Stakeholder Input on the Current Co-Development Paradigm

Framing Today's Discussion

The FDA's Companion Diagnostics process was designed to accommodate the co-development of a drug with a companion diagnostic test to allow the test to identify that subpopulation of patients most likely to respond to the drug. The clinical utility of the test is demonstrated in the phase 3 drug trial. Such a parallel path of development was designed to benefit all stakeholders.

Everyone Agrees There Are Problems

- Regulatory uncertainty
- Reimbursement uncertainty
- Erosion of device company's investment and inherent clinical utility of the device established in the phase 3 trial
- Anticipated clinical difficulties when many separate companion diagnostic tests needed on small tissue samples for cancer

Stakeholder Problems with CoDx

- Device Manufacturer
  - IVD ≠ LDT, but can use LDT as more rapid path
  - “not fair playing field”
  - Want FDA to clarify oversight of IVDs and LDTs
- Clinical Laboratories
  - IVD =? LDT
  - Need tests by cancer type for all drugs due to limited tissue
  - Need consolidated testing platforms and low costs
  - Provides service for patient management; not just tests
  - Regulated under CLIA, CAP, NYSDOH

Stakeholder Problems with CoDx

- Third Party Payers
  - Pay for IVD or LDT; cannot tell difference by codes
  - Exception is Palmetto, path forward with concept?
- Health Care Providers
  - IVD =? LDT
  - Want a good test for patient management decisions
- Pharma Companies
  - IVD =? LDT
  - Want to sell safe drug to targeted patient population that improves patient outcomes

Stakeholder Proposed Solutions

- **Coalition for 21st Century Medicine**: The regulatory pathway for co-developed tests needs to be clarified for both pre- and post therapeutic approval including a pathway for tests to be developed for off-label use of drugs when such use is recognized as standard of care in medical practice; Developers (whether industry or laboratories) of new tests or new versions of established co-developed tests should offer proof of the clinical validity of these versions in order to obtain coverage; coverage and reimbursement should be based on the performance of each unique test and the evidence that supports it.

Stakeholder Proposed Solutions

- **ACLA**: CLIA role should be strengthened to assure clinical validity of laboratory tests, a test registry should be established to improve the transparency of public information, and efforts should be directed at expanded oversight of genetic tests directly marketed to consumers.
- **AdvaMed**: Tests should be regulated according to risk instead of according to the business model for test development.

Stakeholder Proposed Solutions

- **CAP**: Define relevant analyte for drug efficacy rather than specific test; test submission should include sufficient details of the biologic basis for the test and its performance characteristics such that these could be used as benchmarks for comparison of other tests; a test results repository would allow a more rapid assessment of the clinical usefulness of testing
- **Individual Proposal**: Include test cost in drug price

Stakeholder Proposed Solutions

- **ASCO**: Need a better understanding of the tumor biology and drug-target interactions involved in use of a predictive biomarker; locking into a single CoDx prevents further understanding of biomarker; need regulatory certainty regarding FDA oversight of LDT CoDx's; need coordination between CDER & CDRH

Questions for Participants to Address

- Would these proposed solutions address the problems identified?
- Are there other solutions to propose?
- What steps could be taken to implement solutions that would be effective?

And in 10 slides for 10 minutes per speaker!