Morgan Lewis

alert

life sciences and healthcare lawflash
from the FDA Practice

July 31, 2014

FDA Releases Details of New Framework for Laboratory Developed Tests Regulation

FDA sends notice to Congress on LDTs.

The U.S. Food and Drug Administration (FDA) has notified Congress that it intends to issue draft guidance to propose a risk-based, phased-in framework for oversight of laboratory developed tests (LDTs) and, in a strategic move, has provided the anticipated details of the LDT guidance in the notification.

The notification sent on July 31 was required by the Food and Drug Administration Safety and Innovation Act, which requires notification to Congress at least 60 days prior to the issuance of draft or final guidance. Accordingly, the highly politicized environment surrounding changes to the regulation of LDTs can be expected to continue during the 60-day waiting period as industry, academia, and other stakeholders react to the proposed framework.

FDA's risk-based approach will rely on the existing medical device classification system (Class I, II, or III) to evaluate the risk of a category of LDTs and, informed by the expressed interest in participating in the discussion of the classification process, will use expert advisory panels to help classify devices not previously classified by FDA. FDA intends to issue draft guidance to describe what it considers generally to be Class I, II, or III within 24 months of finalizing the LDT guidance. FDA anticipates that it will phase in enforcement of regulatory requirements for LDTs over the next 10 years. The phased-in enforcement for the different device categories is summarized in the following table.

FDA Enforcement of Regulatory Requirements for Categories of LDTs—Time Frames			
Device Category	**Notification or Registration and Listing/ Adverse Event Reporting Requirements**	**Premarket Review Requirements**	**Quality System Regulation Requirements**
Low-risk devices, traditional LDTs, and LDTs for rare disease and unmet needs	Enforcement discretion.	Enforcement discretion.	Enforcement discretion.
Moderate-risk devices	Six months after guidance is finalized.	Phased-in enforcement will begin five years after guidance is finalized. FDA plans to announce priority list for class II within four years of finalized guidance.	Enforced once FDA issues a clearance order.
High-risk devices	Six months after guidance is finalized.	Phased-in enforcement will begin 12 months after guidance is finalized. FDA plans to announce priority list within 24 months of finalized guidance.	Enforced once premarket approval application is submitted.

FDA's notification on the LDT guidance can be accessed at http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/UCM407409.pdf. Additional analyses of the impact of the new regulatory framework for LDTs, FDA's guidance on in vitro companion diagnostics, and FDA's actions focusing on personalized medicine will be forthcoming from Morgan Lewis.

On September 26, 2014, we will sponsor a session to discuss the potential impacts on changes to the regulation of LDTs at the BIO IP & Diagnostics Symposium at the Hilton Alexandria Old Town Hotel in Virginia. For more information, visit http://www.bio.org/sites/default/files/2014_BIO_IPDx_Symp_Overview_Registration_Form.pdf.

Contacts

If you have any questions or would like more information on the issues discussed in this LawFlash, please contact any of the following Morgan Lewis lawyers:

Washington, D.C.

Phoebe Mounts	+1.202.739.5898	pmounts@morganlewis.com
M. Elizabeth Bierman	+1.202.739.5206	mebierman@morganlewis.com

About Morgan, Lewis & Bockius LLP

Founded in 1873, Morgan Lewis offers more than 1,600 legal professionals—including lawyers, patent agents, benefits advisers, regulatory scientists, and other specialists—in 25 offices across the United States, Europe, Asia, and the Middle East. The firm provides comprehensive litigation, corporate, transactional, regulatory, intellectual property, and labor and employment legal services to clients of all sizes—from globally established industry leaders to just-conceived start-ups. For more information about Morgan Lewis or its practices, please visit us online at www.morganlewis.com.