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E-CIGARETTES GET A "SMOKING" BREAK: D.C. Circuit Clarifies Scope of FDA's Authority Over E-Cigarettes

By Deborah M. Shelton and Allie Frumin

On Tuesday December 7th, the D.C. Circuit Court of Appeals affirmed a lower court's ruling in *Sottera, Inc. v. FDA*, No. 10-5032, (D.C. Cir. Dec. 7, 2010) holding that that the Food and Drug Administration (FDA) could not regulate as a medical device the electronic cigarettes (often referred to as "e-cigarettes") at issue in that case. Instead, the court affirmed the district court's finding that FDA's authority over these e-cigarettes, as labeled, was limited to that over traditional tobacco products.

E-cigarettes are battery-powered reusable products that allow users to inhale nicotine vapor without fire, smoke, ash, or carbon monoxide. Manufacturers of e-cigarettes market their electronic nicotine delivery products as a safer, cheaper, and more environmentally-friendly alternative to traditional cigarettes. Designed to look like traditional cigarettes complete with a small LED light on the tip that glows red when activated, each contains an atomizer and a rechargeable battery. These products are viewed by some as a potentially viable alternative to traditional cigarettes, causing their popularity to increase in recent years.

The case was brought first in the U.S. District Court for the District of Columbia (*Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62 (D. D.C. 2010)) ("*Smoking Everywhere*"), by two e-cigarette distributors, Smoking Everywhere and Sottera, Inc. (doing business as NJOY). They filed the case after inbound shipments of their e-cigarettes were denied entry into the United States by FDA based on the Agency's claim that the products were an unapproved drug-device combination under the Food, Drug, and Cosmetic Act ("FDCA"). The plaintiffs sought to enjoin FDA from regulating e-cigarettes as a drug-device combination and from denying entry of those products into the United States. The plaintiffs argued that FDA's authority over their e-cigarette products did not extend beyond that of FDA's more limited authority over traditional cigarettes. The district court agreed with the plaintiffs and granted the injunction. FDA appealed and the D.C. Circuit Court of Appeals has now affirmed.

Before the U.S. District Court, FDA argued that e-cigarettes should be regulated like nicotine replacement gum or patches pursuant to FDA's jurisdiction over medical devices. FDA has authority under the FDCA to regulate articles that are "drugs," "devices," or "drug/device combinations." The FDCA defines drugs to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals."21 U.S.C. § 321(g). Similarly, "device" is defined as "an instrument, apparatus, implement ... or other similar or related article, including any component, part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals…" 21 U.S.C. § 321(h).In sum, FDA's statutory authority to regulate a product as a "drug" or "device" is limited to products that are intended to be used to affect a structure or function of the body or that are intended for use in the cure, mitigation, treatment, or prevention of disease.

FDA also has statutory authority to regulate traditional cigarettes and other tobacco products under the FDCA as a result of the Family Smoking Prevention and Tobacco Control Act of 2009 (the "Tobacco Act"), but that authority is more limited than that applicable to drugs and devices. Specifically, FDA may regulate "tobacco products," which the FDCA defines as "any product made or derived from tobacco that is intended for human consumption." 21 U.S.C. 321(rr)(1); however, the act excludes any "article that is a drug under 21 U.S.C. § 321(g)(1), a device under 21 U.S.C. § 321(h), or a combination product described in 21 U.S.C. § 353(g)." 21 U.S.C. § 321(rr)(2)-(3). Under its authority over tobacco products, FDA may impose restrictions on their sale, advertising and promotion, regulate their mode of manufacture, and establish other standards for their production and distribution. Unlike its more expansive authority over drugs and devices, however, FDA's authority over conventional tobacco products does not include a pre-marketing clearance or approval requirement.

In the *Smoking Everywhere* litigation, the plaintiffs argued that e-cigarettes are the same as traditional cigarettes in their use and purpose, and therefore FDA must be required to regulate them under the Tobacco Act the same as it does traditional cigarettes. Conversely, FDA argued that nicotine is a drug that affects the structure or function of the body, and that, as a nicotine delivery mechanism, e-cigarettes are medical devices. If e-cigarettes were to be classified as a medical device because of their nicotine-delivery feature, the products would require FDA's premarketing approval under the FDCA, subject to a rigorous demonstration of safety and effectiveness, as well as a host of other regulatory requirements.

The district court found for the plaintiffs, holding that since the e-cigarettes were neither labeled nor advertised as having any therapeutic uses, FDA could not regulate them as drugs or devices. FDA appealed the decision.

The appellate court agreed with the district court that e-cigarettes must be regulated the same way as other traditional tobacco products under the FDA's Tobacco Act authority. The court noted that FDA itself frequently expressed the view that "cigarettes are beyond the scope of the [FDCA] absent health claims establishing a therapeutic intent on behalf of the manufacturer or vendor." *Sottera, Inc. v. FDA*, at 9. The court found dispositive that, in enacting several statutes on tobacco regulation, "Congress has acted against the backdrop of the FDA's consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco absent claims of therapeutic benefit by the manufacturer." *Id*., citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 144 (2000). Following the Supreme Court's reasoning in *Brown & Williamson*, the court held that FDA can only regulate tobacco products marketed for therapeutic purposes under the FDCA's drug/device provisions. Since the e-cigarettes at issue in the case were neither labeled nor marketed with any claim of therapeutic use, the court held that these products could not be regulated as drugs or medical devices, and that therefore FDA's detention of them was unlawful.

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