



FDA Oversight of LDTs: Where Are We, and Where Are We Going?

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- CAUTION
- Everything I say here is provisional
- The statements made in this presentation do not represent a final decision by FDA
- Statements are intended to provide insight, but not guidance

LDT Oversight

- Long-running discussion on need for oversight of LDTs
 - SACGHS and other recommendations for oversight in last 2-3 yr
- FDA Public Meeting held July 19-20, 2010
 - Comments to docket closed Sept 15, 2010
 - Analysis of comments underway
- Framework document tbd

LDTs are Medical Devices

- Definition under FFDCA 201(h)
- IVD regulation under 21 CFR 809.3
- Public commentary regarding authority since at least 1992
- FDA seeking to regulate *devices* not *labs*

History

- Medical Device Amendments of 1976
- Many (most) LDTs were tests using regulated components with “subjective” interpretation
 - Stains
 - Equipment, e.g. microscopes, centrifuges
 - General lab reagents

More LDT History

- Genetic testing as LDT (late 80's)
- Recognition of safety/effectiveness concerns when RUO components used
 - No regulations existed for genetic test components
- ASR Rule implemented 1997
 - Light control of reagents as ASRs, GPRs

Even More LDT History

- Technology advances, human genome completion
- New tests using unregulated devices begin to appear as LDTs
- Explosion of LDTs with:
 - Increasing complexity
 - Dependence on instrumentation function
 - Prefabricated reagents
 - Kits

Result

- Enforcement discretion becomes a loophole
 - Many LDTs now dependent on components assembled and marketed by others
 - Business models leverage enforcement discretion for rapid market access, avoid FDA oversight
 - Parallel industry with traditional IVD mfrs

Initial FDA Approach

- IVD MIA—most unlikely type of test for enforcement discretion
 - Highly dependent on uncontrolled components
 - Highly dependent on developers understanding complex validation issues
- Definition issues, piecemeal approach

Current FDA Approach

- Look at ALL LDTs
 - How many, what is tested, what is risk?
 - We don't know. Do you?
- Framework to implement oversight of LDTs
 - Public meeting to initiate stakeholder input
 - Open docket for comments
 - Meetings with industry groups

Possible elements of framework

- Risk-based oversight
 - FDA has always regulated on risk
 - Addresses highest risk first
- Some type of registration and listing
 - Need to know who is offering what
- Classification panels
 - Classify tests with no predicates or existing regs
 - Avoid numerous de novo actions



Operational Plan

- Develop oversight plan
- Publish guidances
 - General requirements
 - Information on complying
- Continue stakeholder interaction

DTC Oversight

- FDA: DTC model not appropriate for enforcement discretion
- Letters, meetings with DTC offerers
- Various offerings and methodology
- Beginning interactions to define timelines, requirements
- Some offerers leave DTC market



- Thanks!
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