

Legal and Ethical Challenges of Direct to Consumer (DTC) Recreational Genetic Testing:

“It’s Just A Little Spit” or is it?

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Everybody knows... DTC Genetic Recreational Testing



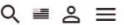
Thanks for the Mito*, Mom!

HAPPY MOTHER'S DAY



* Mito is short for "mitochondria," which are small structures inside of cells that have their own DNA. Since children (both boys and girls) only inherit their mitochondrial DNA from their mother, it can be used to trace a person's maternal line.

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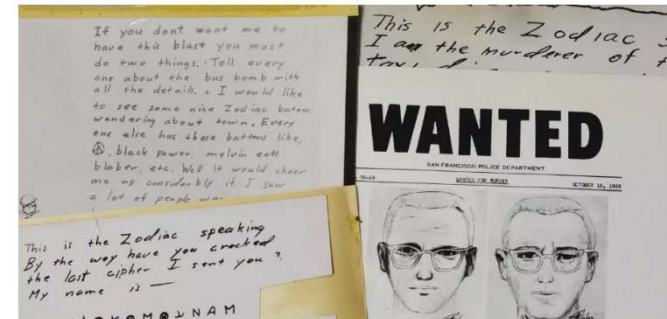
Police hunting Zodiac Killer deploy DNA technique used to identify suspected Golden State Killer

Detectives hopeful of breakthrough in notorious case after genealogy websites help to snare former police officer suspected of 12 murders

Chris Baynes | 5 days ago | 0 comments



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Traditional Clinical Tests

- Physician obtains informed consent and orders tests
- Physician or lab obtains sample
- Physician interprets lab results for patient
- Genetic counseling available

DTC Recreational Genetic Tests



- No physician involvement.
- Tests marketed directly to consumers via print ads, TV or internet
- Consumers provide a DNA sample from home
 - by spitting into a vial (eg. Ancestry DNA and 23 and Me) or
 - a cheek swab (eg. Family Tree DNA and Living DNA)
- Results provided directly to consumer by mail or internet without physician order or interpretation

What is DTC Genetic Testing?

Diversity of DTC Recreational Genetic Tests

DTC recreational genetic tests range from raw sequencing or genotyping services without interpretation to reports on:

- Heritage, ethnicity, ancestry, geography
- Locating long lost relatives, siblings, parents
- Nutrition, Nutrigenics and Supplements
- Pharmacogenetics
- Child talent
- Lifestyle
- Sports acumen, superhero traits
- Dating compatibility
- Paternity
- Disease Prediction, Carrier Testing
- Race



The Numbers are Huge

“The number of people who have had their DNA analyzed with direct-to-consumer genetic genealogy tests more than doubled during 2017 and now exceeds 12 million, according to industry estimates....Ancestry.com... announced that it has tested more than seven million people, including 2 million during the last four months of 2017... 23 and me has tested more than three million, followed by MyHeritage and FamilyTreeDNA.”

Antonio Regalado, 2017 was the year consumer DNA testing blew up MIT Technology Review (2018), <https://www.technologyreview.com/s/610233/2017-was-the-year-consumer-dna-testing-blew-up/> (last visited May 15, 2018).

Meaning....

Approximately 1 in 25 adult Americans have access to their personal genetic data.

It's a Lucrative Market....



- DTC genetic testing market was \$99 million in 2017; projected to reach \$233.7 million by 2018 and to exceed \$310 million in 2022

Source: Kalorama Information

- In 2015, Genetech entered into a deal with 23andMe for approximately 60 million dollars for access to 23andMe's database.

Matthew Herper, SURPRISE! WITH \$60 MILLION GENENTECH DEAL, 23ANDME HAS A BUSINESS PLAN, FORBES(2015)<https://www.forbes.com/sites/matthewherper/2015/01/06/surprise-with-60-million-genentech-deal-23andme-has-a-business-plan/> (last visited May 15, 2018).

- “A discounted kit from 23andMe for health and ancestry testing was in the top five best-selling items from Amazon on Black Friday during the 2017 holiday shopping season, just behind a Wi-Fi smart plug and the Instant Pot pressure cooker.”

