Published on *The National Law Review* https://natlawreview.com

FDA Publishes Draft Guidances on Regulatory Framework for Laboratory Developed Tests for Public Comment

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On October 3, 2014, FDA announced in the Federal Register the availability of a draft guidance titled **"**Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)**"** and the availability of a companion draft guidance titled **"**FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)**."** The draft guidances, if finalized, would implement a new regulatory framework for oversight of LDTs. Both draft guidances will be open for public comment for 120 days following the announcement.

Publication of the draft guidances follows FDA's 60-day notice to Congress (which ended September 29) and a hearing before the Health Subcommittee of the House Energy and Commerce Committee on September 9.

The published draft guidances are largely the same as those FDA submitted to Congress, which we summarized in a recent e-Alert, but with two "technical amendments." FDA amended the definition of companion diagnostic to be consistent with the recently-issued "In Vitro Companion Diagnostic Devices" final guidance. FDA also clarified the language of one of the factors the agency would use to define "Traditional LDTs."

The draft guidances will be open for public comment through February 2, 2015. Comments may be submitted on any aspect of the draft guidances, but FDA has specifically asked for comments on the following topics:

- **Definition of LDTs Used for Rare Diseases:** FDA requested comment on the suitability of the proposed factors for defining which LDTs will qualify as "LDTs Used for Rare Diseases." In particular, FDA sought comment on whether the Humanitarian Use Device definition or some other standard should be used.

- **Definition of Traditional LDTs and LDTs for Unmet Needs:** The draft guidances propose to limit enforcement discretion for "Traditional LDTs" and "LDTs for Unmet Needs" to LDTs developed and used by a healthcare facility laboratory for a patient that is being diagnosed and/or treated at that same healthcare facility or within that facility's healthcare system. FDA requested feedback on the appropriateness of this limitation and on which types of facilities should be considered within a healthcare system.

- **Phase-In of Quality System Requirements**: FDA invited feedback on the proposed timing of the phased-in enforcement of the quality system regulation requirements. FDA specifically requested feedback on the timing of applying design control requirements to the highest-risk category of LDTs.

- **Notification:** Although a test offered in multiple laboratories within the same network would not meet FDA's proposed definition of an LDT, FDA requested feedback on whether a single "notification" by the laboratory network should be permitted. FDA also asked for comment on whether there are certain types of LDTs for which FDA should not require notification or registration and listing.

Comments can be submitted electronically at regulations.gov. Comments on the regulatory framework draft guidance should be submitted to Docket No. FDA-2011-D-0360 and comments on the notification and reporting draft guidance should be submitted to Docket No. FDA-2011-D-0357.

FDA also announced that it will hold a webinar on October 23, 2014 to address clarification questions on the draft guidances. Participation information is available on FDA's website. The agency also intends to hold a public meeting in early January 2015 to collect additional input during the comment period.

National Law Review, Volume IV, Number 282