legally be imported into the U. S. without the safety testing required for drug or medical devices. The *Sottera* decision, which the FDA may decide to appeal, has already resulted in actions such as local governments enacting laws regulating the use of e-cigarettes, and also has paved the way for the legal marketing and sale of e-cigarettes, as governed by applicable state, local, and federal laws pertaining to the marketing and sale of tobacco products.

Although *Sottera, Inc. v. FDA* applies to the regulation by the U. S. government of e-cigarettes, the issue of the legal sale and use of e-cigarettes poses an issue for international employers and business owners as well. This article will provide general information and advice to employers worldwide who may find it necessary to address the use of e-cigarettes in their workplaces to the extent they have not done so already.

What are e-cigarettes? E-cigarettes, which were invented and first marketed in the mid-2000s, are battery-powered products allowing users to inhale nicotine vapor without fire, smoke, ash, or carbon monoxide, and are designed to look like a traditional cigarette. Each e-cigarette consists of a plastic nicotine cartridge, the atomizer (or heating element), and the battery and electronics. The cartridge serves as the mouthpiece and contains liquid nicotine, water, propylene glycol, and glycerol. The atomizer vaporizes the liquid nicotine, and the battery and electronics power the atomizer and monitor the air flow. When the e-cigarette user inhales, the electronics detect the air flow and activate the atomizer, the liquid nicotine is vaporized, and the user inhales the vapor (which is sometimes called "vaping".) This product is seen by many as an alternative to tobacco products which are smoked, by creating the experience of smoking cigarettes without the resulting combustion, flame, smoke, or cigarette smell and, allegedly, without cancerous or harmful by-products. E-cigarettes are sold in various flavors, as well as either with nicotine or without nicotine. E-cigarettes have gained worldwide use and attention, with the governments and scientific organizations of many countries reviewing the safety of e-cigarettes, and, in many cases, enacting laws regulating them in some way. It is estimated that the e-cigarette industry generates \$100 million in annual sales.

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U. S. laws regulating e-cigarettes. In the United States, following the Sottera decision, state and local governments may now focus on regulating the sale and advertising of e-cigarettes to minors, as well as both beginning and continuing efforts to prohibit e-cigarettes in the workplace and other venues. For example, in 2010, the State of New Jersey expanded its current statute prohibiting the smoking of tobacco products in all enclosed indoor places of public access and workplaces to include a workplace ban on e-cigarettes. On December 16, 2010, the King County, Washington State, Board of Health passed a proposal prohibiting the use of e-cigarettes in the same places, including workplaces, that smoking of real cigarettes, cigars, and pipes is not allowed in the State of Washington. However, in the Commonwealth of Virginia, regulators have held that e-cigarettes do not violate state laws banning smoking in restaurants and other public places. Numerous legal issues have been, or are likely to be raised, challenging an employer's attempts to ban the use of e-cigarettes in the workplace. For example, on December 29, 2010, an administrative law judge ruled that the U.S. National Air Traffic Controllers Association is required to use the review process outlined in a memorandum of understanding on workplace smoking rather than through an unfair labor practice charge resulting from the Federal Aviation Administration's decision to treat e-cigarettes as regular cigarettes, and thus subject to the agency's policy on cigarettes. There are also possible privacy and disability discrimination complaints that could be brought regarding an employer's restrictions on the use of e-cigarettes.

Banning of e-cigarettes by U. S. Employers and Armed Services entities. At this time, many employers are beginning to review the use of e-cigarettes in their facilities. In addition, the U.S. Air Force decided to ban e-cigarettes from use in most of their facilities based on the categorization by its Surgeon General's office in 2010 of e-cigarettes as "tobacco products". The Air Force's Surgeon General also cited the FDA test findings announced in a June 2009 news release that a laboratory analysis of samples of certain e-cigarettes found they contained "carcinogens and toxic chemicals such as diethylene glycol, an ingredient used in antifreeze". The Air Force Surgeon General noted, though, that due to the variability among products, that analysis should not be used to draw conclusions about what substances are or are not present in particular e-cigarettes.

