JUDGES & LAWYERS BREAST CANCER ALERT

THE 24th ANNUAL ELLEN P. HERMANSON MEMORIAL SYMPOSIUM

LEGISLATING GENETIC TESTING: IS KNOWLEDGE POWER?

CAN – AND SHOULD – OUR NATION'S HEALTHCARE SYSTEM DO MORE TO EMPOWER AMERICANS WITH KNOWLEDGE ABOUT THEIR GENETIC PRE-DISPOSITION TO CANCER?

December 9, 2020

INTRODUCTION

I. Why is DNA data more sensitive than other types of health information?

- **a.** Identifies predispositions, disease risk and predicts future medical conditions
- **b.** Reveals information about the individual's family members, including future children
- **c.** Produces unexpected information or information of which the full impact may not be understood at the time of collection
- **d.** Provides cultural significance for groups or individuals

II. What is the difference between 23andMe (off-the-shelf DNA testing kits) and medical provider genetic testing?

- **a.** Validation
- **b.** Types of medical information returned
- **c.** Medical information is returned differently when direct-to-consumer (DTC) rather than through a medical provider

III. Some things to consider when submitting DNA for direct-to-consumer testing

A recent study concluded that around 60% of Americans of European descent could be matched to a third cousin or closer relation. And this percentage is only set to grow in the coming years, as more people give their genetic information over to these companies

a. Recent examples of law enforcement use of DNA databases

- **i.** GEDmatch: where people can upload their ancestry results from popular websites such as Ancestry.com and 23andMe to find potential relatives
- **ii.** Golden State Killer – 40-year-old cold case (GEDmatch)
- **iii.** Alabama Double Homicide in 1999 (GEDmatch)
- **iv.** FamilyTreeDNA allows investigators to upload suspect's DNA profiles to find potential relatives
- **v.** Terrence Miller, 1972 unsolved murder

b. 23andMe's Enhanced Privacy Policy

- **i.** Uses
- **ii.** To provide services, for research (with consent); targeted online advertising
- **iii.** Choice with whom to share data
- **iv.** Doesn't share with public databases

v. Doesn't share with employer or insurer
vi. Doesn't share with law enforcement unless required by law
vii. Multi-Factor Authentication
viii. Employee access controls
ix. Encryption
x. Ability to share with others via social media
xi. If you do not consent for research purposes, your saliva sample and DNA are destroyed
xii. *National Institutes of Health Certificate of Confidentiality
xiii. Confidentiality contractual provisions with third parties
xiv. User Rights
xv. Access, correction, deletion (unless already shared with third parties)

c. Another example: Parabon NanoLabs: Engineering DNA for Next-Generation Therapeutics and Forensics

HEALTH LAWS, GUIDELINES & RELEVANT CASES

I. Health Insurance Portability and Accountability Act (HIPAA):

https://www.govinfo.gov/content/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf

Protects genetic information when shared with health care providers.

Although the statute does not contain provisions specific to genetic information, it does require all covered providers/entities to meet the requirements that apply to the use or disclosure of any individually-identifiable (as strictly defined by the Privacy Rule) health information (including genetic information) for research.

a. HIPAA Privacy Rule

National standards to protect individuals' medical records and other protected health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Rule requires that appropriate safeguards be implemented to protect the privacy of protected health information, and it sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Rule also gives patients rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections. However, there are many, many legally permissible disclosures allowed without express consent, such as treatment; payment activities like determining eligibility or coverage under a health insurance plan and adjudicating claims, and billing and collection activities; and health care

operations, *i.e.*, administrative, financial, legal, and quality improvement activities of a covered entity that are necessary to run its business and to support the core functions of treatment and payment.

b. HIPAA Security Rule

Establishes national standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a covered entity. The Security Rule requires appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information.

