



FOR IMMEDIATE RELEASE

September 28, 2006

WLF CALLS ON FDA TO CEASE ATTEMPTS TO REGULATE CLINICAL LABORATORIES

The Washington Legal Foundation (WLF) today filed a formal petition with the Food and Drug Administration (FDA), calling on FDA to cease its efforts to enforce its “medical device” regulations against clinical laboratories that provide physicians with in-house developed and validated tests used to assist in making diagnoses and in developing treatment regimens. WLF’s Citizen Petition asserted that FDA lacks statutory authority to regulate tests developed by laboratories for their own use and offered *only* to health care professionals.

WLF noted that clinical labs have long been subject to regulation by another federal agency – the Centers for Medicare and Medicaid Services (CMS) and its predecessors – pursuant to the Clinical Laboratory Improvement Amendments (CLIA). WLF argued that FDA enforcement efforts could undermine effective health care by crippling these labs’ ability to quickly develop tests – *e.g.*, for new or rapidly mutating infectious diseases.

The clinical laboratory services addressed by WLF’s Citizen Petition have no relationship to the Direct-to-Consumer lab services that were the subject of a recent GAO report and Congressional hearings. Instead, the Petition focuses solely on labs providing tests that have been created and validated by medical professionals and that are offered to other medical professionals only from the individual lab that created the test.

Prior to this year, FDA stated repeatedly that it did not regulate such laboratory developed tests (“LDTs,” also known as “home brew” tests). This year FDA has begun enforcement action by telling individual clinical labs that it deems their LDTs to be “unapproved medical devices” and that the labs are violating federal law by providing them to clinicians. Additionally, the labs themselves are subject to FDA regulation as medical device “manufacturers.” In private meetings, FDA officials have stated that the labs could either submit “voluntarily” to FDA regulation or stop offering their LDT services. On September 7, 2006, FDA published a draft Guidance Document (the “draft IVDMA Guidance”), in which it publicly reversed its longstanding and clear boundaries between FDA enforcement of the Federal Food, Drug, and Cosmetic Act and CMS’s enforcement of CLIA.

The WLF Citizen Petition challenges FDA’s actions on several grounds, including: (1) Congress assigned the regulation of clinical labs and the assays they

develop to CMS under CLIA, not to the FDA; (2) FDA's draft IVDMIA Guidance goes far beyond regulating a service and extends to regulating new medical knowledge employed by physicians; and (3) FDA violated administrative law requirements by adopting a new substantive policy without first employing the notice-and-comment rulemaking required by the Administrative Procedure Act (APA).

WLF asserted that under FDA's new policy, even widely used LDTs that are well accepted by the medical community might no longer be available. WLF noted that LDTs not cleared by FDA will be deemed "investigational" medical devices and will be subject to numerous restrictions imposed on such devices. Because many health insurers do not provide coverage for "investigational" devices or services, the costs of these LDTs would far exceed the ability of most consumers to pay, WLF charged.

"FDA's insistence on imposing a new, unnecessary regulatory framework on these innovators would have extraordinary – and immediate – adverse effects on individual patient care and on public health preparedness to identify and respond rapidly to the new diseases that appear regularly," said WLF Chief Counsel Richard Samp. "FDA should cease this unlawful activity immediately. At the very least, *before* FDA takes action against any lab, it must comply with APA notice-and-comment rulemaking requirements – thereby permitting all interested parties to fully understand what FDA is doing and to provide informed input on the lawfulness and effect of FDA's proposed actions," Samp said.

WLF is a public interest law and policy center with supporters in all 50 states. WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, and a limited and accountable government. WLF often advocates before FDA and litigates against it in support of the needs of sick Americans, including winning a landmark case this year that established a constitutional right for terminally ill patients to gain access to investigational medications when no other treatment options are available.

* * *

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