Press Release

WASHINGTON LEGAL FOUNDATION
Keeping Free Enterprise Free

FOR IMMEDIATE RELEASE August 19, 2026

Media Contact: Glenn Lammi | glammi@wlf.org | 202-588-0302

Fifth Circuit Rejects FDA's Regulatory Bait-And-Switch

(*NicQuid L.L.C. v. FDA*)

"Today's ruling is a win for the rule of law. The appeals court correctly held that FDA cannot impose its comparative-efficacy standard through secret memos and informal adjudication—it must follow the APA's notice-and-comment process."

— Cory Andrews, WLF General Counsel & Vice President of Litigation

WASHINGTON, DC—The U.S. Court of Appeals for the Fifth Circuit today vacated the Food and Drug Administration's (FDA's) marketing denial orders for the petitioners' flavored electronic nicotine delivery systems (ENDS) and remanded back to the agency. The decision was a victory for Washington Legal Foundation, which argued in an amicus brief that FDA's actions violated NicQuid's due-process rights and the Administrative Procedure Act (APA).

The case arose from FDA's approval process for ENDS. After FDA decided that manufacturers needed premarket approval to sell ENDS in the United States, it gave guidance on what information the applications should include. NicQuid closely followed that guidance when submitting its 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 ultimately denied NicQuid's marketing applications.

In its brief supporting NicQuid, WLF showed why FDA's denial order was arbitrary and capricious. The Fifth Circuit agreed, explaining that while FDA's new comparative-efficacy standard was not an unlawful change in position or a "tobacco product standard" under the Tobacco Control Act, is a substantive rule under the APA. Because the FDA adopted that rule through informal adjudication rather than notice-and-comment rulemaking, the denials violated the APA and must be set aside.

###