c. No private right of action

Bond v. Conn. Bd. of Nursing, 622 F. App'x 43, 44 (2d Cir. 2015) (Plaintiff's HIPAA claims dismissed as time-barred; "is doubtful that HIPAA provides a private cause of action at all" but if there were a private action that may exist under HIPAA, it "would not have a longer statute of limitations than the ADA."); *Williams v. NY City Dept. of Educ.*, 2020 US Dist LEXIS 32403, at *15-16 (SDNY Feb. 25, 2020, No. 18-CV-11621 (RA)) (Plaintiff's claim that defendant violated HIPAA when it ordered two faculty members to go to her doctor's office to verify her medical condition and treatment dismissed as time-barred; in *dicta*, the court noted that even if it were not time-barred, it was unlikely plaintiff would have a private cause of action.); *Marquez v. Klein*, 2019 US Dist LEXIS 186423, at *5-6 (SDNY Oct. 28, 2019, No. 19-CV-8867 (CM)) (Plaintiff's HIPAA claim that defendants made false statements about his mental health dismissed because HIPAA does not authorize a private right of action.); *Mora v. Hughes*, 2019 U.S. Dist. LEXIS 101805, at *3, n 2 (W.D.N.Y. June 17, 2019, No. 6:15-CV-06038 EAW) (rejecting plaintiff's HIPAA claim that the physician assistant's statements in the declaration violated HIPAA, stating that "although HIPAA generally provides for the confidentiality of medical records, . . . an individual cannot sue for its enforcement or for damages caused by disclosures."); *Bruno v. CSX Transp., Inc.*, 262 F.R.D. 131 (N.D.N.Y. 2009) (HIPAA did not provide plaintiff with private right of action to extent that there was any wrongful disclosure of plaintiff's medical records and plaintiff's only recourse under HIPAA would be to request state official or Secretary of Health and Human Services to bring action on his behalf).

II. Genetic Information Non-Discrimination Act (GINA):

https://www.eeoc.gov/statutes/genetic-information-nondiscrimination-act-2008

Protects against discrimination by covered health insurers and employers by prohibiting them from discriminating against employees on the basis of genetic information. GINA's health-insurance and employment provisions both prohibit requesting, requiring, or purchasing genetic information.

a. **Background (Pre-GINA)**

i. 1968–1993:

Lawrence-Berkeley Laboratories, a state and federal research institution, conducted pre-employment and annual medical examinations of its employees. It told its employees that it was testing for cholesterol without disclosing that it also tested for syphilis, sickle cell genetic markers, and pregnancy. The discovery of its actions led to a class action lawsuit, in which the federal circuit appeals court observed that if these tests were truly unauthorized, they constituted a significant invasion of the employees' constitutional privacy interests.

Burlington Northern Santa Fe Railroad told its employees that its health tests were to ascertain whether they possessed a type of inherited neuropathy which causes carpal tunnel syndrome (which arguably was work-related). The company was secretly testing for several other conditions, including diabetes and alcoholism. The EEOC commenced a lawsuit that quickly settled when the company agreed to, among other things, halt its testing immediately.

b. GINA's legislative history

Included stories of employees who tested positive for heightened genetic risk and were then asked to switch insurance policies to save their employers money. *See* Jessica L. Roberts, "Preempting Discrimination: Lessons from the Genetic Information Nondiscrimination Act," 63 VAND. L. REV. 439, 470-71 (2010).

c. Following enactment

i. *Fink v. MXEnergy* (2010) – the first GINA case: Defendant fired one of its employees, plaintiff Pamela Fink, following preventative double mastectomy she underwent upon discovering that she carried the BRC2A gene associated with a higher risk of breast cancer; before the surgery, Fink had informed her supervisors about her genetic tests and the preventative measures she was taking and she was terminated shortly afterward, despite glowing reports and generally positive accounts of her performance up until that point. The matter was settled confidentially in the Equal Employment Opportunity Commission phase.

ii. **Note:** After *Fink v. MXEnergy*, and in the 10 years since GINA's enactment, none of the lawsuits filed for discrimination based on genetic-test results have proven successful. Instead, most of the successful cases under GINA have involved impermissible requests for protected data. *See e.g. Powell v. Lab Corp.*, 789 Fed. Appx. 237, 240 (2d Cir. 2019) (affirming the District Court's dismissal of plaintiff's GINA claim because

