Advancing utility and adoption of clinical genomic diagnostics – Part I: A diagnostic industry perspective

Russel K. Enns, Ph.D.

Chief Regulatory Officer

Cepheid

Sunnyvale, CA

AdvaMedDx

A Division of the Advanced Medical Technology Association

AdvaMedDx Description

- Functioning as an association within AdvaMed, AdvaMedDx is the only multi-faceted, policy organization that deals exclusively with issues facing *in vitro* diagnostic companies both in the United States and abroad.

- AdvaMedDx member companies produce advanced, *in vitro* diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and reduce overall health care costs.

- AdvaMed members have played a key role in developing many novel diagnostic tests used today to care for patients.

AdvaMedDx
A Division of the Advanced Medical Technology Association

Key barriers to new diagnostics

Establishing clinical use

- Regulatory safety and effectiveness
- Medical necessity, or even better – medical “added value”
- Reliable, accurate performance standards

AdvaMedDx
A Division of the Advanced Medical Technology Association

Establishing clinical use: Regulatory safety & effectiveness

- FDA's regulatory requirements
  - Novel technologies present great challenges for premarket review paradigm
- Need for adoption of a modernized, risk based regulatory approach for all diagnostics based on risk
  - Support public health and encourage innovation
  - Improve transparency of FDA decision process
  - Focus review resources on products with highest/unknown risk
- Focus of Congressional hearings—Exploring reform and ways to support US global leadership and access to new technologies
- Reasonable and acceptable clinical evaluation designs
  - Appropriate outcomes

AdvaMedDx
A Division of the Advanced Medical Technology Association

Establishing clinical use: Paying for "added value"

- Payment reform needed to recognize value of advanced medical diagnostic tests, impact on health care, resources needed to develop and validate tests
- Inadequate payment impacts innovation, patient access to new tests
- CMS coverage and reimbursement policies must change but change is SLOW
  - Current reimbursement rates for diagnostic tests based on outdated and flawed fee schedule (Clinical Lab Fee Schedule)
  - CMS placed new molecular test codes on Physician Fee Schedule but no payment attached for 2012
- Congressional fix may be needed
  - Improve transparency/Involve all stakeholders
  - Proposals being considered to address payment reform (e.g., rate setting for new tests, independent advisory panel, coding improvements, gapfill process)

Establishing clinical use: Reliable, accurate performance stds

- Develop platform performance standards
  - E.g. ACMG, AMP, ASCO, ASCP, CAP, CLSI, FDA, NCCN
    - Test attributes: analytical sensitivity (LoD) & specificity, interference, precision, reproducibility, and clinical sensitivity & specificity (NPV & PPV), etc.
  - Patients deserve standardized, consistent test results regardless of where or when tests are performed!

Conclusion

- S.O.S. or ?????
- Overcoming barriers
- Evidence, Outcomes
- Performance Standards
- Regulatory process improvements
- Reimbursement reform
- We can and should do much better going forward!