



Proposed Regulatory Framework for Laboratory Developed Tests Update

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Director,

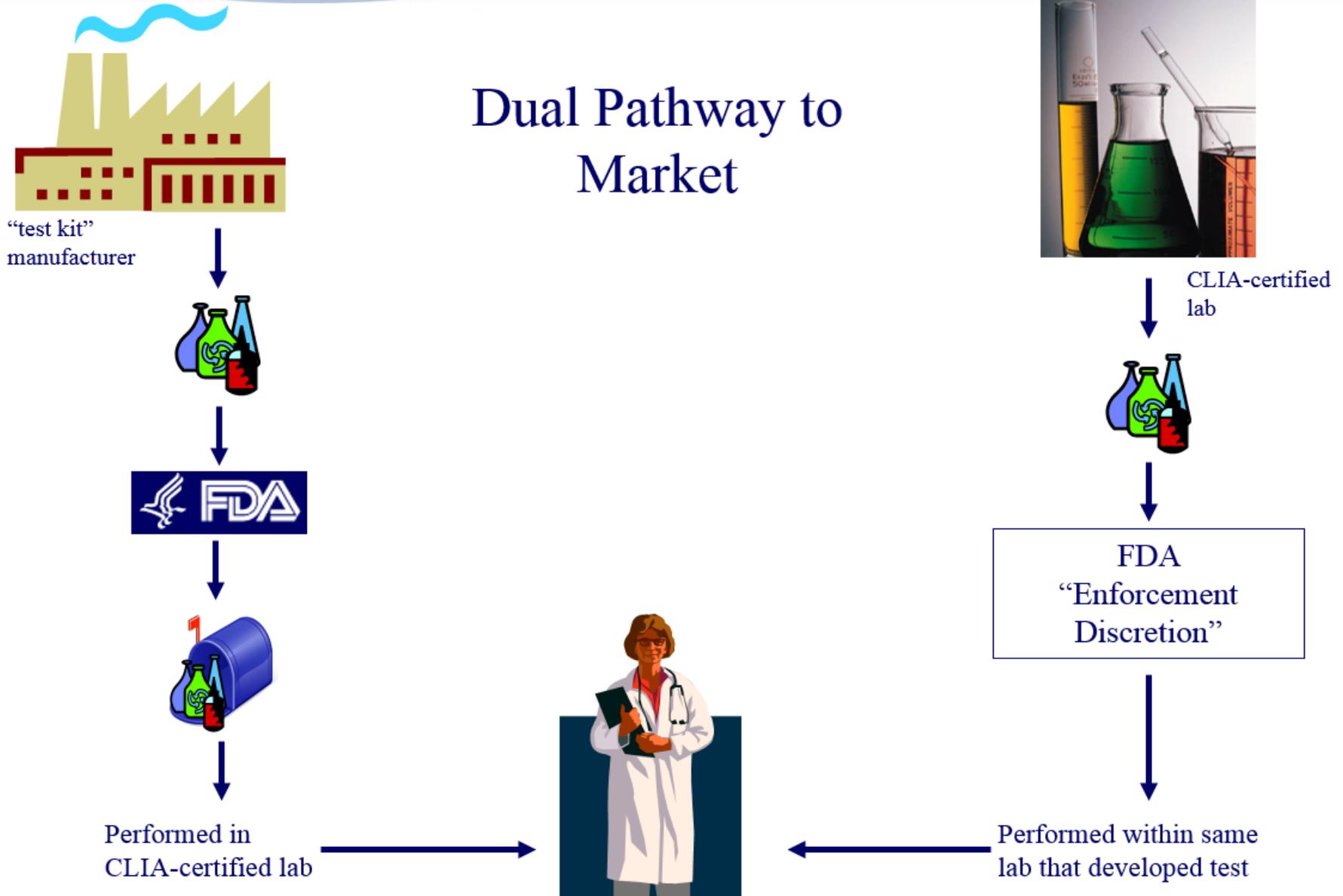
Office of In Vitro Diagnostics and Radiological Health

FDA Center for Devices and Radiological Health

CLIAC

November 19, 2015

Dual Pathway to Market



Process To Date

- Initial Public Feedback
 - 2010 Public Meeting
- Draft Guidances - LDT Framework Guidance & Notification/MDR Guidance
 - Notice to Congress sent July 2014
 - Published October 2014
- 120 Day Comment Period
 - 2-day Public Meeting
 - >300 comments received



FDA's Current Proposal

1. Collect basic information on all LDTs through new notification process (i.e., no-fee alternative to R&L)
2. Use public process (i.e., advisory committees) to obtain input on risk and priority for regulation
3. Phase-in regulatory framework over ~9 years based on risk
4. Continue some enforcement discretion for specific categories determined by FDA to be in the best interest of public health

Overview of LDT Public Comments

Support from patient advocates, the oncology community, consumer groups, conventional IVD manufacturers, and payers

- Benefits of FDA oversight include patient safety, transparency, clinical validation

Mixed views from some professional medical societies

- Support FDA oversight limited to very narrow group of higher risk tests (black box algorithms)

Opposition received from some labs, pathologists, and hospitals

- Concerns about cost, patient access, duplicative regulation, practice of medicine

LDT Public Comments – Highlights

- **Labs need more time – extend timelines**
 - Notification
 - First round of PMA submissions
 - Quality Systems compliance
- **The volume of existing LDTs is very high**
 - Many existing LDTs have been in use for years
 - Compliance with premarket review and quality systems will be difficult, time-consuming, and costly
- **Some labs frequently modify their LDTs**
 - Provide guidance on modifications that are likely to result in a new LDT
 - Provide guidance on modifications are NOT likely to result in a new LDT