drug tests are not "genetic tests" within the meaning of GINA); *Hawkins v. Jam. Hosp. Med. Ctr. Diagnostic & Treatment Ctr. Corp.*, No. 16 CV 4265 (RRM) (CLP) (E.D.N.Y. Mar. 27, 2018) (plaintiffs had standing to bring their claim for damages for hospital's unlawful requirement of job applicants that they disclose their genetic information, in violation of GINA); *Farmer v. Patino*, 2019 US Dist LEXIS 1824, at *14 (E.D.N.Y. Jan. 3, 2019, No. 18-cv-01435 (AMD) (LB)) (plaintiff's GINA claim dismissed because he failed to show that defendants took any kind of action related to his genetic information, let alone discriminated on that basis); *Jackson v. Regal Beloit America, Inc*., 2018 Wage & Hour Cas. 2d (BNA) 220260, 2018 WL 3078760 (E.D. Ky. 2018) (employer had violated GINA by requiring an employee to submit to a medical examination in which genetic information was sought from her; because the doctor was acting as an agent of the employer, the doctor's unlawful request for genetic information was "tantamount" to the request by the employer, given employer's affirmative duty to ensure that the doctor did not violate GINA during the medical examination); *Lowe v. Atlas Logistics Grp. Retail Servs. (Atlanta), LLC*, 102 F. Supp. 3d 1360, 1364 (N.D. Ga. 2015) (finding that employer-conducted genetic testing for investigative purposes violates GINA).

Thus, GINA has functioned more as a protection against invasions of privacy than as a protection against discrimination.

iii. **Note**: GINA defines statutorily protected genetic information as (1) a person's genetic tests, (2) the genetic tests of her family members, and (3) manifested conditions in her family members. Some courts have held that GINA does not protect *spouses* of those who share genetic information (increased cost of insurance premiums), and does not protect against third-party sharing of information, *e.g.*, an employee may share her genetic information with a third party "objective" source. The employer cannot "collect" genetic information from that third-party unless it falls under certain narrow categories. Collect means: "request, require, or purchase genetic information", so in most cases GINA will not permit an employer to collect the information from a third-party source, unless it falls under an exception, like publicly available information.

iv. **Note: HR 1313 - Preserving Employee Wellness Programs Act:****

Exempts workplace wellness programs from: (1) limitations under the Americans with Disabilities Act of 1990 on medical examinations and inquiries of employees, (2) the prohibition on collecting genetic information in connection with issuing health insurance, and (3) limitations under the Genetic Information Nondiscrimination Act of 2008

on collecting the genetic information of employees or family members of employees. This exemption applies to workplace wellness programs that comply with limits on rewards for employees participating in the program.

**This was a proposed bill and never passed.

III. Patient Protection and Affordable Care Act (ACA)

The first part of the comprehensive health care reform law enacted on March 23, 2010.

The law was amended by the Health Care and Education Reconciliation Act on March 30, 2010. The name "Affordable Care Act" is usually used to refer to the final, amended version of the law. (It's sometimes known as "PPACA," "ACA," or "Obamacare.")

The law provides numerous rights and protections that make health coverage more fair and easy to understand, along with subsidies (through "premium tax credits" and "cost-sharing reductions") to make it more affordable.

The ACA, passed two years after GINA, rendered moot some of GINA's most central provisions. The ACA protects against insurers' use of all medically relevant information, not just genetic data. It bans preexisting condition exclusions, eliminates health-status-based rating in the individual and small group markets, and outlaws medical underwriting. The ACA also guarantees coverage of certain preventive health services, (including BRCA testing for certain women and mammograms for women ages 40 and up, but not including screening and preventive services needed once someone learns that they carry a mutation – *i.e.*, annual breast MRIs starting at age 25, alternating with annual mammograms starting at age 30, screening for ovarian cancer, risk-reducing surgeries (bilateral salpingo-oophorectomy/hysterectomy and bilateral mastectomy)), protects people enrolled in clinical trials, and prohibits health plans from putting annual or lifetime dollar limits on most benefits, and more.

After the ACA was enacted, health insurers could no longer deny coverage for preexisting conditions, set discriminatory premiums, or make eligibility decisions based on any medically relevant risk-related information, including genetic information.

If Congress were to repeal the ACA, or the Supreme Court were to revisit the statute's constitutionality, GINA's health insurance portion, which currently overlaps with the ACA, would become more relevant, even though it still will not apply if someone has manifest disease, meaning that a BRCA positive individual with cancer could be discriminated against.

