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## **WLF Urges Supreme Court To Bar Agencies From Pulling Regulatory Bait-And-Switches** *(FDA v. Wages and White Lion Investments, L.L.C.)*

**“The Fifth Circuit’s decision properly bars agencies from telling regulated parties one thing and then doing the exact opposite.”**

—John Masslon, WLF Senior Litigation Counsel

WASHINGTON, DC—Washington Legal Foundation (WLF) today urged the U.S. Supreme Court to affirm a decision from the United States Court of Appeals for the Fifth Circuit vacating the Food and Drug Administration’s regulatory bait-and-switch. In an amicus brief, WLF argues that FDA’s actions violated a respondent’s 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 needed premarket approval to sell ENDS in the United States, it gave guidance on what the applications should include. A respondent 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 also be included in the applications. It thus sent a respondent a form denial letter.

In its brief urging affirmance, 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 leaving out that information is the antithesis of fair notice.

WLF’s brief also describes why FDA’s denial orders were arbitrary and capricious. The application included data showing that the 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 specific products. Finally, WLF’s brief explains how FDA’s actions could endanger Americans’ health. Besides encouraging combustible tobacco use, pharmaceutical companies will be less likely to develop life-saving drugs if they cannot rely on FDA’s regulatory guidance when submitting applications.

*Celebrating its 47th 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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