



# Genetic Testing and Insurance

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# Outline

- Underwriting/Risk classification
- Adverse selection
- Current genomics landscape
- Social/Ethical issues
- Existing Federal and State Statutes
- Summary



# Underwriting and Risk Classification

- Underwriting (risk classification) is the process that insurers use to identify and classify a person's risk of dying prematurely, becoming disabled or needing long-term care.
- Health information that has been shown to be accurate predictors of risk is collected and analyzed (e.g., build, blood pressure, cholesterol, tobacco use, family history, existing or past disease, etc.).
- By law, similar risks must be treated similarly.
- A key benefit of underwriting/risk segmentation is that it enables insurers to make products widely available at the lowest prices to as many people as possible.
- Unlike health and property/casualty insurance, life, disability income and long-term care underwriting is a one time event.



# Adverse or Anti-Selection

- Adverse or anti-selection occurs when the applicant knows information that would increase his mortality/morbidity risk but doesn't disclose it on the application. This leads the insurer to assign the applicant to a lower risk pool than they otherwise would have.
- To avoid adverse selection, there must be a level playing field of information. That is, the insurer needs to know what the applicant knows about their health.
- Adverse selection can destabilize the voluntary individual insurance market, because it tends to lead to premium increases which discourages healthy individuals from purchasing coverage.
- Studies show adverse selection occurs, especially in long-term care insurance.

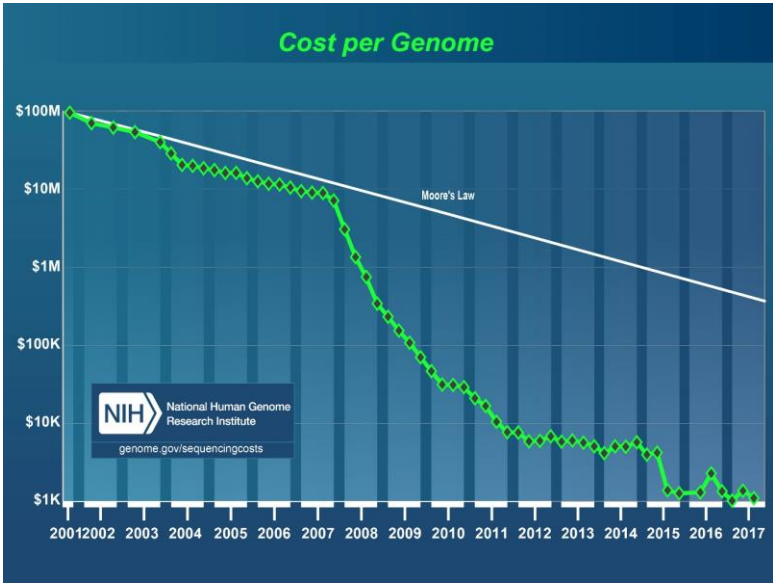
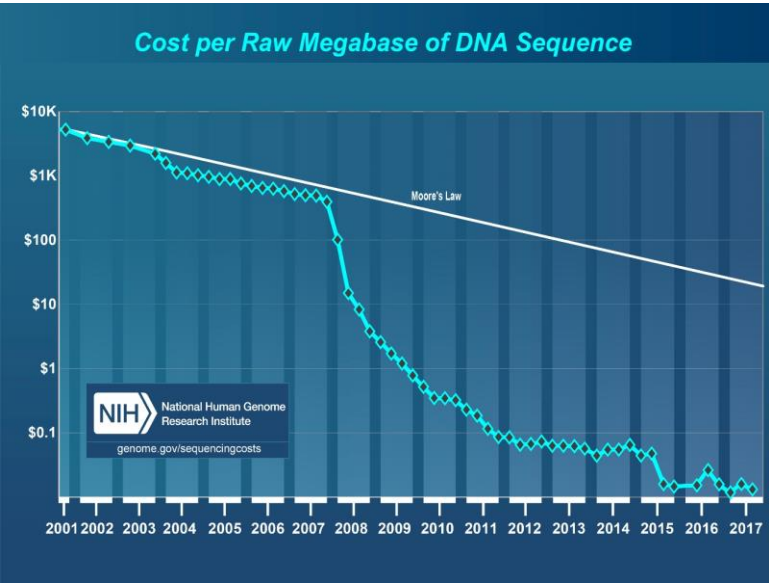
# A Brief History of Genetics

- 1865 – Gregor Mendel discovers laws of basic genetics
- 1953 – Watson and Crick describe the double helical structure of DNA
- 1977 – Sanger and Maxon/Gilbert develop DNA sequencing methods
- 1983 – first human disease mapped with DNA – Huntington’s disease
- 1989 – gene for cystic fibrosis identified
- 1990 – human genome project launched in the US
- 1995 – first bacterial genome sequenced
- 2003- finished version human genome sequence completed
- 2015 – first effective gene editing by CRISPR technique published

