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DC Circuit to Hear Oral Argument in Challenge to FDA's "Deeming Rule" for E-Cigarettes

(*Nicopure Labs, LLC v. FDA*)

"Whether the appeals court undertakes an appropriately stringent application of the *Central Hudson* test or something even stricter, the Constitution does not authorize the government to 'pre-approve' truthful, non-misleading speech before commercial speakers may utter it."

—Cory Andrews, WLF Senior Litigation Counsel

WASHINGTON, DC—The U.S. Court of Appeals for the District of Columbia Circuit will hear oral argument on Tuesday, September 11 at 1:30 pm., to consider whether to overturn a Food and Drug Administration (FDA) regulation that restricts the truthful speech of e-cigarette manufacturers and retailers. WLF's Senior Litigation Counsel Cory Andrews will be available Tuesday afternoon following oral argument to discuss the case's likely outcome.

In a brief filed in *Nicopure Labs, LLC v. FDA*, WLF argues that FDA's Deeming Rule, which requires FDA's preapproval before manufacturers and retailers may inform the public of vapor products' uncontested health advantages over traditional tobacco products, imposes a prior restraint on legally protected speech in violation of the First Amendment.

In May 2016, FDA deemed e-cigarettes to be "tobacco products" subject to the federal laws that govern the promotion and marketing of conventional cigarettes. Under the Deeming Rule, e-cigarette manufacturers are now subject to a host of onerous regulatory requirements, including the Tobacco Control Act (TCA). Under the TCA's regulation of "modified-risk tobacco products," manufacturers and retailers must obtain FDA's permission before claiming their products present a lower risk of tobacco-related disease or are less harmful than traditional tobacco products. But FDA's own studies readily concede the truth of those claims.

When a coalition of vapor industry manufacturers and retailers brought a First Amendment challenge against FDA, the U.S. District Court for the District of Columbia granted judgment in FDA's favor. Although the district court explicitly found that the Deeming Rule constitutes a "clear restriction on truthful and non-misleading speech," it nonetheless upheld the Rule under an unusually relaxed application of the *Central Hudson* test.

But as WLF's brief explains, the Supreme Court's decision in *Sorrell v. IMS Health* unequivocally holds that all speaker- and content-based restrictions on commercial speech must withstand "heightened" judicial scrutiny to survive. Although *Sorrell* does not articulate a precise test for the mandated "heightened scrutiny," it makes clear that such review entails a First Amendment scrutiny at least more exacting than the *Central Hudson* intermediate review the district court applied here.

Celebrating its 41st year, WLF is America's premier public-interest law firm and policy center advocating for free-market principles, limited government, individual liberty, and the rule of law.