Privacy Regulation and the Digital Economy

Catherine Tucker

Who am I?

- Someone who takes econometric approaches for ‘policy evaluation’ developed in labor economics and applies them to privacy policies and regulation

Prior Work: Documenting negative effects from privacy regulation

- Health privacy regulation that suppresses transfer of medical records suppresses adoption of digital health technologies (around 20%).
- Laws promoting encryption don’t stop data breaches - instead they seem to encourage carelessness.
- Privacy regulation in Europe reduces ad effecveness (around 66%)s.

Current Work: Trying to understand what works and doesn’t work

- Today I will focus on genetic testing as a ‘case study’ to understand the broader issues
- Genetic digital is an ideal case study as plenty of experimental regulatory approaches and meaningful consequences of privacy breaches

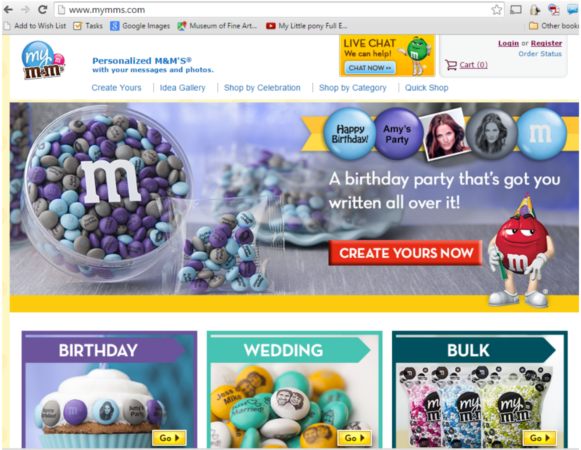
Research Question: Joint work with Amalia Miller

What kinds of privacy protections encourage and what kinds of privacy protections discourage the spread of personalized medicine?

What is Personalized Medicine?

- Personalized medicine is about making the treatment as individualized as the disease
- Medical decisions, practices, and products being tailored to the individual patient
- Craig Venter (Institute for Genomic Research) ‘most drugs only work on 30% of the population due to differences in genetics.’

Isn't that just like..?



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with your messages and photos.

A birthday party that's got you written all over it!

No - personalized medicine may actually imply less choice

- Patient’s genetic makeup rather
- Involves identifying genetic and genomic information that allows accurate predictions to be made about a person’s susceptibility of developing disease, the course of disease, and its response to treatment.

Example: BRCA1 mutation

s

Where are we going with this?

- Exploit changes in state privacy regulation over last decade
- See how these affect consumer decisions to have a genetic test
- Straightforward methodology

Who has done a 23andme test?

The Human Genome Project completed in 2003

- Why don’t we all do genetic tests?
  - Clinician education
  - Reimbursement and efficacy
  - Patient privacy concerns
- We focus on the latter (most novel)

Deep Privacy Concerns

Arguments for Genetic Exceptionalism

- Pro: Genetic information as uniquely powerful and poses special threats to privacy and discrimination that mandate dedicated and higher levels of legal protection
  - Irrevocability of information
  - Implications for family members not just individual being tested
- Con: Genetic information is just one of a number of sources of personal health and medical information, and there is no need for any higher or special protections
  - For example, is Genetic information more ‘special’ than the results of a positive HIV test?
- Arguments clouded by unpredictability of technological progress

Three general approaches to privacy which have been echoed in state approaches to genetic privacy regulation

- Informed consent (EU privacy directive of 1996)
- Regulating data use (US approach?)
- Establishing property rights over data (Coasian)

Outline

- What is Personalized Medicine?
- Frameworks for thinking about Privacy Protection
- Data and Institutional Background
  - Privacy Laws
  - Genetic Testing Data
- Econometric Analysis
- Summing Up

State Law Timing Variation

State	Years of Genetic Privacy Changes
Alaska	2004
Arkansas	2001
Arizona	2002
Colorado	2002
DC	2005
Idaho	2006
Maine	2009
Massachusetts	2000
Michigan	2000
Minnesota	2001 and 2006
Nebraska	2001
Oklahoma	2010
Oregon	2002 and 2003
Pennsylvania	2001
South Dakota	2001
Utah	2002
Virginia	2002
Washington	2004
Wyoming	2003