IV. Clinical Laboratory Improvement Amendments (CLIA) (Lab certifications, e*tc*.)

The primary regulatory body for laboratories that perform genetic testing is the Center for Medicare and Medicaid Services (CMS). CMS certifies the accuracy and reliability of a laboratory to perform testing under Clinical Laboratory Improvement Amendment (CLIA) guidelines. 42 CFR Part 493 defines federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, with the exception

of clinical trials and for basic research purposes. CLIA allows certain qualified laboratories to apply for a CLIA license as an exemption from having to request authorization for every test.

Thus, laboratory tests, including genetic tests, are subject to federal oversight when performed for clinical or diagnostic purposes, with the objective to ensure the accuracy, reliability, and timeliness of test results regardless of where the test was performed.

All laboratory tests conducted for the purpose of providing information for use in diagnosis or health care must be performed in a CLIA-certified laboratory or a laboratory certified under state requirements that meet federal criteria.

https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia-

New York is one of only two states in the country that has a state laboratory accreditation framework that exceeds the floor set by the federal CLIA statute. As such, clinical laboratories in New York State are governed by the NYS Clinical Evaluation Laboratory Program (CLEP).

https://www.wadsworth.org/regulatory/clep/laws

a. Note: There is a regulatory gap between the FDA and CLIA

The FDA has traditionally regulated clinical genetic testing (not the lab that produces it) on a case-by-case basis depending on the type of test offered. The FDA claims jurisdiction over laboratory-developed tests (LDTs). Tests in which a physician sends a sample to a laboratory for analysis by scientists are classified as LDTs.

Diagnostic testing, and interpreting those tests, is considered the practice of medicine. The FDA is not allowed to regulate the practice of medicine. Yet, it is responsible for regulating medical devices. Diagnostic tests use machines, sample tubes, and other tools that are clearly medical devices. LDTs are not physical items for sale, however, but a process performed by researchers in a laboratory.

Historically, the FDA has exercised its discretion in declining to oversee genetic tests, choosing not to regulate them. If the FDA declines, the regulation of the device falls within the jurisdiction of CLIA.

Meanwhile, CMS, an entirely different administrative agency, does not require (1) registration of available LDTs, (2) demonstration of clinical validity, (3) adverse event reporting, (4) any mechanism or quality system assurance to demonstrate safe manufacture of tests, or (5) post-market tracking of LDTs.

Ultimately, there is an inconsistent regulatory landscape, potentially resulting in a lack of assurance around safety and clinical validity and a lack of adverse event reporting.

i. **Note**: there is currently draft federal legislation in the work that would shift regulatory authority for genetic tests (in fact, all in vitro diagnostics and laboratory developed tests) to the FDA. It's called the VALID Act.

V. The Federal Policy for the Protection of Human Subjects -a/k/a the "Common Rule"

a. **45 C.F.R. Part 46**

Department of Health and Human Services "Common Rule" regulations: outlines the basic provisions for institutional review boards, informed consent, and assurances of compliance. Any human-subject research conducted or supported by the National Institutes of Health, or any other Department of Health and Human Services agency, with the exception of the FDA, must follow 45 C.F.R. 46 Subpart A, which is the HHS version of the Common Rule.

The Common Rule was last revised in 2019. During the notice-and-rulemaking process that led up to that revision, significant debate occurred about a proposal that would make all biospecimen research equivalent to "human subject research," which would subject even basic research to review by institutional review boards and consent requirements. The proposal was based on the concept that all human tissue contains genetic material, and genetic material is intrinsically individually identifiable. After much controversy, the agency did not finalize this proposal in the Final Rule. However, the agency did commit to revisiting this decision every four years, based on whether risks of reidentification would increase as science advanced.

b. **Note**: New York is one of the few states in the country with a law that requires coverage of "Screening and diagnostic imaging for the detection of breast cancer, including diagnostic mammograms, breast ultrasounds, or magnetic resonance imaging, covered under the policy shall not be subject to annual deductibles or coinsurance." Most states do not require coverage beyond mammograms.

VI. New York Public Health Law Article 24-A

Regulates "human research," defined as "any medical experiments, research, or scientific or psychological investigation, which utilizes human subjects and which involves physical or psychological intervention by the researcher upon the body of the subject and which is not required for the purposes of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of medical condition for the direct benefit of the subject." (Pub. Health Law § 2441(2))

This New York State law differs in many key ways from the federal Common Rule. However, this state law is pre-empted if a research institution has voluntarily opted to apply the federal Common Rule to its research.

