

Vol. 3, No. 195

Thursday, Oct. 5, 2006

LEGAL GROUP CHALLENGES REGULATORY ENFORCEMENT FOR SOME DIAGNOSTIC TESTS

The **Washington Legal Foundation** (WLF) has called on the FDA to cease its efforts to impose device regulations on clinical laboratories that provide diagnostic tests developed and validated in-house to physicians.

The WLF filed a formal petition Sept. 28 with the agency asserting the FDA "lacks the statutory authority to regulate tests developed by laboratories for their own use and offered only to healthcare professionals."

The issue points to the two-pronged regulatory structure over diagnostic tests. There are two separate channels of oversight, depending on the type of test:

- The FDA is responsible for overseeing test kits. The agency clears test devices for the market and categorizes tests by their complexity; and
- Tests developed in private laboratories are approved based on the requirements of the Clinical Laboratory Improvement Amendments (CLIA) approved by Congress. The Centers for Medicare & Medicaid Services establish laboratory qualification and standards, including personnel standards, and oversees laboratories' compliance with CLIA's requirements. Lab inspections are done by state agencies. The Centers for Disease Control and Prevention conduct research on laboratory issues and house the CLIA advisory committee.

Some have noted the need for more consistency in how tests are approved.

FDA enforcement efforts could cripple those labs' abilities to quickly develop tests for such urgent cases as new or rapidly mutating infectious diseases, the WLF said.

The FDA's draft guidance for industry, clinical laboratories and FDA staff, "In Vitro Diagnostic Multivariate Index Assays," goes far beyond regulating a service and extends to regulating new medical knowledge employed by physicians, the WLF said. The agency also violated administrative law requirements by adopting a new substantive policy without first employing the notice-and-comment period required by the Administrative Procedure Act, the group said.

The petition can be viewed at www.wlf.org/upload/Clinical%20Labs-%20FDA%20Citizen%20Petition.pdf.