We use federally collected data

- National Health Interview Surveys (NHIS) distributed by the National Center for Health Statistics, part of the Centers for Disease Control and Prevention (CDC).
- In 2000, 2005, 2010 they asked questions about genetic testing.
  - 32,374 survey responses in 2000
  - 31,428 survey responses in 2005
  - 27,157 survey responses in 2010

Pros and Cons of Data Sample

- Yeah: Representative, large, national sample
- But: Under lock and key

Pros and Cons of Data Sample

- Yeah: Dependent variable is for medically indicated testing for predictors of breast, ovarian cancer. That is testing which allows interventions that reduce morbidity or mortality.
- But: Dependent variable has few positive observations
  - In 2000, 0.4% of respondents responded positively.
  - In 2010, 0.6% of respondents responded positively.

Pros and Cons of Data Sample

- Yeah: Test conducted in hospitals
- But: Not clear how this generalizes to 23andme.com etc

Other Controls

- Demographics from NHIS: Age, Female, White, Black, Family Cancer, Private Insurance, No Insurance
- State characteristics: Uninsured, Private Insurance, Medicare, Medicaid, GDP

Table : Genetic Testing Information and State Laws: Summary Statistics

	Mean	Std. Dev.	Obs.
Genetic Test	0.0054	0.073	81543
Heard of Genetic Testing for Cancer Risk	0.43	0.50	81543
Age	45.3	17.5	81543
Female	0.52	0.50	81543
White	0.82	0.39	81543
Black	0.11	0.32	81543
Private Insurance	0.68	0.47	81543
No Insurance	0.17	0.37	81543
Family Cancer	0.38	0.48	81543
Ever Had Testable Cancer Diagnosis	0.019	0.14	81543
Genetic Consent Law	0.29	0.45	81543
Genetic Anti-Discrimination Law	0.89	0.31	81543
Genetic Redisclosure Law	0.52	0.50	81543
Health Privacy Disclosure Law	0.80	0.40	81543
HIV Test	0.35	0.48	81543
Flu Shot	0.23	0.42	81543

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We estimate a simple model

We model the genetic testing rate $\mathit{GeneticTest}_{jt}$ for an individual i in state j in year t

$$\begin{aligned} \mathit{GeneticTest}_{ijt} = {} & \beta_1 \mathit{GeneticPrivacyPolicy}_{jt} + \beta_2 \mathit{HealthPrivacyPolicy}_{jt} \\ & + \alpha \mathit{Demographics}_{ijt} + \theta \mathit{StateCharacteristics}_{jt} \\ & + \gamma_j + \delta_t + \epsilon_{ijt} \end{aligned} \tag{1}$$

- Linear probability model
- Robust standard errors clustered at state level

Table : Initial Results

	(1) Genetic Test	(2) Genetic Test	(3) Genetic Test	(4) Genetic Test	(5) Genetic Test
Genetic Consent Law	-0.0039**				-0.0045***
Genetic Anti-Discrimination Law		0.0010			0.00084
Genetic Redisclosure Law			0.000057		0.0037**
Health Privacy Disclosure Law				0.0033***	0.0030***
Age	0.0000078	0.0000077	0.0000076	0.0000082	0.0000082
Female	0.0027***	0.0027***	0.0027***	0.0027***	0.0027***
White	0.00098	0.0010	0.00100	0.00094	0.00095
Black	0.0024**	0.0024**	0.0024**	0.0024**	0.0024**
Family Cancer	0.0051***	0.0051***	0.0051***	0.0051***	0.0051***
Private Insurance	-0.0011	-0.0011	-0.0011	-0.0011	-0.0011
No Insurance	-0.0020*	-0.0020*	-0.0020*	-0.0020*	-0.0020*
State Uninsured	0.000086	-0.00022	-0.00017	-0.000089	-0.000020
State Private Insurance	-0.000053	-0.00030	-0.00025	-0.00021	-0.00019
State Medicare	0.00034	0.00020	0.00021	0.00020	0.00034
State Medicaid	0.00033	0.000084	0.00013	0.00017	0.00026
State GDP (000)	0.00022	0.00026	0.00026	0.00026	0.00020
State Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
N	81543	81543	81543	81543	81543
r2	0.0032	0.0031	0.0031	0.0032	0.0033

Table : Main Specification

	Genetic Test
Genetic Consent Law	-0.0045***
Genetic Anti-Discrimination Law	0.00084
Genetic Redisclosure Law	0.0037**
Health Privacy Disclosure Law	0.0030***
Individual and State Controls	Yes
State Fixed Effects	Yes
Year Fixed Effects	Yes
N	81543

What about the controls?

