

Genetic Testing and Public Policy in 2012

Vincent Stine, PhD
Director, AACC Government Affairs

Disclosure information

- No financial relationships to disclose.

Learning Objectives

- Understand the current political landscape
- Learn about ongoing legislative and regulatory initiatives affecting genetic testing
- Be familiar with ongoing projects that may serve as 'building blocks' for future actions

Political Landscape

- Election year -- Congress unwilling to take up difficult political issues (e.g., budget deficit)
 - Senate doesn't plan on voting on a budget
- Health committees focusing on oversight of health care reform rather than new initiatives
- Questions over the future of Health Care Reform – Supreme Court to rule in June

What does this Mean for Genetic Testing

- A quiet year – Agencies and public/private partners can focus on current endeavors rather than responding to outside pressures

What is Hidden Behind Door #3

- Genetic testing is always one story away from making national headlines – many times good, sometimes not

Media Reports

- **CNN** (Feb. 2010) *The Government has your babies DNA*
- **Washington Post** (July 2010) *Genetic testing mix-up reignites debate over degree of federal regulation needed*
- **Contra Costa Times** (August 2010) *Berkeley attracts DNA samples - and political heat*
- **Science Progress** (April 2011) *One Step Closer to Designer Babies*
- **NPR** (April 1, 2012) *N.Y. Preschool Starts DNA Testing for Admission*
 - Stories illustrate public concerns about GT, particularly for discriminatory purposes

Political Response

- Media stories on genetic testing can often serve as ‘focusing events,’ which can result in the issue being placed on the policy agenda. This can often result in:
 - Congressional hearings
 - Legislation
 - Agency actions

Key Items in 2012

- Regulatory
 - Personalized Medicine
 - Direct-to-Consumer Genetic Testing
 - Laboratory Developed Tests
- Legislative
 - Burgess LDT legislation
 - MDUFA reauthorization

Key Items in 2012

- Reimbursement
 - AMA new Molecular Codes
 - PhD Reimbursement
- Information Gathering
 - PCORI – comparative effectiveness research
 - USPTO study on confirmation genetic testing
 - NIH Voluntary Genetic Testing Registry

Personalized Medicine

- July 2011 FDA released draft companion diagnostics guidance
 - Defines what is and what is not a companion diagnostic
 - Identifies individual and subgroups likely to respond or not respond to a particular drug intervention or monitor patient's treatment with potential for adjustments
 - Generally requires approval or clearance for diagnostic at time of the FDA approves therapeutic
 - Exceptions
 - The new therapeutic is to treat a serious or life threatening condition
 - Already approved therapeutic
 - Final Guidance – sometime 2012

Personalized Medicine

- Co-development Guidance
 - Draft expected late summer, early fall
 - Will address coordinated development of diagnostic and therapeutic
 - Guidance will discuss:
 - When a test is ready for use in clinical trials
 - What information is needed about the test prior to clinical trials
 - Laboratory performance

Direct-to-Consumer Genetic Testing

- Direct-to-Consumer Genetic Testing
 - 2006/2010 GAO reports document DTC false claims to consumers
 - 2006/2010 Congressional hearings exam quality of DTC tests
 - 2010 Pharmacies announce intent to sell DTC genetic tests – pull back after FDA involvement

Direct-to-Consumer Genetic Testing

- Direct to Consumer Testing
 - 2010/2011 FDA sends letters to manufacturing requesting submissions
 - 2011 FDA holds public meeting/panel recommends greater physician involvement
 - 2012 FDA working on DTC guidance – publication date unknown (projected by end of year)

Laboratory Developed Tests

- Laboratory Developed Tests
 - 2006 IVDMA draft guidance
 - 2008 Genentech petition to FDA to regulate all LDTs
 - 2010 public meeting FDA announces its expanding oversight to all LDTs
 - Will focus on high risk tests
 - gradual implementation

Laboratory Developed Tests

- Laboratory Developed Tests
 - FDA outlining policy in three future guidance documents
 - separate guidance to provide general oversight of LDTs;
 - standards for FDA notification and medical device reporting; and
 - quality system requirements
- Sometime in 2012

Burgess LDT Legislation

- H.R.3207, *Modernizing Laboratory Test Standards for Patients Act* (Burgess legislation)
 - Would shift sole responsibility for LDTs (and DTCs) to CLIA'88
 - Labs must file certain data on existing tests to new test registry subject to CMS review
 - Labs must file similar data for new LDTs subject to CMS review

Burgess LDT Legislation

- H.R.3207, Modernizing Laboratory Test Standards for Patients Act
 - AACC requesting Congress address certain questions before taking action on legislation
 - Impact on patient access
 - Affect ability of different providers to offer LDTs
 - What funds would CMS need to comply
 - What fees would CMS charge labs
- Best vehicle for passage this year is MDUFA reauthorization—unlikely to happen given AdvaMed opposition

MDUFA Reauthorization Agreement

- FDA and Industry reached a five year user fee agreement
- Manufacturers pay fees that allow agency to hire additional personal to review device applications
- FDA attached to deal, at the request of ACLA, language that specifies labs will not be assessed user fees for review of LDTs under MDUFA if agency expands oversight of LDTs

New Molecular Pathology Codes

- New Molecular Pathology Codes
 - CMS and other payers concerned there are not specific codes to genetic tests, only methods/procedures – worried about fraud
 - AMA developed new codes
 - CMS will determine in 2012 where to place codes (announcement for July new lab code meeting will give first clue)

PhD Reimbursement

- New Molecular Pathology Codes (cont.)
 - AMP/AACC working with other lab and medical groups to get Congress to allow certain board-certified PhD to bill for interpretive services on physician fee schedule
 - Looking for sponsor
 - Costs expected to be negligible
 - Need legislative vehicle

USPTO Study on Genetic Diagnostic Testing

- America Invents Act
 - Requires USPTO to conduct a study on the lack of independent second opinion testing on sole patent/single user genetic tests.
 - The study examines:
 - the scope of the problem
 - impact on quality of care
 - Innovation
 - Health care costs
 - Study to Congress by June 15, 2012

NIH Voluntary Genetic Testing Registry

- Launched registry February 29th
- Includes links to genetic, scientific and literatures sources through National Laboratory of Medicine
- Laboratories provide info on:
 - Purpose and limitations
 - Name and location of test provider
 - Whether it is a clinical or research test
 - Methods used
 - What is measured
 - Data on analytic & clinical validity and clinical utility

Final Thoughts



vstine@aacc.org
202/835-8721