Courtesy: National Human Genome Research Institute

<https://www.genome.gov/imagegallery/viewimage/?imageID=26964377742>. Accessed 1/20/17

# Cost of Sequencing



Source: <https://www.genome.gov/sequencingcostsdata>. Accessed 8/5/18

# Direct to Consumer (DTC) Testing

- Market directly to consumers online
- Simple saliva collection
- Provide information on health risks (using single-nucleotide polymorphism - SNP analysis), medication sensitivities, inherited conditions and traits
- Examples:
  - 23andMe
  - Ancestry.com
  - MyHeritageDNA
  - Color (physician order required)
  - GenePlanet
- November 2013 – FDA notified 23andMe to stop marketing their personal genome service
- April, 2017 – FDA announces approval for 23andMe to market a revised panel



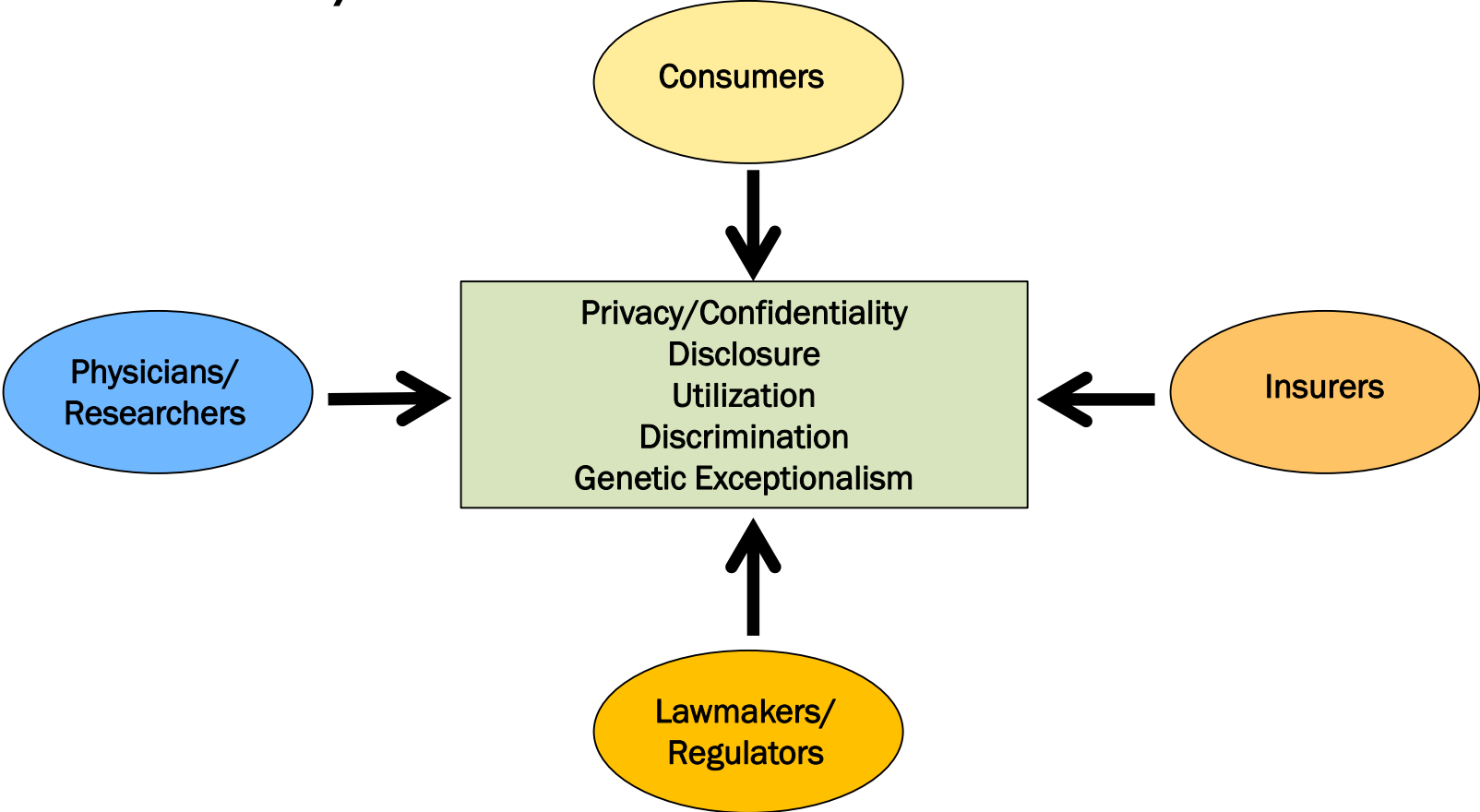
# Types of Genetic Tests

- **Diagnostic** - confirms a clinically suspected disease. Example – cystic fibrosis
- **Predictive** – determines risk for a particular disorder. Example – BRCA breast cancer gene
- **Screening** – parental (carrier testing), perinatal and newborn screening
- **Pharmacogenomics** – identifies variation in an individual’s genetic makeup to determine whether a drug is suitable for the individual, and safest/most effective dose
- **Tumor analysis** – examines genetic markers in a tumor to guide treatment
- **Whole genome or exome sequencing** – examines entire genome or exome to discover genetic alterations that may be cause of disease

