

Engagement from the Trenches & Benches

*Individuals and participation in research:
sharing, controlling, collaborating*

Greg Biggers

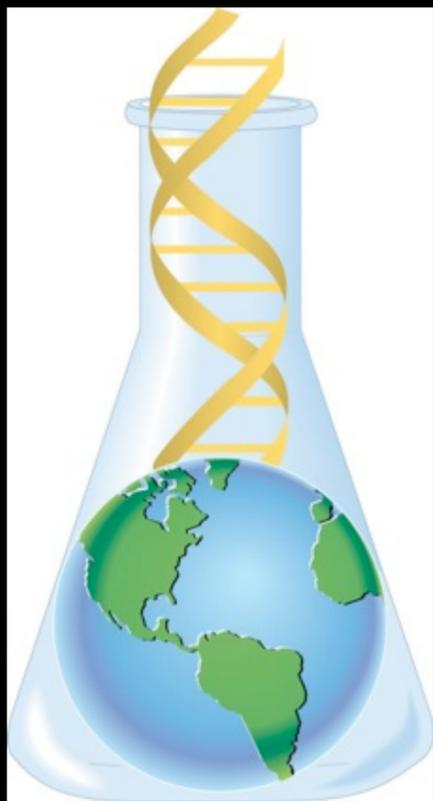
greg@genomera.com



Network of over 10,000 organizations

1200 advocacy organizations

**Devoted to improving health through collaboration,
organizational culture, and openness**



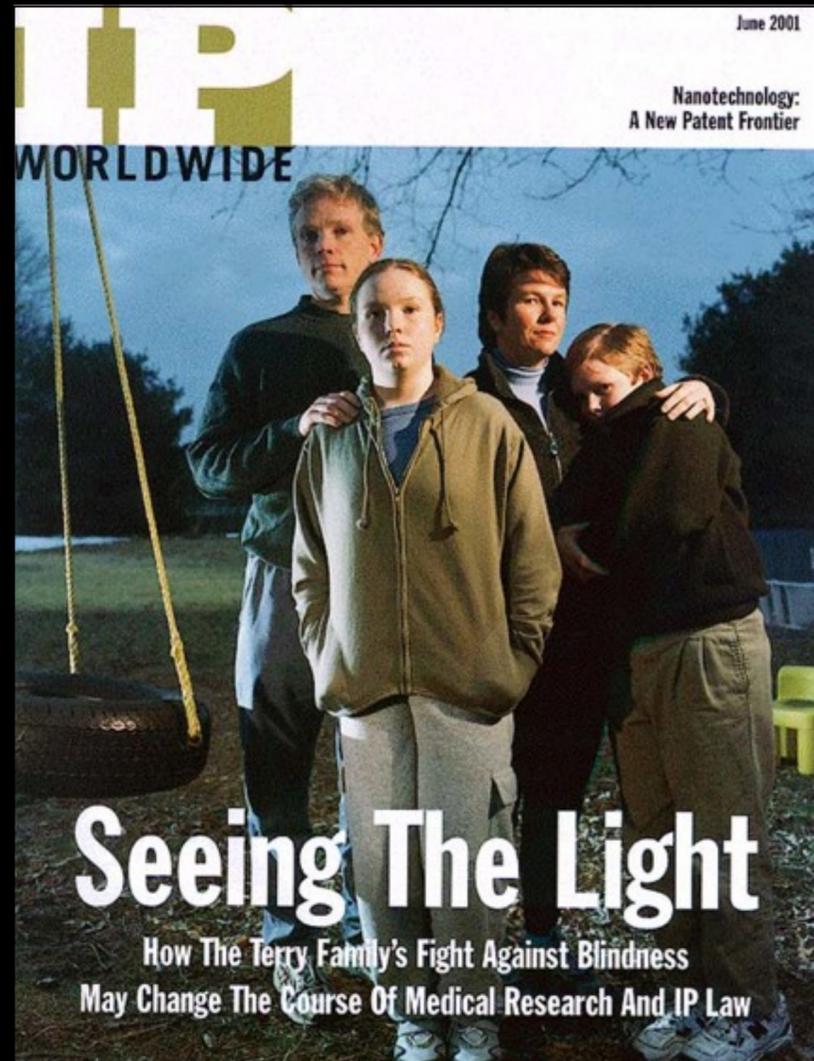
BioBank

Testing

Clinical
Diagnostic Test
Development via
FDA & CLIA
Regulatory
Strategies

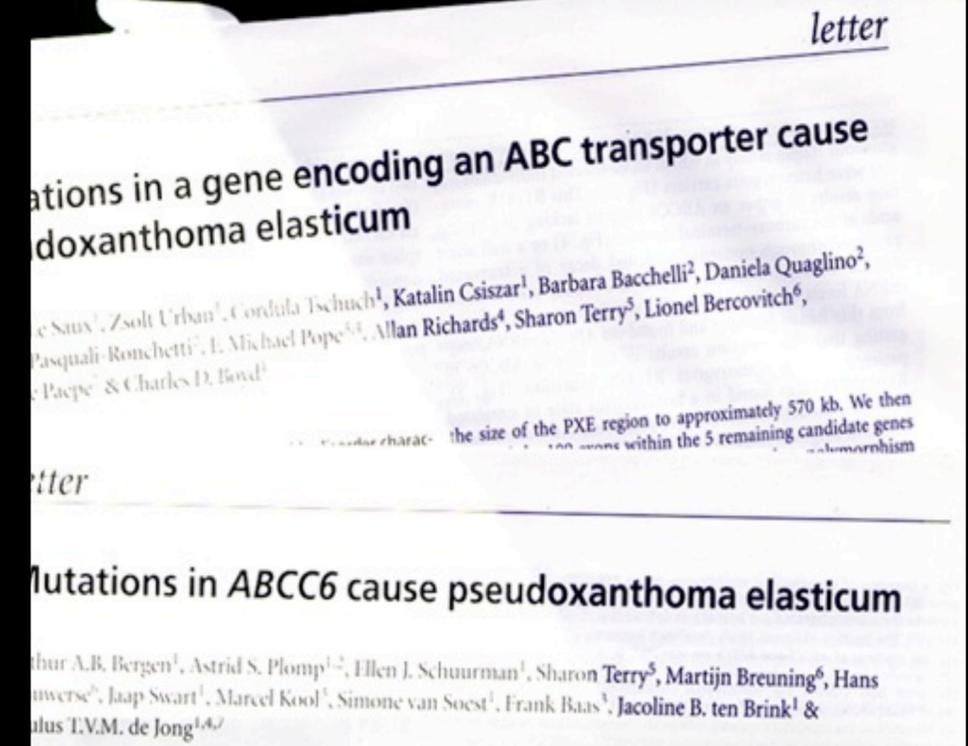


Gene Discovery



Licensing & Intellectual
Property Management

nature Genetics



Human Clinical Trials

Drug Screening & Development Approaches

Therapeutics
— Small Molecules
— Nonsense mutants



“Because success will depend on earning the public’s trust, scientists must also trust the public.”

A participant’s involvement in research doesn’t have to end the day a sample is collected.

Treat donors as partners in biobank research

Proposed rules to protect research subjects will impede progress, say **Krishanu Saha** and **J. Benjamin Hurlbut**. Instead, give donors more say in how samples are used.

26 October. This is an opportune moment to reconsider the role and rights of participants in biomedical research.

Current practices in managing biobanks tend to see the public as little more than a resource for mining data and materials, and as a potential source of resistance. Participants provide information or tissues with little or no knowledge of the researchers’ priorities, goals or expected outcomes. Barriers are erected.

Materials and information are ‘de-identified’ to protect people’s identities. Participants are told how their data will be used or what the research produces.

As they stand, the proposed changes to the Common Rule risk further widening the divide between researchers and donors.

The changes encourage blanket consent, asking donors to opt-in to virtually everything, with opt-out checkboxes for predefined categories of research that might pose “unique concerns”, such as creating a cell line⁵. Scientists could use the samples for additional projects without seeking re-consent. The changes are intended to ensure that the scope of authorized research is clear to all parties, thereby circumventing the ambiguities that were at the heart of the Havasupai case. But this is achieved by telling donors next to nothing about how and for what purpose their donation will be used. Although this may reduce administrative complexity, we believe that it will decrease, not increase, public involvement in biobanks and fail to deliver on its ethical aim of better protecting participants’ rights.

