



## No Appeal of LDT Decision Means Ball Is Back in FDA's Court for Policy Clarification

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Over the weekend, the Department of Justice (DOJ) did not file an appeal of the U.S. District Court for the Eastern District of Texas' decision to vacate and set aside the agency's final rule on the regulation of laboratory developed tests (LDTs), titled Medical Devices; Laboratory Developed Tests (the LDT Rule). The LDT Rule would have required laboratories to ensure that their offered LDTs met medical device requirements under a multistage phase out of Food and Drug Administration's (FDA) enforcement discretion policy. While the government's decision not to appeal this ruling may not have been a surprise, questions remain as to how FDA plans to clarify its policy towards lab test offerings going forward.

Some detail regarding FDA's next steps might come from the release of the Unified Agenda, expected shortly. The Unified Agenda could indicate if FDA is planning an issuance formally withdrawing the LDT Rule or potentially offering additional policy relating to LDTs. The court's decision raises numerous questions, such as the exact scope and nature of lab test offerings that the court deemed to fall outside of FDA's jurisdiction, and the extent to which the decision limits FDA's previous approach to lab test offerings intended to be marketed as a device. The court's decision also has potential implications beyond lab testing that the agency might choose to address.

### Categories

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