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FDA's Announced Framework for Regulating Laboratory Developed Tests (LDTs) Leaves Open Many Questions

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As previously highlighted, the FDA recently notified Congress of its intent to issue two draft guidance documents proposing to implement a new regulatory framework fo***r LDTs (Laboratory Developed Tests).***

Our recent e-Alert provides a detailed analysis of the proposed framework described in the two documents FDA provided to Congress. The drafts describe a risk-based and phased-in approach to applying the medical device requirements of the FDCA to LDTs. FDA's drafts also describe continued enforcement discretion for certain regulatory requirements and types of LDTs. The documents outline in general terms proposed timelines for phased-in compliance.

According to FDA's website, at the conclusion of the 60-day Congressional notification period (which ends September 29, 2014), the agency will post the draft guidance documents for public comment for 90 days. The draft guidance documents will likely be contentious given the significant impact the proposed framework would have on the development and use of LDTs, and the ongoing debate over whether FDA has the statutory authority to regulate LDTs.

FDA has not yet specified the risk classification of existing LDTs, and the classification process is expected to take several years. The drafts also do not provide details on how FDA intends to handle the large resource burden of enforcing these requirements for the estimated over ten thousand LDTs currently offered by several thousand laboratories. In the drafts, FDA is proposing to use or expand third-party programs to implement and enforce some of the premarket review and Quality System Regulation requirements, but it remains unclear whether FDA will have the resources to implement the new framework in the timeframes proposed in the drafts.

In addition, the drafts leave open many questions with which laboratories and FDA will have to grapple in implementing the new regulatory framework. Details can be found in our e-Alert.

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