- Female, black, family cancer positively affect decision
- No insurance (weakly) negatively affects decision
- State characteristics, age, private insurance aren’t significant

Robustness checks

- Controls
- Federal Law
- Functional Form

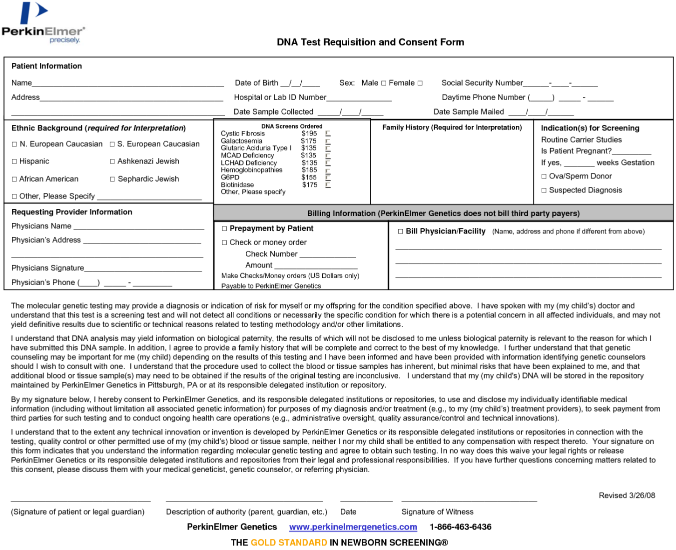
Table : Robustness Checks

	Controls (1) Genetic Test	(2) Genetic Test	GINA (3) Genetic Test	Probit (4) Genetic Test
Genetic Consent Law	-0.0038***	-0.0045***	-0.0046***	-0.33***
Genetic Anti-Discrimination Law	0.00091	0.00083		0.00014
Genetic Redisclosure Law	0.0032**	0.0037**	0.0047**	0.39**
Anti-Discrimination (GINA)			-0.0020	
Age 35-50		-0.00015		
Age $>$ 50		0.00054		
Female		0.0027***	0.0027***	0.19***
White		0.00093	0.00093	0.075
Black		0.0024**	0.0024**	0.18**
Family Cancer		0.0051***	0.0051***	0.32***
Private Insurance		-0.0010	-0.0011	-0.068
No Insurance		-0.0019*	-0.0020*	-0.14**
State Uninsured		-0.000021	0.000095	0.036
State Private Insurance		-0.00019	-0.000062	0.0051
State Medicare		0.00034	0.00043	0.033
State Medicaid		0.00026	0.00035	0.029
State GDP (000)		0.00020	0.00019	0.013
Age			0.0000081	0.00080
State Fixed Effects	Yes	Yes	Yes	Yes
Health Privacy Laws	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes
N	81543	81543	81543	80817
r2	0.0015	0.0033	0.0033	

What is going on?

- Consent - highlights powerlessness?
- Discrimination laws - not effective?
- Data ownership - Coasian solution to externalities?
    - Or the illusion of control?

Figure : Pure consent



PerkinElmer
precisely.

DNA Test Requisition and Consent Form

Patient Information

Name______________________________ Date of Birth __/__/____ Sex: Male ☐ Female ☐ Social Security Number______-____-______

Address______________________________ Hospital or Lab ID Number______________ Daytime Phone Number (_____) _____ - ______

______________________________ Date Sample Collected _____/____/_____ Date Sample Mailed ____/____/______

Ethnic Background (*required for Interpretation*)

☐ N. European Caucasian ☐ S. European Caucasian

☐ Hispanic ☐ Ashkenazi Jewish

☐ African American ☐ Sephardic Jewish

☐ Other, Please Specify ______________________

DNA Screens Ordered

Cystic Fibrosis	$195	☐
Galactosemia	$175	☐
Glutaric Aciduria Type I	$135	☐
MCAD Deficiency	$135	☐
LCHAD Deficiency	$135	☐
Hemoglobinopathies	$185	☐
G6PD	$155	☐
Biotinidase	$175	☐
Other, Please specify		

