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WLF CRITICIZES FDA EFFORTS TO REGULATE CLINICAL LABORATORIES, ASRs

The Washington Legal Foundation (WLF) this week called on the Food and Drug Administration (FDA) to withdraw draft guidance documents that seek to impose additional layers of regulation on clinical laboratories and manufacturers of analyte specific reagents (ASRs). In formal comments filed with the agency, WLF argued that FDA's proposed regulatory activity violates FDA's statutory mandate, the Administrative Procedure Act, and the First Amendment.

FDA's proposed guidance documents, issued on September 9, 2006, would (among other things) classify many clinical tests developed by laboratories as "medical devices" (thereby imposing significant regulatory burdens on anyone seeking to market such tests) and would impose significant new burdens on manufacturers who supply ASRs to clinical labs. (ASRs are complex chemicals -- such as antibodies and nucleic acid sequences -- that are used by laboratories as the "building blocks" for tests developed and validated by those labs (often referred to as "laboratory-developed tests" or LDTs)).

WLF's comments noted that LDTs are used to assist in making diagnoses and in developing treatment regimens; moreover, they are offered to physicians only, not directly to consumers. WLF asserted that FDA lacks authority under the Medical Device Amendments of 1976 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. WLF also testified in opposition to the proposed guidance at a February 2007 FDA hearing.

Prior to 2006, FDA stated repeatedly that it did not regulate LDTs (also known as "home brew" tests). In 2006, FDA began enforcement action by telling individual clinical labs that it deemed their LDTs to be "unapproved medical devices" and that the labs are violating federal law by providing them to clinicians. Additionally, FDA claimed, 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. In

September 2006, FDA published a draft Guidance Document (the “draft IVDMIA 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.

WLF challenged 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.

In response to the ASR Draft Guidance, WLF argued: (1) the document changes the definition of ASRs, with the result that the definition is ambiguous and purports to preclude the sale of ASRs that are lawful under existing regulations; (2) the proposed changes violate the APA, which requires any changes in substantive regulations to be undertaken only in connection with notice-and-comment rulemaking; and (3) the proposed changes violate the First Amendment because they seek to limit dissemination of truthful information about ASRs.

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 in May that established a constitutional right for terminally ill patients to gain access to investigational medications when no other treatment options are available.

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For further information, contact WLF Chief Counsel Richard Samp, 202-588-0302. Copies of both sets of the WLF comments filed with FDA on March 5, 2007 are posted on its web site, www.wlf.org.