Congress and the Diagnostic Accuracy and Innovation Act

Arizona State University Molecular Diagnostics Meeting
April 12, 2017

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Congressional Agenda

• Other key issues are consuming substantial time
  • Health care – including payment systems
  • Tax reform
  • Budget
    • Agency budget
    • NIH
  • Debt ceiling
• User fees (a “must pass”?)
  • Unusual circumstances
  • High probability will pass without major change
  • Impact of hiring freeze and “one for two” rule
• User fee riders
  • Fewer than normal
• 1st Amendment/intended use (Griffith bill)
• 21st Century Cures implementation
• Diagnostic Accuracy and Innovation Act (DAIA)
Diagnostic Test Regulation Background

- Long history of regulatory controversy over diagnostic test regulation
  - 1969 Bacto-Unidisk S. Ct case
  - 1976 MDA reverses Bacto-Unidisk
- Key statutes
  - 1976/1990 FDA provisions
  - 1988 – CLIA
- Rise of lab developed tests (LDTs)
- LDTs resisted FDA oversight
  - Service v. product
  - Practice of medicine
- Several legislative proposals
- 2014 FDA draft guidance
- 2017 FDA white paper
Legislative and External Environment

Key Issues (real or perceived)

• Inaccurate tests
  • Lack of analytical validity
• Lack of clinical validity
• Need to modernize CLIA
• Lack of consistency in test results across institutions
• Lack of transparency (e.g. Theranos and others)
• Inconsistent regulation and unfair regulation
  • Same test regulated very differently
• Inapplicability of medical device regulations to diagnostic tests
  • Excessive burden on labs
  • Inefficient/inapplicable for industry
• Barriers to innovation
• Duplicative regulation and gaps in regulation
• Need for certainty
• Infringing on the practice of medicine
Competing Conceptual Approaches

- FDA oversight of labs
  - Use existing device law and regulation
- CLIA only lab oversight
- Concurrent or overlapping jurisdiction
- Regulate at least some labs or tests as practice of medicine
- Put oversight into a new or different agency (e.g. CPSC or FTC)
- Regulate differently based on test type
  - “High risk” LDTs under FDA
  - Moderate and low risk LDTs under CLIA
- Exempt all AMC LDTs
DTWG

• DTWG process
  • Cross sector group
  • “Safe space” for discussions
  • “Blank piece of paper”
  • Includes physicians, technical experts, regulatory experts and lawyers

• Prepared a consensus proposal
  • Evolutionary improvements over time
  • Incorporated ideas from many stakeholders including FDA, industry, labs, physician societies, and patient groups

• Complex and fascinating initiative
  • Move from theory to real world
  • Need to understand “real life”
  • Address cross sector of actors (the “good, bad and the ugly”)
  • Complex political dynamics
Core DTWG Conclusions

- Existing device rules don’t fit IVCTs
- Diagnostic products serve a fundamentally different role than therapeutic products
  - Information v. therapy
- Proper standard is analytical validity and clinical validity
  - Safe and effective not appropriate standard
- Regulate by activity; not by entity type
  - Same activity regulated (or not) the same way
- Risk based approach
- Improvements would benefit access and innovation
- Everyone must compromise
Diagnostic Accuracy and Innovation Act (DAIA)

- Bipartisan discussion draft released 2 weeks ago
  - Rep. Bucshon (R Ind.)
  - Rep. DeGette (D. Col.)
- Comments requested by April 7th
  - Multiple comments were provided
- Discussion draft intended to provide balance between competing interests
- Addresses both FDA and CLIA
- Next steps
Scope and Definition

- New FDCA category called *in vitro* clinical tests (“IVCTs) which includes:
  - Platforms
  - Tests
    - Finished products (aka kits)
    - Laboratory test protocols (aka LDTs)
  - Software
- Includes current IVDs and LDTs
- Excludes
  - Forensic tests
  - Tests for non-clinical purposes
    - Genealogy
    - DOA
  - Excludes laboratory operations
Key DAIA provisions

- **Exclusive jurisdictional lines**
  - FDA – test kit manufacturing and test development
  - CLIA – laboratory operations
  - Practice of medicine
- **IVCT standard is analytical validity and clinical validity**
- **Clinical utility is outside of FDA jurisdiction**
- **New three tiered risk based classification system**
  - Based on test use (e.g. is it the “sole determinate” of care
  - Based on knowledge of the test (known technology, how to interpret the test, etc.)
- **New submission process**
  - Submission content and review
  - No 510(k) system
  - New timelines
    - 120 and 75 days
1. IVCT Design
2. IVCT Development
3. IVCT Validation
4. Preparation of reagents and other materials for use in more than one CLIA facility or by a third-party
5. Preparation of reagents and other material for use in one CLIA facility
6. Development of lab SOP, verifying lab performance
7. Pre-analytical Processes
8. Performing the IVCT
9. Reporting the IVCT Output
10. Interpretation and Consultation

FDA

CLIA
Classification Structure

High risk
- Not well characterized
- Sole determinant
- Serious or life threatening diseases
- Life threatening impact of wrong result

Moderate risk
- Well characterized but otherwise high risk
- Non serious impact of wrong result
- Not sole determinant
- Existence of risk mitigating factors

Low risk
- All others
Other Concepts

- No special rules based on technology
  - No special rule for NGS
- No special rules for companion diagnostics
  - Some may be moderate risk
- No special rules for IVCT type
  - No special rules for genetic tests for example
- Objective is a uniform system that seamlessly adapts to:
  - New technology
  - New medical/clinical information
  - Evolving practice guidelines
  - Experience with a test
  - Field results
Key DAIA provisions

• **New approach to modifications**
  • Leverage quality systems
  • Leverage prior approvals
    • Within approved specs, no submission
  • Limit to new intended uses or meaningful clinical impacts
  • Address special circumstances such as specimen stability changes

• **Other aspects**
  • Listing provisions
  • User fees – with 30% cap
  • Preemption
  • Standard IDE type processes
  • Standard enforcement and inspection provisions
Special Pathways

- Rare disease
  - 8,000 incidence/50,000 prevalence
  - Role of post market
  - No premarket review
- Emergency use
  - National or regional
  - Limited submission content
  - Role of post market
  - 10 day clock
- Unmet need
  - Regulated as moderate risk
- AWCPO
  - New approach utilizing post market data
  - Avoid reimbursement issues
- Custom IVCTs
- Platforms
Key DAIA Provisions

- Transparency
  - Listing and summary information
- Post market provisions
  - Focused adverse event reporting
  - Post market surveillance
- CLIA modernization
- Grandfathering
  - Complex and challenging issue
  - Competing interests
  - All existing LDTs grandfathered in
  - Ability to “pull” products
- Transition
  - 3 years to develop regulations
  - 2 years to implement
CLIA Provisions

- Need to update and modernize CLIA
  - Needed for jurisdictional matters as well
- CLIA has exclusive jurisdiction over laboratory operations
- Maximize role of professional society standards (e.g. CAP)
- Preemption of state approval processes
  - Delegate inspections/third party review
- One uniform standard for all patients
- Updated and tailored quality systems
  - Harmonize with FDA as appropriate
Current Status and Next Steps

• Further work on DAIA Bipartisan discussion draft
• Senate HELP
• Anecdotal summary of positions
  • Industry
  • Laboratories
  • Patient groups
  • Physician/professional societies
  • New administration
• Legislative pathway and timing open questions;
• Thoughts, comments and input?
A health care intelligence business

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