Family History (Required for Interpretation)

Indication(s) for Screening

Routine Carrier Studies

Is Patient Pregnant?_________

If yes, _______ weeks Gestation

☐ Ova/Sperm Donor

☐ Suspected Diagnosis

Requesting Provider Information

Physicians Name ______________________

Physician's Address ______________________

____

Physicians Signature______________________

Physician's Phone (____) _____ - _________

Billing Information (PerkinElmer Genetics does not bill third party payers)

☐ **Prepayment by Patient**

☐ Check or money order

Check Number ____________

Amount ________________

Make Checks/Money orders (US Dollars only)
Payable to PerkinElmer Genetics

☐ **Bill Physician/Facility** (Name, address and phone if different from above)

The molecular genetic testing may provide a diagnosis or indication of risk for myself or my offspring for the condition specified above. I have spoken with my (my child's) doctor and understand that this test is a screening test and will not detect all conditions or necessarily the specific condition for which there is a potential concern in all affected individuals, and may not yield definitive results due to scientific or technical reasons related to testing methodology and/or other limitations.

I understand that DNA analysis may yield information on biological paternity, the results of which will not be disclosed to me unless biological paternity is relevant to the reason for which I have submitted this DNA sample. In addition, I agree to provide a family history that will be complete and correct to the best of my knowledge. I further understand that that genetic counseling may be important for me (my child) depending on the results of this testing and I have been informed and have been provided with information identifying genetic counselors should I wish to consult with one. I understand that the procedure used to collect the blood or tissue samples has inherent, but minimal risks that have been explained to me, and that additional blood or tissue sample(s) may need to be obtained if the results of the original testing are inconclusive. I understand that my (my child's) DNA will be stored in the repository maintained by PerkinElmer Genetics in Pittsburgh, PA or at its responsible delegated institution or repository.

By my signature below, I hereby consent to PerkinElmer Genetics, and its responsible delegated institutions or repositories, to use and disclose my individually identifiable medical information (including without limitation all associated genetic information) for purposes of my diagnosis and/or treatment (e.g., to my (my child's) treatment providers), to seek payment from third parties for such testing and to conduct ongoing health care operations (e.g., administrative oversight, quality assurance/control and technical innovations).

I understand that to the extent any technical innovation or invention is developed by PerkinElmer Genetics or its responsible delegated institutions or repositories in connection with the testing, quality control or other permitted use of my (my child's) blood or tissue sample, neither I nor my child shall be entitled to any compensation with respect thereto. Your signature on this form indicates that you understand the information regarding molecular genetic testing and agree to obtain such testing. In no way does this waive your legal rights or release PerkinElmer Genetics or its responsible delegated institutions and repositories from their legal and professional responsibilities. If you have further questions concerning matters related to this consent, please discuss them with your medical geneticist, genetic counselor, or referring physician.

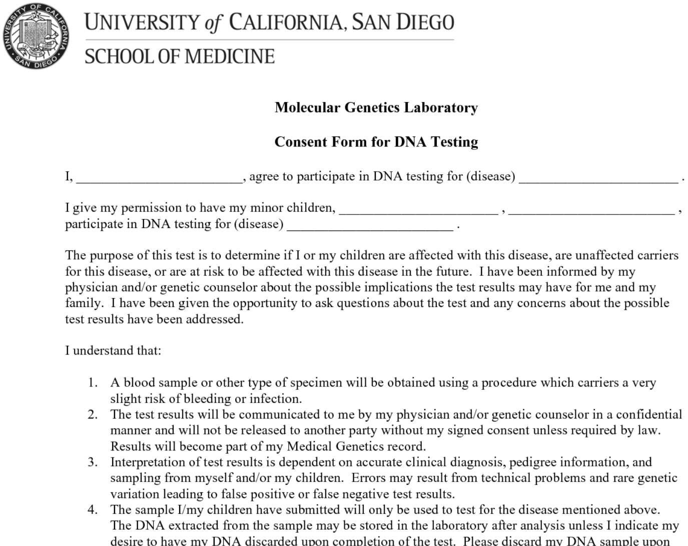
Revised 3/26/08

(Signature of patient or legal guardian) Description of authority (parent, guardian, etc.) Date Signature of Witness

PerkinElmer Genetics www.perkinelmergenetics.com **1-866-463-6436**

THE GOLD STANDARD IN NEWBORN SCREENING®

Figure : Consent with Property Rights



UNIVERSITY *of* CALIFORNIA, SAN DIEGO
SCHOOL OF MEDICINE

Molecular Genetics Laboratory

Consent Form for DNA Testing

I, ________________________, agree to participate in DNA testing for (disease) ________________________ .

