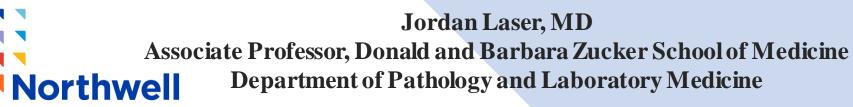
# Regulatory and Health Policy Issues: Consumer Genomics



Health™

### **AMP Position Statements**

- 2007-
  - Only healthcare provider, only CLIA
- 2015
  - OK DTC with conditions
    - Intent
      - Healthcare related
      - Business driven
      - Ancestry
      - Recreational



### **AMP Position Statements**

- 2019-
  - Expansion and depth
    - Clinical
      - Transparency
        - » Analytical/clinical validity
      - CLIA
      - Consumer focused
        - » Education, impact on consumer (+/-family), negative not negative, comprehension, referral to genetic counselors healthcare providers
    - Privacy



# Future of Privacy Forum Best Practices



#### PRIVACY BEST PRACTICES FOR CONSUMER GENETIC TESTING SERVICES

#### PROMOTES TRANSPARENCY

#### Consumers are provided:

- A high level overview of key privacy practices and detailed explaination of how Genetic Data is collected, used, and shared
- Educational resources about the basics, benefits, and risks of genetic testing
- Annual transparency reports describing law enforcement requests

#### **PROVIDES CHOICES**

#### Consumers can:

- Give express consent for the collection and use of Genetic Data
- Give informed consent for research
- Access, correct, and delete their Genetic Data
- · Request destruction of biological samples

#### **ENHANCES PROTECTIONS**

#### Companies will:

- NOT share Genetic Data with employers, insurance companies, and educational institutions without consent
- Require valid legal process for disclosing Genetic Data to law enforcement
- Employ strong data security practices and privacy by design

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# Legal/Regulatory Protections of Consumers

### • Federal:

- HIPAA
  - Business associate of a covered entity→ data becomes
     PHI
- GINA
  - Genetic discrimination by health insurers and employers
- ADA
  - Discrimination in employment, public services, accommodations, and communications
    - 1995- prevents employment discrimination based upon genetic information related to illness, disease or other disorders



# Legal/Regulatory Protections of Consumers

- Federal cont:
  - -45 CFR 46
    - Protection of human subjects
  - Patient Protections and Affordable Care Act
    - Prevents health insurance to prevent coverage based on 'pre-existing conditions' (genetic information)



# Legal/Regulatory Protections of Consumers

### • State:

- 48 + DC- genetic discrimination in health insurance
- − 35+ DC- employment
- 17- life insurance
- 17- disability insurance
- 8- long term care insurance
- CalGINA- emergency medical services, housing, mortgage lending, education and other state funded programs



## Summary

- Industry in evolution
  - Clinical
    - Appropriateness, safety, validity, regulation
      - Regulatory environment
    - Privacy
      - Call for clarity and transparency
      - Best practices
      - Legal and regulatory protections
    - Incorporation into routine healthcare
      - Unfamiliar, provider education