LDT Public Comments - Highlights

- **Labs need more certainty and clarity**

- Classification and prioritization should occur as soon as possible, use public advisory panels
- Describe how CLIA labs could comply with QS regulations
 - What current activities could be leveraged
 - What QS reg requirements may not apply

- **FDA should provide outreach and education**

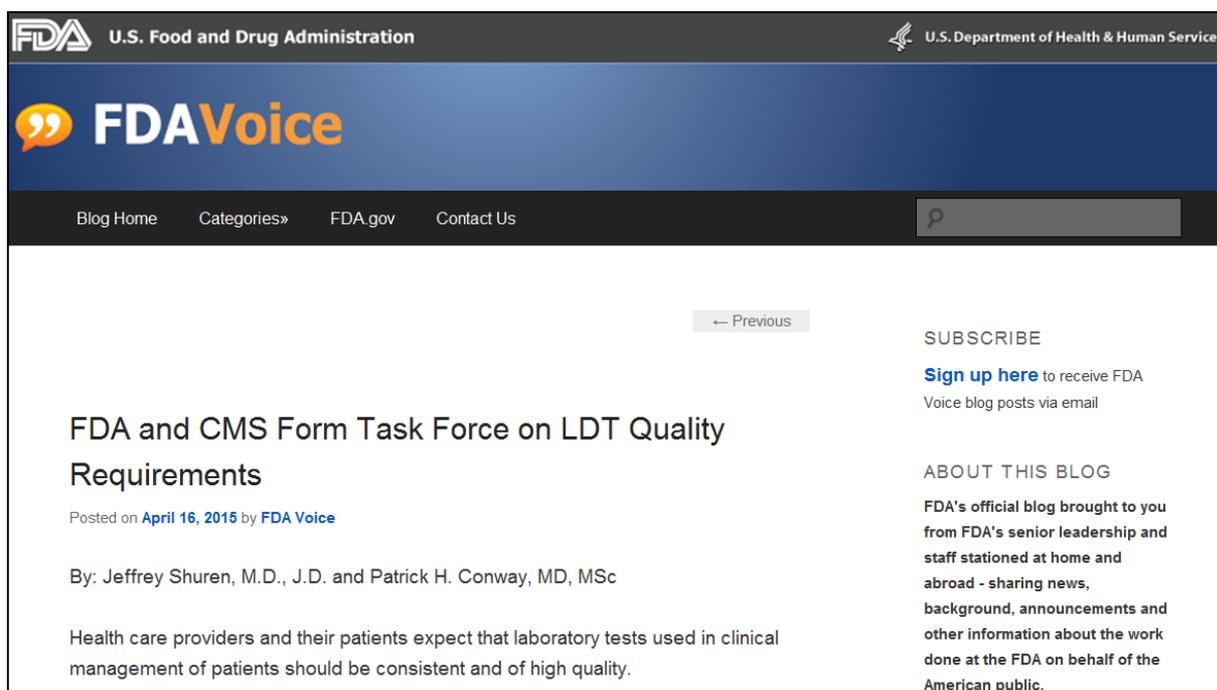
- Continued engagement during phase-in
- Inspections focused on education
- Additional guidance

LDT Public Comments – Highlights

- **Categories under continued enforcement discretion for premarket review should be modified**
 - Traditional LDTs
 - Should be under full enforcement discretion
 - LDTs for unmet needs
 - Ending enforcement discretion once one test is cleared or approved could lead to market monopolies, access issues
 - Healthcare system factor is problematic
 - Concerns about patient access, testing external samples
- **Certain LDTs for public health purposes should also remain under continued enforcement discretion**

FDA-CMS Task Force

- **Announced in April 2015**
- **Overarching goal:** to clarify and coordinate roles of CMS and FDA with respect to LDT quality



The screenshot shows the FDA Voice blog interface. At the top, there are logos for the FDA and the U.S. Department of Health & Human Services. Below that is the 'FDA Voice' logo. A navigation bar includes links for 'Blog Home', 'Categories', 'FDA.gov', and 'Contact Us', along with a search box. The main content area features a post titled 'FDA and CMS Form Task Force on LDT Quality Requirements', dated April 16, 2015, by FDA Voice. The author is listed as Jeffrey Shuren, M.D., J.D. and Patrick H. Conway, MD, MSc. The post begins with the text: 'Health care providers and their patients expect that laboratory tests used in clinical management of patients should be consistent and of high quality.' To the right of the post, there is a 'SUBSCRIBE' section with a link to sign up for email updates, and an 'ABOUT THIS BLOG' section describing it as the FDA's official blog.

FDA-CMS-CDC-NIH Task Force

- Senior leadership and SMEs from all Agencies
- Effort to identify similarities in regulations under CMS and FDA
- Streamline requirements for labs regulated by both CMS and FDA
- Public outreach



DTWG Proposal

- Recognizes that laboratory developed tests can be regulated similarly to distributed tests
- Recognizes that laboratories perform some functions that distributed manufacturers do not
- Recognizes the need for all test to be clinically valid
- Recognizes that regulation can be risk-based



Other Proposals

- AMP
- CAP/AMA



Public Hearing in Congress

- November 17th
 - FDA and CMS testified

Getting to Final Guidance

- Review and synthesize public comments
- Modify guidance documents based public input received
- Provide robust response to comments
- Intend to issue final guidance in 2016
- Provide ongoing education and training



Questions?

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