Press Release

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WLF Urges Supreme Court To Bar Agencies From Pulling Regulatory Bait-And-Switches

(*Avail Vapor v. FDA*)

"If allowed to stand, the Fourth Circuit's decision could endanger American lives."
—John Masslon, WLF Senior Litigation Counsel

WASHINGTON, DC—Washington Legal Foundation (WLF) today urged the U.S. Supreme Court to hear a case in which the United States Court of Appeals for the Fourth Circuit blessed the Food and Drug Administration's bait-and-switch. In an amicus brief, WLF argues that FDA's actions violated the petitioners' due-process rights and the Administrative Procedure Act.

The case arises from FDA's approval process for electronic nicotine delivery systems (ENDS). After FDA decided that manufacturers need premarket approval to sell ENDS in the United States, it gave guidance on what the applications should include. The petitioners closely followed that guidance and submitted applications. But FDA then yielded to political pressure and said that additional information, which it previously said was unnecessary, must be included in the applications. It thus sent the petitioners a form denial letter.

In its brief supporting the petition, WLF argues that the Due Process Clause bars agencies from not giving regulated parties fair notice of regulatory requirements. Fair notice is at the heart of due process. And as the brief explains, telling parties they need not include information in applications and then denying the applications for not including that information is the antithesis of fair notice.

WLF's brief also describes why FDA's denial orders were arbitrary and capricious. The petitioners submitted data showing that their products do not appeal to youth and help current smokers quit or reduce their combustible tobacco use. FDA, however, ignored this evidence and cited generic studies that do not address the petitioners' products. Finally, WLF's brief explains how FDA's actions could endanger Americans. Besides encouraging combustible tobacco use, health-product manufacturers, such as pharmaceutical and medical-device companies, will be less likely to develop life-saving products if they cannot rely on FDA's regulatory guidance when submitting applications.

Celebrating its 46th 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.

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