# DIRECT-TO-CONSUMER GENETIC TESTING

## A CROSS-ACADEMIES WORKSHOP

# AGENDA

**August 31-September 1, 2009**
**The National Academies' Keck Center**
**500 Fifth Street, NW**
**Room 100**
**Washington, DC**

**Moderators**

Frederick R. Anderson, Jr., *Partner, McKenna, Long, & Aldridge LLP*
&
Barbara E. Bierer, *Professor of Medicine, Harvard Medical School and Senior Vice President, Research, Brigham and Women's Hospital*

**August 31, 2009**

**7:30** Breakfast

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| 8:00 am – 10:40 | **Session 1: Overview of Research on DTC Genetic Testing and its Trajectory** |

Direct-to-consumer genetic testing represents a $730 million global market, with projected growth of 20% annually. While many direct-to-consumer genetic tests assess risk for illnesses with strong genetic heritability and raise concerns over adequate counseling and appropriate outlets for such information, still other genetic tests to guide risk management for diseases with much smaller genetic components, or no clear genetic basis at all, have rapidly emerged and present new dilemmas for consumers and health care providers alike. With the costs of genetic analyses falling rapidly and entrepreneurs finding more and more creative uses for these technologies and the test results they produce, the future of genetic testing is being ushered in with both the hope that its tremendous promise will be realized and concern over the accompanying cultural, professional, and regulatory challenges to be faced.

**Issues to Address:**

Direct-to-consumer genetic tests have uncertain analytical and clinical validity, and questionable clinical utility.

What exactly can one tell based on these tests? What can't one tell? This will have implications for the testing companies' claims.

What types of genetic testing will become available over the next five to ten years?

What will the future market look like?

**8:00 Introduction to the Scope of the Workshop**

David Korn, *Vice Provost for Research, Harvard University*

**8:20 Drivers of Innovation: The Human Genome Project, Microarrays, the HapMap and the $1,000 Genome**

Alan Guttmacher, *Acting Director, National Human Genome Research Institute, National Institutes of Health*

**8:40** Discussion

**9:00 Direct-to-Consumer Genetic Testing: History and Scientific Foundation**

Muin Khoury, *Director, Office of Public Health Genomics, Centers for Disease Control and Prevention*

**9:20** Discussion

**9:40 Evolution of Direct-to-Consumer Genetic Testing: Present and Future Markets**

K. David Becker, *Chief Scientific Officer, Pathway Genomics Corporation*

**10:00** Discussion

**10:20** Break

| 10:40-12:45 | **Session 2: The Regulatory Framework** |
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With the implementation of the Clinical Laboratory Improvement Act (CLIA) predating major advances in genetics and the FDA only able to regulate genetic test kits, the vast majority of lab-derived genetic testing operates with sparse regulatory oversight relative to other laboratory tests of comparable capacity to explain and predict health and disease. In addition, no claims by direct-to-consumer genetic testing companies have been challenged by the FTC to date. As the technology advances at a dizzying clip and consumer interest continues to grow, the lagging federal, state, professional and consumer regulatory entities will need to consider how best to ensure valid tests and accurate advertising without stymieing innovations that promise what could be the next medical paradigm shift – or is this just more unregulated hype?

**Issues to Address:**

Differentiating regulatory issues for DTC testing vs. genetic testing generally.

DTC-specific regulatory issues include examining whether oversight of advertising/claims is adequate. Are the claims verifiable?

Spell out the roles of various agencies in oversight, state, and federal roles.

What is the impact of regulatory uncertainty on DTC companies?

What are the codes of professional conduct for informed consent, analysis, and disclosure?

Is it possible to create safeguards without hindering rapid technological advances?

If testing procedures aren't "approved" can they be quality assured?

**10:40 Existing oversight of genetic testing in the U.S. and U.K.**

Andrea Ferreira-Gonzalez, *Professor of Pathology, Virginia Commonwealth University and Director, The Molecular Diagnostics Laboratory, Virginia Commonwealth University Health System*
Timothy Aitman, *Professor of Clinical and Molecular Genetics, Division of Clinical Sciences, Imperial College London*

**11:20** Discussion

**11:55 Monitoring direct-to-consumer genetic testing**

Gregory Kutz, *Managing Director, Forensic Audits and Special Investigations, Government Accountability Office*
Sandra Soo-Jin Lee, *Senior Research Scholar, Stanford Center for Biomedical Ethics*