VII. New York's Genetic Testing Law – Civil Rights Law § 79-l

New York enacted Civil Rights Law **§** 79-l in 1996. The law sets forth specific requirements related to written consent for genetic tests and disclosure of genetic test results. In addition, any person who consents for a genetic test must be advised that they may want to seek professional genetic counseling.

The current law uses different terms to describe whether genetic tests may be run, without a consent, on samples that are no longer able to be linked to an identifiable individual. The law does not explicitly recognize whether the term "anonymous samples" is meant to be equivalent with different but related terms that are used commonly by the research community (i.e., "individually identifiable" under the Common Rule, or "deidentified" under HIPAA).

In the approximately 25 years since the law was passed, significant advances in genetic testing technologies have challenged how this law should be applied today.

Bin Sultan Bin Abdul-Aziz Al Saud v. NY & Presbyt. Hosp., 2019 NY Slip. Op. 32153[U], *1-2 (Sup. Ct., N.Y. Co. 2019) (Petitioner alleged he was the son of decedent, the Crown Prince of Saudi Arabia, who died at the hospital and sought to obtain the decedent's DNA samples from the hospital. Civil Rights Law § 79-l permits courts to "authorize genetic testing in the absence of written consent, provided that the court consider factors including the privacy interests of the individual subject of the genetic test and of close relatives of such individual and the public interest." The court granted Petitioner's request, reasoning that Petitioner's interest in obtaining the decedent's DNA outweighed the privacy interests of the decedent and his relatives.)

VIII. New York's Access to Patient Information – Public Health Law §§ 17 and 18

New York State Public Health Law §§ 17 and 18 each contain provisions relevant to a patient's request for and access to the patient's own medical information. Questions often require an analysis to determine whether a particular provision of these state laws is pre-empted by federal HIPAA. In 2002, the New York State Department of Health issued several pre-emption charts that provide additional information about these statutes and other provisions of New York law.

https://www.health.ny.gov/regulations/hipaa/preemption_charts.htm

IX. Mandatory Genetic Testing

New York State contains several types of mandatory genetic testing laws. Newborn screening programs are adopted in every state, including New York, such that each program varies with respect to the specific disorders screened. Interestingly, the prevalence of Tier 1 genetic conditions—Hereditary Breast and Ovarian Cancer, Lynch Syndrome, and Familial Hypercholesterolemia – is far more common than birth defects. Most of the disorders on the newborn screening panel are genetic metabolic disorders. Screenings are required by law and do not require parental consent. New York State

Public Health Law § 2500-a. The basis for such programs is the state's *parens patriae* power, or in other words, the government's ability and authority to act as the legal protector of its citizens. Other individuals may face mandatory genetic testing for law enforcement purposes, armed service enrollment, or insurance coverage.

X. Duty To Warn and Genetic Testing

Genetic testing related to inheritable conditions can also raise ethical and legal questions that become a balancing act between a patient's privacy rights and a "duty to warn" related family members who also may be at risk for the genetic condition.

Courts have not generally recognized a "duty to warn" family members of a patient's genetic test results that would justify overriding the patient's privacy protections.

However, two notable non-New York cases have addressed this issue with opposite results.

Safer v. Estate of Pack, 677 A.2d 1188, 1192 (N.J. Super. Ct. App. Div. 1996), held that (i) physicians do have a duty to warn, (ii) the duty encompasses identifiable third parties known to be at risk of avoidable harm from a genetically transmissible condition, and (iii) physicians should take "reasonable steps" to warn at-risk family members.

Pate v. Threlkel, 661 So. 2d 278, 282 (Fla. 1995), held that a physician had a duty to warn a patient regarding the genetic risks related to her medullary thyroid carcinoma, clarifying that, "in any circumstances in which the physician has a duty to warn of a genetically transferable disease, that duty will be satisfied by warning the patient."

PRIVACY
(with Thoughts on Security & How It Is Different)

I. New York Gen. Bus. Law § 899–aa: The Stop Hacks and Improve Electronic Data Security Act ("SHIELD Act")

Applies to any business that owns or licenses the "private information" of any New York resident. (GBL § 899-aa(2))

Safeguards "personal" and "private" information including biometric information.

Requires notification of breach of security systems.

Recent amendments – broadly impose the requirement that businesses of all types create plans for "data security protections."