FDA, Congress Return Attention to Direct-to-Consumer Genetic Testing, AACC, <https://www.aacc.org/publications/cln/articles/2018/janfeb/fda-congress-return-attention-to-direct-to-consumer-genetic-testing> (last visited May 15, 2018).

Current State and Federal Law is a Patchwork

- Privacy
- Non Discrimination Laws
- Consumer Protection
- Medical Device Laws
- Lab Regulation
- Contract Law
- Data Security
- Practice of Medicine?



DTC data vs Medical data

- Justification
- Cost vs benefits
- Protection

Traditional genetic tests

- Fiduciary relationship between doctor and patient
- Results kept confidential subject to state and federal confidentiality laws – HIPAA, CA Civil Code 56 et. al.
- Clinical tests must take place in CLIA certified lab

DTC genetic tests

- Terms of service based on commercial online browse wrap or shrink wrap agreement
- Often includes social marketing component
- Participants encouraged to upload information to public sites to find relatives, prepare a family tree
 - 23andMe offers access to DNA Relatives tool to be used to connect to other users to find relatives
 - Ancestry helps link DNA to create family tree

DTC Genetic Tests Challenge Traditional Regulatory Schemes

HIPAA

HIPAA (Health Insurance Portability and Accountability Act of 1996)

- Minimum nationwide privacy standards for personally identifiable health care information (PHI)
- Must advise consumers of use and disclosure of PHI; Use of PHI for marketing requires written consent
- Requirements for storage, access, replication of data, breach notification requirements, workforce training

HIPAA Does Not Apply

HIPAA applies to information provided to, created by, or maintained by “covered entities” e.g., health care clearinghouses, health plans and health care providers

DTC companies are not “covered entities”

HIPAA does not apply to use or sale of de-identified data

Privacy and Confidentiality

GINA

GINA- Federal Genetic Information Nondiscrimination Act of 2008

- Applies to health insurance and employment

Limitations

- Does not apply to disability insurance, life insurance, long term insurance, housing, wellness programs (????)
- Only protects individual who has not been diagnosed with a disease or disease is not “manifest”
- Doesn't limit commercial use, targeted ads or use of aggregated data

Non Discrimination

DNA Sudoku

- No DNA data is completely anonymous; re-identification is always possible

Paul Ohm, Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization, 57 UCLA Law Review 1701m 1704-6 (2010)

- Can identity names and identities of genomic research participants in de-identified data bank by cross-referencing their data with publicly available information

Yaniv Ehrlich, Whitehead Institute Study 2013, Cambridge, Mass.

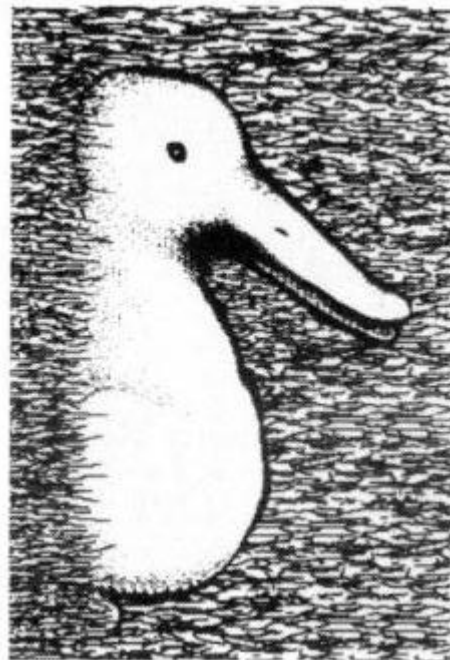
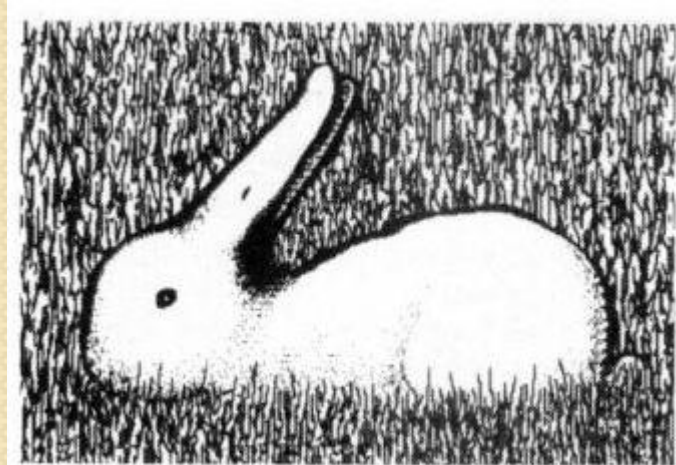
- Prof. Sweeney, Dir. Harvard Data Privacy Lab, showed 87% of all Americans could be uniquely identified using only three items: zipcode, birthdate and sex.