International issues involving e-cigarettes. Although e-cigarettes have only been sold since 2004, there appears to be a growing number of users internationally. Employers considering how to address the "vaping" of e-cigarettes in their workplaces are faced with new laws, proposed legislation, approaches and research reports, often of a diverse and conflicting nature, which are continuing to be published regarding this product. Since e-cigarettes began being marketed and sold, many countries have either made pronouncements about e-cigarettes, or have regulated them in some way. For example, it has been reported that in some countries, such as Denmark, Canada, Israel, Singapore, Australia, and Malaysia, the sale, import, or marketing of e-cigarettes is either banned, regulated in various ways, or the subject of health advisories by government health organizations. It also has been reported that there are either fewer or no restrictions in other countries, such as the United Kingdom, China, Russia and the Netherlands. In some countries, certain e-cigarettes are regulated as drugs and can only be purchased in pharmacies. However, since e-cigarettes are still in relatively early stages of sale and marketing, and there are studies still being conducted and published, many

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countries and regions of the world are in the process of actively considering possible regulations of this product.

Reasons why employers might consider banning e-cigarettes from the workplace. The reasons provided by the King County Health officials for passing its law banning e-cigarettes in the workplace were that e-cigarette vapors, which have less of an odor than do regular cigarettes and have no combustion, are so similar to real cigarettes that they may cause people to think it is acceptable to smoke in public, which could lead to more people becoming addicted to nicotine, and therefore more people being harmed by the dangers of second-hand smoke. The King County Health officials were concerned that the use of e-cigarettes could threaten what has become the norm in its county of not smoking in public or in the workplace. Other possible reasons why employers might want to ban e-cigarettes from the workplace, are: 1) the laws of certain countries, as well as state and local U. S. jurisdictions, currently ban or regulate the use of e-cigarettes in the workplace; 2) employees who see co-workers use e-cigarettes may try to smoke real cigarettes in the workplace, or at least question why they cannot do so; 3) it is possible that the vapor emitted from e-cigarettes could be an annoyance to co-workers; 4) it is also possible that e-cigarette vapors, depending on the product, are not harmless, and could cause safety concerns for both the person using e-cigarettes and co-workers, or even chemical or manufacturing processes; 5) nicotine is addictive; and 6) there may be environmental and practical issues regarding how to dispose of used e-cigarettes.

Reasons employers may not want to ban the use of e-cigarettes in the workplace. Some proponents of e-cigarettes argue that: 1) employees addicted to nicotine will be able to continue using nicotine without the harmful effects of smoking real cigarettes by using e-cigarettes, and should be able to do so in the workplace; 2) e-cigarettes are not a safety hazard, either to the user or to co-workers as only a harmless vapor is emitted as opposed to smoke; 3) e-cigarettes, even those not touted as smoking-cessation products, assist individuals in stopping smoking regular cigarettes, and will prevent countless numbers of deaths that occur due to smoking cigarettes, cigars, and pipes; 4) smokers often take breaks from working at their desks to go outside or to other areas designated for smoking, with complaints from co-workers from a morale and perceived productivity standpoint; and 5) the FDA and other groups have engaged in scare tactics about e-cigarettes with unfounded claims about the alleged dangers of this product. In addition, as stated above, employment law and union issues such as privacy, disability discrimination and unfair labor practices could be raised if employers ban e-cigarettes in the workplace.

General advice to employers worldwide. Employers worldwide should anticipate that the issue of whether or not e-cigarettes are allowed in the workplace will be raised in their organizations, and should consider now what their response will be when employees either are found "vaping" e-cigarettes at work or ask to do so. Among the considerations of employers should be: 1) determining whether the use of e-cigarettes is allowed in their jurisdictions, including in the workplace; 2) whether unions, works councils, or other laws raise barriers to employers instituting policies regulating e-cigarettes; 3) in jurisdictions where the use of e-cigarettes is unregulated, employers should determine whether they would allow such use in the workplace, and understand any possible legal

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risks of either allowing such use or not allowing it; and, 4) to stay apprised of the new legal and scientific study data that is certainly going to continue to be published regarding e-cigarettes.