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July 21, 2010

COURT URGED TO RESTRICT FDA POWER TO BROADLY DEFINE “MEDICAL DEVICES”

(Smoking Everywhere, Inc. v. FDA)

The Washington Legal Foundation (WLF) this week urged the U.S. Court of Appeals for the District of Columbia Circuit to prevent the Food and Drug Administration from broadening its own jurisdiction by expansively interpreting what is meant by a “medical device.”

In a brief filed in *Smoking Everywhere, Inc. v. FDA*, WLF argued that FDA’s authority to regulate “medical devices” is limited to products promoted for their therapeutic benefits. WLF asserted that the products at issue in this case, electronic cigarettes (or “e- cigarettes”) are not “medical devices” because they are not promoted for any therapeutic use. If FDA wishes to regulate the sale of e-cigarettes, it may do so only in connection with its authority to regulate tobacco products, WLF said.

WLF’s brief was drafted with the *pro bono* assistance of Coleen Klasmeier and Rebecca K. Wood, attorneys in the Washington, D.C. office of Sidley Austin LLP.

E-cigarettes are plastic cartridges that allow users to inhale a nicotine vapor – distilled from tobacco leaf – in a way that simulates smoking of traditional cigarettes. When a users puffs on the device, a portion of the liquid nicotine mixture in the cartridge is vaporized and can be inhaled by the user. E-cigarettes are intended to give users the sensation of smoking, but without the flame, tar, and ash of cigarettes.

Manufacturers of e-cigarettes began exporting their products to the United States and they quickly became popular with American consumers. That popularity drew the attention of FDA, which initiated steps in 2009 designed to prevent the sale and distribution of e-cigarettes in this country. FDA alleged that e-cigarettes are “medical devices,” which cannot be marketed to the public until after they have undergone extensive testing and FDA regulators have been convinced that they are safe and effective for their intended uses.

The Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to regulate as “drugs” and “devices” those products that are “intended for use” in the diagnosis, cure, mitigation, treatment, or prevention of disease or “intended to affect” the

structure or any function of the body. Courts have long interpreted that statutory mandate to mean that a product is not “intended for use” or “intended to affect” within the meaning of the FDCA unless the manufacturer has promoted it for that particular use or effect. Nicotine is a chemical that unquestionably can have an effect on the structure or function of the body. But e-cigarette manufacturers have never promoted their products by touting those effects; rather, they have promoted it as a smokeless alternative to cigarette smoking. Two manufacturers responded to FDA’s assertion of jurisdiction by filing suit against FDA in federal court in Washington, D.C.

In January 2010, the district court agreed with the plaintiffs’ position that e-cigarettes are not medical devices and issued an injunction preventing FDA from interfering with their sale or distribution. FDA appealed that decision to the D.C. Circuit, which has temporarily stayed the injunction while FDA’s appeal is pending. WLF filed its brief in connection with that appeal.

WLF’s brief argued that FDA’s authority to regulate “medical devices” does not extend beyond products for which the manufacturer makes therapeutic claims. The Supreme Court, in its 2000 *Brown & Williamson* decision, overturned FDA’s efforts to regulate cigarettes as “medical devices” precisely because cigarette manufacturers had made no therapeutic claims for their products, WLF noted. It warned that if the courts uphold FDA’s attempt to assert authority in this case, the way would be cleared for FDA to assert authority over “off-label” uses of FDA-approved drugs and devices – even when the manufacturer has done nothing to promote such off-label uses.

FDA argues that it is entitled to regulate e-cigarettes under a wide variety of alternative bases, including the inherent characteristics and effects of the product, actual consumer use, and circumstance surrounding distribution. WLF responded that there is no case law supporting any of those theories. WLF noted that FDA was recently granted regulatory authority over tobacco products and argued that if it wants to regulate e-cigarettes, it should do so pursuant to that authority.

WLF is a public interest law and policy center with supporters in all 50 States. WLF regularly appears before federal and state courts to promote economic liberty and a limited and accountable government.

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For further information, contact WLF Chief Counsel Richard Samp, 202-588-0302. A copy of WLF’s brief is posted on WLF’s web site, www.wlf.org.