<https://www.ama-assn.org/content/genetic-testing> (Accessed 11/1/18)



# Social/Ethical Issues



# Social/Ethical Issues

- Ethical, Legal and Social Implications (ELSI) Program
  - Established National Human Genome Research Institute (NHGRI/NIH) in 1990
  - Purpose: fund research on the ethical, legal and social implication of genetic research for individuals, families and communities
  - Priorities: genomic research, genomic health care, broader societal issues and legal, regulatory and public policy issues
  - Funded four grants 2016 to research ethical, legal and social implications of genomics

<https://www.genome.gov/10001618/the-elsi-research-program/#al-1>

# Consumer Privacy Protections

- Existing federal and state laws protect both confidentiality and security of consumer health information:
  1. HIPAA Privacy Rule - *Standards for Privacy of Individually Identifiable Health Information*
  2. Federal Fair Credit Reporting Act
  3. NAIC Privacy of Consumer Financial and Health Information Model Regulation
  4. NAIC Standards for Safeguarding Customer Information Model Regulation
  5. NAIC Insurance Information and Privacy Protection Model Act



# Notice of Adverse Underwriting Decision

- Insurers must notify applicants of any adverse underwriting decision
  - Notification must include the right to access the reason for the adverse underwriting decision and the right to access and correct the information
  - Adverse notification is defined as
    - Declination of coverage
    - Offer to insurer at worse than standard rates
    - Failure to apply at an insurer requested by the applicant that the agent represents

# Federal Regulation

- Genetic Information Nondiscrimination Act (GINA)
  - Passed by Congress 2008
  - Prohibits insurers use of genetic test results and family history in determining eligibility for health insurance
  - Prohibits insurers from requesting or requiring a genetic test for health insurance
  - Prohibits employers from using genetic information or requesting a genetic test in determining employment eligibility
  - Allows an insurer to determine health insurance premium or eligibility based on a genetic disorder only if there is manifested disease
  - Does not apply to life, long-term care (LTC) or disability insurance (DI)

Source: <https://www.gpo.gov/fdsys/pkg/FR-2013-01-25/pdf/2013-01073.pdf>. Accessed 1/20/17

# State Statutes

- **VT 18 V.S.A. § 9334\*** (1999)
  - No policy of insurance shall be underwritten on the basis of:
    - Any requirement to undergo genetic testing
    - The results of genetic testing of a family member
- **VT 8 V.S.A. § 4724\*\*** – Unfair discrimination:
  - Conditioning insurance rates on the results of genetic testing where there is no relationship between the information and the risk
  - Insurer can rely on actual or reasonable anticipated experience to establish the relationship

\*Vermont Title 18 Vermont Statute Annotated 9334 – Genetic testing as a condition of insurance coverage \*\*Vermont Title 8 Vermont Statute Annotated 4724 – Unfair methods of competition or unfair or deceptive acts or practices defined

# State Statutes

- ***MA 175 § 120E\* (2006)***

- Insurer may not use genetic test results to determine eligibility/premium unless action relates to insurer's mortality or morbidity based on sound actuarial principles or reasonable expected experience
- Insurer may not require an applicant to undergo a genetic test as a condition issuance or renewal of a policy
- Insurer may ask an applicant if she/he has undergone a genetic test. Applicant is not required to answer, but if they decline to answer, the application must note that this may result in a higher premium or denial of coverage
- If applicant provides genetic information, insurer may use that information to determine eligibility or premium provided the information relates to insurer's mortality or morbidity based on sound actuarial principles or reasonable expected experience

\*Massachusetts General Laws Chapter 175 Section 120E – Life insurance policies; genetic tests; discrimination based on genetic information

# State Statutes

- ***MD § 18-120\* (2008)***

- Long-term care insurers may not:

- Request or require a genetic test as a condition of insurance
    - Use the results of a genetic test to deny or limit coverage or charge a different rate
    - Long-term care insurers may deny or limit coverage or charge a different rate based on the results of a genetic test provided the action is based on sound actuarial principles

\*Maryland Code, Insurance Section 18-120 – Prohibited acts



# In Conclusion

- The economic success of voluntary insurance products hinges on a level playing field of information for appropriate and fair risk categorization
- The field of genomics is growing logarithmically
- The clinical use of genetic information remains limited, but is expanding at a rapid pace and will become commonplace over time
- Public discourse needs to consider all stakeholders in order to maintain wide access to competitively priced insurance products while protecting individual privacy rights and allaying concerns over proper information use

Questions?