But NOT genetic information or medical information – HIPAA Security Rule/HITECH Breach Notification Rule preempts the New York SHIELD Act's application to genetic/health data; however, note that there is a requirement to notify the New York

Attorney General of a breach under HIPAA/HITECH (if notification is required and provided to the U.S. Office for Civil Rights).

II. General Data Protection Regulation (GDPR)

- **a.** Many research studies are international and the ability to share information between the U.S. and Europe is a necessary component of those studies. GDPR Article 9 permits processing and cross-border transfer of genetic data with the explicit consent of the data subject. GDPR Article 89 allows for processing and transfer under certain circumstances if the genetic data is pseudonymized or de-identified.
- **b.** Anonymization vs. deidentification – Anonymization in Europe takes you out of the personalization realm.
- **c.** Value of data = long-term privacy protections.
- **d.** All of Us Project – Major U.S. longitudinal study > recent article in JAMA > social justice.
- **e.** Cannot deidentify tissue – anonymization is impossible.

GENETIC TESTING
(MEDICAL PROVIDER REQUIREMENTS, & LICENSING ISSUES)

I. Practice of Medicine

Understanding of the human genome and its functional significance has increased exponentially since the completion of the Human Genome Project (HGP) in 2003. The HGP fueled the discovery of more than 1,800 disease genes and paved the way for researchers to identify and test for genes suspected of causing inherited diseases. Currently, there are more than 1000 genetic tests for human diseases and conditions on the market. These tests can play an integral role in the delivery of health care by providing information that could potentially form the basis for profound life decisions, such as whether to undergo a prophylactic mastectomy, whether to terminate a pregnancy, or whether to take a particular drug or medication dose.

Traditionally, genetic tests were available only through healthcare providers. There is an increasing trend, however, for genetic test companies to market and sell their genetic test products directly to consumers. Direct-to-consumer (DTC) genetic testing provides a consumer with access to his or her genetic information without necessarily involving a doctor in the process.

Over the past year there has been much debate about the legality of DTC genetic testing. At least two states have sent “cease and desist” letters to companies, arguing that they were in violation of state law regulating the unlicensed practice of medicine. DTC genetic testing has become more controversial as the number of available single gene tests has

increased and particularly with the introduction of personal genome testing services, which provide risk assessment information for many diseases, traits, and conditions by genotyping thousands of gene loci in each individual. The variety of genetic information tested for complicates the issue of whether these companies are providing information for recreational purposes only or whether they are also providing medical diagnostic information. The pertinent legal issue relates to whether the services offered by DTC genetic testing companies fall within the scope of medical practice, and if so, to what extent must a physician or other health care provider be involved.

II. Licensing Issues – *e.g.*, Genetic Counselors

New York does not currently require licensure of genetic counselors, though bills have been introduced to enact such license requirements. Only about half of the states currently do. States that do require licensure of genetic counselors generally consider the scope of practice for a genetic counselor to include obtaining medical histories to determine genetic risk, ordering genetic tests, explaining the clinical implications of the same and more.

a. Education Law § 6530(11) states that "permitting, aiding or abetting an unlicensed person to perform activities requiring a license" constitutes unprofessional conduct.

b. 8 N.Y.C.R.R. § 29.1(b)(9): unprofessional conduct includes practicing or offering to practice beyond the scope permitted by law, or accepting and performing professional responsibilities which the licensee knows or has reason to know that he/she is not competent to perform, or performing without adequate supervision professional services which the licensee is authorized to perform only under the supervision of a licensed professional, except in an emergency situation where a person's life or health is in danger.

c. "The fact that an unlicensed person may be 'capable' of performing the task does not confer legal authorization for him/her to engage in an activity that is restricted to licensed persons. Licensed professionals, including physicians, who knowingly delegate a medical task to a person who is not legally authorized to perform such a task are guilty of professional misconduct." New York Office of the Professions, Practice Information, "Utilization of Unlicensed Persons in Clinical Settings and Private Medical Offices", April 2010, revised December 2019.

III. Medicare Exclusions from Coverage, the Ban on Preventive Care

> Social Security Act § 1862(a) (42 U.S.C. § 1395y(a).
>
> Medicare is prohibited from covering services unless a person has "signs, symptoms, complaints, or personal histories of disease"):
>
> No payment may be made under part A or part B for any expenses incurred for items or services –
>
> (1)(A) which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member …
>
> * * *
>
> tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute.

