Institute of Medicine: Advancing Utility and Adoption of Clinical Genomic Diagnostics

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Quest Diagnostics

Leading provider of diagnostic testing, information and services

Proven capability in bringing innovative tests and advanced IT solutions to market

- Develop Laboratory Developed Tests under CLIA oversight
- Commercialize IVD kits under FDA oversight

Unparalleled access, distribution and capabilities

- Serve half of all U.S. physicians and hospitals
- Provide genetic counseling services for physicians
- Work closely with major pharma companies to facilitate introduction of new therapeutics and companion diagnostics

Serving patients 150 million times each year

Regulation, Innovation and Genome-based Tests

Lab testing is **low-cost, high value** contributor to healthcare

- **Driving force** behind personalized medicine

Reducing costs and delivering services based on **evidence of value** are vital to healthcare in the 21st Century

The **issues are complex**: overwrought regulation or limits to physician discretion could **stifle innovation and the practice of medicine**

Limiting the incentive to develop or access innovative tests could **hamper patient management** advancements in:

- Fast-changing infectious diseases (i.e. HIV, H1N1),
- Cancer (EGFR mutation pathway, breast cancer prognosis),
- CVD (clopidogrel/plavix sensitivity, HCM)

Create a regulatory environment and reimbursement framework that **encourages** patient benefits, **innovation** & economic **growth**.

Solutions

Provide clear **regulatory certainty** for genomic test development

Avoid duplicative federal regulation (i.e., FDA clearance of CLIA-regulated LDTs)

Build on what works -- modernize CLIA (Congressman Burgess legislation)

Enhance public transparency of agency decision-making

- Rulemaking by notice-and-comment rather than through guidances

Public / private partnerships with qualified NGOs

Patience to observe progress:

- AMA CPT coding
- CMS reimbursement procedures regarding CPT code stacking
- NIH Genetic Test Registry


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