Direct-to-Consumer (DTC) Genetic Testing

A Cross-Academies Workshop

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Academy Participants

- NAS Committee on Science, Technology, and Law
- NAS Board on Life Sciences
- IOM Roundtable on Translating Genomic-Based Research for Health
- IOM National Cancer Policy Forum
- IOM Forum on Drug Discovery, Development and Translation

Workshop Planning Committee

- Fred Anderson, McKenna, Long & Aldridge
- Barbara Bierer, Harvard Medical School
- Joseph Fraumeni, NCI
- Patricia A. Ganz, UCLA Schools of Medicine and Public Health
- Mikhail Gishizky, Entelos, Inc.
- Alberto Gutierrez, FDA
- Kathy Hudson, Genetics and Public Policy Center
- Muin Khoury, CDC
- David Korn, AAMC
- Jonathan Moreno, Center for Bioethics, U Penn

Goal of the Project

- To organize a workshop that will bring together the scientific, medical, legal, and policy communities along with members of the public to explore the opportunities and challenges posed by direct-to-consumer genetic testing.

Areas of Emphasis

- Current State of Knowledge and the Future Research Trajectory
- Shared Genes and Emerging Issues in Privacy
- Regulatory Framework
- Education of the Public and the Medical Community

Current Knowledge and Research Trajectory

- What is the current status (overview) of the DTC genetic testing industry?
- What do we know about the analytical validity, clinical validity, and clinical utility of DTC tests?
- What exactly can one learn from these tests? What can't one learn?
- What types of genetic testing will become available over the next five to ten years?
- What will the future market look like?

Shared Genes and Emerging Issues in Privacy

- How to balance consumer desire for self-awareness 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
- On-line social networks based on direct-to-consumer genetic testing results

Regulatory Framework Issues

- 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?
- What are the roles of various agencies in oversight both at state and federal levels.
- 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?

Education of the Public and Medical Community Issues

- Do patients desiring DTC tests require better guidance from health professionals?
- Are providers well enough informed about genetic testing?
- How do we ensure proper interpretation of the tests in context?
- What is the minimum knowledge required to make informed decisions based on DTC testing?
- Have relevant lessons been learned from other diagnostic tests and procedures?

- Workshop to be held in summer or early fall.

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Thank You.