**12:30** Discussion

**1:00** Lunch

| 1:45-3:20 | **Session 3: Shared Genes and Emerging Issues in Privacy** |
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Genetic information has implications for the health and well-being of others beyond the individual whose DNA was sequenced, simultaneously suggesting the need to protect the sequenced individual from unethical treatment based on undesirable sequence and the potential responsibility to inform those (blood relatives, perhaps others) with a stake in the individual's genetics. The danger of untoward consequences of public genetic data is only further enhanced by the popular notion – correct in some cases but overly simplistic in many others -- that genes are a biological "blueprint" by which attributes from shoe size to temperament are determined. While the Genetic Information Nondiscrimination Act forbids unequal treatment based on one's genetics in many circumstances, it seems naïve to suppose that exposing one's genetic frailties wouldn't pose considerable social risk.

**Issues to Address:**
How to balance the desire for self-awareness among consumers that is driving this market against the need to protect privacy?
What are the risks and benefits for family members of users of these tests? For public figures? For the legal system?
Who owns an individual's genomic data?
Discrimination issues and the effectiveness of GINA
Social networks based on direct-to-consumer genetic testing results

**1:40 Existing Structures for Privacy and Nondiscrimination Protections: Beyond the Genetic Information Nondiscrimination Act**

Susannah Baruch, *Policy Director, Generations Ahead*

**2:00** Discussion

**2:20 Genetic Identity and Community**

Scott Woodward, *Director, Sorenson Molecular Genealogy Foundation*

**2:40** Discussion

**3:00** Break

| 3:20-4:30 | **Session 4: DTC Genetic Testing Companies and Research** |
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Direct-to-consumer genetic testing companies have already taken steps to use the rich data their customers provide them in research to improve their products, to offer new services, and even to benefit the broader research community. It stands to reason that protections for consumers-turned-research-subjects should be equivalent to those for human participants in academic genetics research, but no systematized mechanism for ensuring these protections currently exists. In addition, who should the results of the research benefit? Who owns this information and, by taking on a research role that could serve the public good, do direct-to-consumer testing companies assume an ethical responsibility to ensure that the public benefits?

**Issues to Address:**
Who retains ownership of genetic information when companies use their testing data for research? (IP)
Who should have access to the results?
Who should be allowed to benefit from the advances as a result of this research?
Will genetic information and the research it spurs become a private commodity?

**3:20** **Direct-to-Consumer Genetic Testing Companies as Research Entities: Disclosure, Intellectual Property, and Shared Advances**

Elissa Levin, *Director, Genetic Counseling Program, Navigenics, Inc.*

**3:40** Discussion

**4:30** Adjourn

**Dinner for Planning Committee, Speakers, and Staff**

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**September 1, 2009**

**7:30** Breakfast

**8:15 The FDA and the Regulation of Direct-to-Consumer Genetic Testing**

Courtney Harper, *Acting Director of the Division of Chemistry and Toxicology Devices, Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health, U.S. Food and Drug Administration*

**8:40** Q&A

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| 9:00 a.m. – 12:00 p.m. | **Session 5: The Impact of DTC Genetic Tests on the Medical System** |

If the medical system is no longer required to mediate genetic testing, how will the system cope with losing oversight (and reimbursement) of these services while retaining the full responsibility of caring for patients the services affect?

**Issues to Address:**
Can we model the cost to the medical system of DTC genetic testing?
Reimbursement and DTC genetic testing – are insurance companies involved? Do they have a role?
How can providers navigate DTC testing and results for patients in the clinic?
How do consumers react to DTC testing information, and what is the impact on their health behavior?

**9:00 What Are the Costs and Benefits to the Health Care System?**

Kathryn Phillips, *Professor of Health Economics and Health Services Research, University of California, San Francisco*

**9:20** Discussion

**9:40** **Knowledge of DTC Genetic Testing Among the Public and Health Professionals**

**Public Understanding**
Katrina Goddard, *Senior Investigator, Kaiser Permanente Center for Health Research*

**10:00** **Understanding Among Health Professionals**
Joseph McInerney, *Executive Director, National Coalition for Health Professions Education in Genetics*

**10:20** Discussion

**10:40** **Cooperation or Competition – How Do Health Care and DTC Genetic Testing Coexist?**

Patricia Ganz, *Professor of Health Services, School of Public Health and Professor of Medicine, David Geffen School of Medicine, University of California, Los Angeles*

**11:00** Discussion

**11:20** **The Impact of Direct-to-Consumer Genetic Testing on Public Health**

Harvey Fineberg, *President, Institute of Medicine*

**11:40** Summary Discussion

**12:00** Lunch / Adjourn