I give my permission to have my minor children, ________________________ , ________________________ , participate in DNA testing for (disease) ________________________ .

The purpose of this test is to determine if I or my children are affected with this disease, are unaffected carriers for this disease, or are at risk to be affected with this disease in the future. I have been informed by my physician and/or genetic counselor about the possible implications the test results may have for me and my family. I have been given the opportunity to ask questions about the test and any concerns about the possible test results have been addressed.

I understand that:

1. A blood sample or other type of specimen will be obtained using a procedure which carriers a very slight risk of bleeding or infection.
2. The test results will be communicated to me by my physician and/or genetic counselor in a confidential manner and will not be released to another party without my signed consent unless required by law. Results will become part of my Medical Genetics record.
3. Interpretation of test results is dependent on accurate clinical diagnosis, pedigree information, and sampling from myself and/or my children. Errors may result from technical problems and rare genetic variation leading to false positive or false negative test results.
4. The sample I/my children have submitted will only be used to test for the disease mentioned above. The DNA extracted from the sample may be stored in the laboratory after analysis unless I indicate my desire to have my DNA discarded upon completion of the test. Please discard my DNA sample upon

What is going on?

- Consumer response to privacy protection?
- Or changes in testing availability?

Genetic Testing Availability at Hospitals

	(1) Genetic Hospital b	(2) Genetic System b
Genetic Consent Law	-0.0070*	-0.016***
Genetic Anti-Discrimination Law	0.024	0.031
Genetic Redisclosure Law	-0.0051	-0.0029
Health Privacy Disclosure Law	0.042***	0.059***
Hospital Fixed Effects	Yes	Yes
Year Fixed Effects	Yes	Yes
Hospital Controls	Yes	Yes
Observations	36717	36717
Log-Likelihood	20832.4	15130.5

Variation in Genetic Privacy Laws

- Are laws stricter in states where genetic discrimination is a greater concern?
  - No: not related to GINA cases
- Are laws related to health privacy tastes?
- Are laws related to tastes for preventive care?
  - No: placebo checks on HIV testing and flu shots

Table : Placebo Checks

	HIV Test (1)	Flu Shot (2)
Genetic Consent Law	-0.023	0.020
Genetic Anti-Discrimination Law	-0.020	0.011
Genetic Redisclosure Law	0.036	0.016
Health Privacy Disclosure Law	0.024**	-0.0067
State Fixed Effects	Yes	Yes
Year Fixed Effects	Yes	Yes
N	81543	81543

Stratification

- Try and investigate mechanism
- By studying variation in individual risk
    - High risk of detrimental information
    - Low risk of incremental information

Stratification

- Whether Asymmetric Information matters
  - Size of effects for individuals with higher than average cancer risk
  - No effects (insignificant and inconsistent sign) for those with past cancer diagnosis
- By demand for privacy
  - Larger effects for sub-sample of ‘privacy-protecting’ individuals (hide HIV testing status or full name at testing)
  - Different responses to laws for older and younger individuals

First study of how *different* types of privacy protection drive individual decision-making

- We find that when states give consumers more control over how their private information is shared:
    - Genetic testing increases
    - Particularly for those who are more worried about ‘bad news’
- We find that informed consent deters consumers from testing
    - Speculatively - increases feeling of lack of control
- Data usage policies have little effect
    - Good or bad news depending on how you look at it

There are of course limitations

1. Despite falsification checks may be unobserved heterogeneity
2. No information about enforcement or interpretation
3. Studying early stage of diffusion. Other issues emerging

Where to now? New Policy Issues Emerging

- In general: How do we regulate for future selves rather than simply the technology?
- How do we regulate for a digital future characterized by uncertainty?

Thank you! cetucker@mit.edu