Latanya Sweeney, 2000, LIDAP-WP4, Uniqueness of Simple Demographics in the U.S. Population (Laboratory for Int'l Data Privacy)

A game?

What are the rules?

Game? Rabbit or duck



DTC Calls For A New Regulatory Paradigm

“When it comes to protecting consumers’ privacy from at-home DNA test kit services, the federal government is behind. ...We don't want to impede research but we also don't want to empower those looking to make a fast buck or an unfair judgement off your genetic information....There is no point to learning about your family tree if your privacy gets chopped down in the process...The last gift any of us want to give away this holiday season is our most personal and sensitive information.”

Sen. Chuck Schumer (D-New York), November 26, 2017 asks FTC to investigate privacy policies of DTC at-home DNA test companies

Unique Perpetual familial line-up

- Convergence of emerging technologies :
Same issue with facial recognition

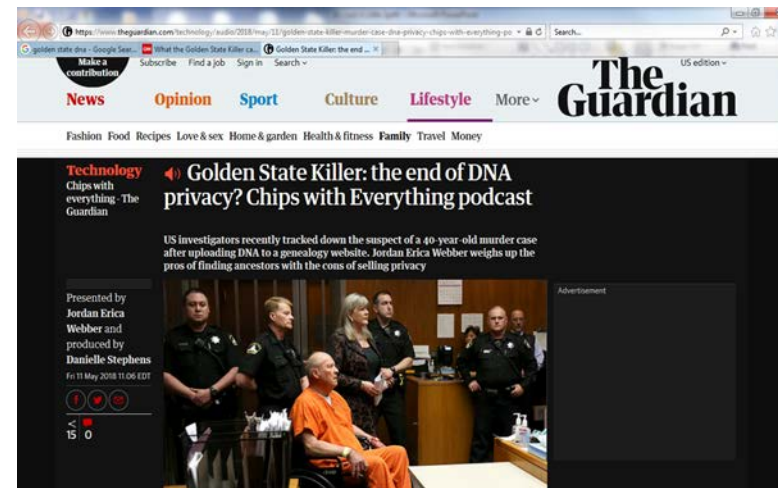
<https://www.perpetuallineup.org/>

- But concerns your whole family



Identification of Golden State Killer

- Law enforcement used GED match, free genealogy website where consumers upload data from any commercial company to find relatives
- Investigators took crime scene DNA profile, identified 100+ matches as distant relatives, created fake profile and family tree, surveilled distant relative compared DNA sample from distant relative to crime scene DNA
 - Can only run sample once a year on federal data base; no limits on running samples on public genealogy sites
 - DNA Doe Project – used public websites to locate Marcia King murdered in 1981 using degraded DNA sample matched to first cousin once removed on GED Match



Potential Solutions

- Contracts that are shorter, clearer; highlight material terms and require opt in to particular terms
 - Under HIPAA, for example, PHI used for marketing requires separate consent
- Use of standardized templates, similar to Medi-Gap, mortgage documents-specific terms must be included, allowing consumers to compare products
 - Terms would include: privacy; ownership of samples, data and test results; storage and destruction; sale, use and disclosure, effect on related parties
- Electronic interactive model of consent
- Examination of marketing ads, claims, validity of test results
- Consumer Privacy Ombudsman – used in bankruptcy
- Stronger data security measures



Thank you

Questions?

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