Ethical and Legal Criteria for Consumable Genetic Testing

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Direct-to-Consumer Genetic Testing
Direct-to-Consumer Genetic Testing

• Obtained and administered by consumer without medical doctor

• Results predict likelihood of a disease occurring
  – NOT indicative of a specific diagnosis
  – NOT a guarantee that you will develop the disease
Criticism: Direct-to-Consumer Genetic Testing

- Results might cause stress, depression
- Lack of governmental regulations
- Lack of awareness about genetic information
  - Inappropriately act upon results

Commercialization of human genome
Ethical Considerations and Recommendations
Do genetic test results cause an increase in stress?

• Study: Risk Evaluation and Education for Alzheimer’s Disease

• Bloss Study
So what should genetic testing companies do to fulfill their ethical responsibility?

• Beyond the hype
  – Explicitly state that results do not guarantee that a disease will (not) occur
  – Warning: consult a genetic counselor or other medical professional before you take any action based on these results
  – Notify customers of federal regulations
Consumer Privacy and Consent

Criticism of genetic testing companies:

- What do companies do with stored samples?

- How do customers know when their information is shared with other companies, or even sold, for more research and/or profit?
Consumer Privacy and Consent

• Genomic Biobanks
  • Not enough information provided
  • Do not obtain informed consent for specific uses

The Common Rule is a federal policy on Human Subjects Protection. It requires that researchers obtain and document informed consent.
Consumer Privacy and Consent

- How should we approach consent?
- Do consumers have a right to clinically important information?
Legal Considerations and Recommendations
Genetic Information Nondiscrimination Act of 2008

- Title I: Genetic Nondiscrimination in Health Insurance
- Title II: Prohibiting Employment Discrimination on the Basis of Genetic Information
Exceptions to GINA

LIFE INSURANCE

Department of Veterans Affairs
Exceptions to GINA

Eileen Wright
zomg my genetic test results say that I'll die when I'm 23 from obesity complications :(
6 minutes ago · Like · Comment

Arielle Isabel Garcia likes this.

Arielle Isabel Garcia Umm... You. Are. So. Fired.
3 minutes ago · Unlike · 1 person

Eileen Wright :'(
2 minutes ago · Unlike · 2 people
YOU HAVE A CONDITION
WE CALL 'NOTUS
ENOUGH US INSURANCE'
Legally ensure that *all* people are insured despite potential genetic-related health risks.
Questions?
Sources

23andme.com
Nytimes.com
http://www.nytimes.com/2010/06/12/health/12genome.html?_r=1
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm111104.htm