CONCLUSION

The proposed legislation (H.E.A.R.T. Act) does NOT include any requirements re:

- education about the basics, risks, benefits and limitations of genetic testing
- explanation of results
- coverage of screening and preventive services if someone tests positive for a genetic mutation
- the collection, use and transfer of the DNA
- data security protections and privacy by design
- banning the sharing of genetic data with third parties
- restrictions on marketing based on genetic data
- access, correction, retention and deletion rights
- the process for the disclosure of genetic data to law enforcement and transparency reporting
- accountability
- enforcement

RECOMMENDATIONS

Best Practices – Any legislation promoting genetic testing must include protocols for:

- Data collection: (taken from The Omnibus Transportation Employee Testing Act regulations for drug testing):
    - Use of tamperproof custody seals on specimen containers
    - Documentation of the chain of custody
    - Confirmatory tests
- Retention
- Use
- Disclosure
- Genetic Counseling
    - education about the basics, risks, benefits and limitations of genetic testing
    - explanation of results

Perhaps the most pressing issue is the ethical considerations discussed throughout the program, given that there are legally permissible uses and disclosures that do not necessarily have patient privacy (and confidentiality) in the forefront.

SUPPLEMENTAL MATERIALS

LINKS & RESOURCES

I. INTRODUCTION

a. Direct-to-Consumer Genomics: Harmful or Empowering? It is important to stress that genetic risk is not the same as genetic destiny
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6143574/

b. 23andMe Privacy Policy
https://www.23andme.com/about/privacy/

c. GEDmatch Privacy Policy
https://www.gedmatch.com/tos.htm

II. HEALTH LAWS, GUIDELINES & RELEVANT CASES

a. Genetic Information Non-Discrimination Act
http://ginahelp.org/GINAhelp.pdf

b. Clinical Laboratory Improvement Amendments
https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia

c. US Preventive Services Task Force (USPSTF) guidelines on BRCA/genetic testing
https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/brca-related-cancer-risk-assessment-genetic-counseling-and-genetic-testing1

III. PRIVACY

a. HIPAA PRIVACY RULE - WHAT EMPLOYERS NEED TO KNOW
https://www.twc.texas.gov/news/efte/hipaa_basics.html

b. Yale team finds way to protect genetic privacy in research
https://news.yale.edu/2020/11/12/yale-team-finds-way-protect-genetic-privacy-research

c. Data Sanitization To Reduce Private Information Leakage from Functional Genomics
https://www.cell.com/cell/fulltext/S0092-8674(20)31233-2

d. Article 9 and 89 of the General Data Protection Regulation
https://gdpr-info.eu/art-9-gdpr/
https://gdpr-info.eu/art-89-gdpr/

IV. GENETIC TESTING (MEDICAL PROVIDER REQUIREMENTS & LICENSING ISSUES)

a. Needles, Haystacks and Next-Generation Genetic Sequencing, 28 Health Matrix 217
https://scholarlycommons.law.case.edu/healthmatrix/vol28/iss1/8/

V. BRCA TESTING

a. National Breast Cancer Coalition, Genetic Testing of Healthy Women for Inherited Predisposition to Breast Cancer: Few Benefits, Many Limitations,
https://www.stopbreastcancer.org/information-center/positions-policies/genetic-testing-of-healthy-women-for-inherited-predisposition-to-breast-cancer-few-benefits-many-limitations/

b. Beyoncé's Dad Has a Mutation More African Americans Should Be Tested For, New York Times
https://www.nytimes.com/2019/10/16/opinion/beyonce-father-breast-cancer.html

c. Genetic Counseling and Genetic Testing
https://ww5.komen.org/BreastCancer/GeneMutationsampGeneticTesting.html

d. Genetic Testing for Breast Cancer – Who Should Be Tested for BRCA?
https://www.nationalbreastcancer.org/genetic-testing-for-breast-cancer

e. Your Jewish Genes
https://sharsheret.org/product/understanding-impact-genetics-genomics/

f. How Do I Tell My Children about My Cancer Gene?
https://sharsheret.org/product/how-do-i-tell-my-children-about-my-cancer-gene

g. Why You Should Get *BRCA* Tested
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