Most people prefer to have a say in how their donations are used. In a study in which donors were asked whether they would

PXE international

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There is new syndicated content from

PXE Research

PXE International has spent \$1.3 million on an epidemiological study as well as supported genetic test is now available from GeneDx, one another and with PXE International. This is faster. For us, it allows investigation of the

Read about our recent agenda setting meeting

Read the summary article published in the **Progress in Diagnostics and Research Towards Treatment Summary of the 2010 PXE International Research Meeting.**

How Can PXEers Participate in Research?

Complete the Online Survey

PXE International is recruiting now for a new epidemiological study. The purpose of this study is to update old information, gather new information, and use those findings to further PXE Research and our understanding of the condition. We are asking PXEers worldwide to **be a part of this study by filling out an online**

Trust It or Trash It?

Is this

I am interested in participating!



Genetic Alliance Registry & BioBank

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Solutions - **NOW!**

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Have you seen our new weekly tips series tailored for advocacy organizations interested in registries and biobanks?

[Click here to view this week's tip](#)

Genetic Alliance Registry and BioBank is a centralized, clinical data registry and sample repository that enables translational research. Founded in 2003, this cooperative venture provides shared infrastructure and customized solutions for disease advocacy organizations to lead sophisticated research initiatives.

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Genetic Alliance Registry and BioBank is a program of Genetic Alliance. For more information about Genetic Alliance, please visit www.geneticalliance.org.

What's New

- [Executive Summary](#)
- [Private Access and Genetic Alliance Announce Strategic Partnership to Accelerate Medical Research While Protecting Privacy](#)
- [Advocacy Gets Technical: Genetic Alliance Biobank and Gene Logic Join Forces](#)
- [Genetic Alliance Registry and BioBank Launched](#)

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Genetic Alliance Registry & BioBank

Infrastructures for
Solutions - **NOW!**

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Home

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Genetic Alliance Registry and BioBank is a program of Genetic Alliance. For more information about Genetic Alliance, please visit www.geneticalliance.org.

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Genetic Alliance Registry & BioBank

- *Tissue samples + clinical records*
- *Cross-Disease Trust Community*
- *Based on Local (Global) Community*
- *Trusted Agent*

PERSPECTIVES

SCIENCE AND SOCIETY

From patients to partners: participant-centric initiatives in biomedical research

Jane Kaye, Liam Curren, Nick Anderson, Kelly Edwards, Stephanie M. Fullerton, Nadja Kanellopoulou, David Lund, Daniel G. MacArthur, Deborah Mascalzoni, James Shepherd, Patrick L. Taylor, Sharon F. Terry and Stefan F. Winter

Abstract | Advances in computing technology and bioinformatics mean that medical research is increasingly characterized by large international consortia of researchers that are reliant on large data sets and biobanks. These trends raise a number of challenges for obtaining consent, protecting participant privacy concerns and maintaining public trust. Participant-centred initiatives (PCIs) use social media technologies to address these immediate concerns, but they also

to proceed. Those who agree to take part in any form of biomedical research are required to give their consent to the use of any donated samples and associated data in the given study before the research commences, and this consent must be informed and voluntary. Informed consent is the norm, but the particular kind of consent — from broad to explicit — that is considered to be appropriate depends on the study. The requirement for consent is reinforced by a number of procedures, practices, policies and legal requirements. For example, approval to carry out biomedical research projects with human subjects must be granted by institutional review boards (IRBs) in the United States. In general, research participants are taken through a consent process that involves ‘one-on-one’ discussions with appropriately trained health professionals and ends with the signing of a paper-based

n = they

n = me

n = we

nature medicine



Chemokine receptor casts NETs
Post-exposure protection against Ebola
War zone medicine

Personalized investigation

Interested parties must first pass that gauges comprehension of...
y disclosing...
ter which...
ir genomes...
are details...
phenotypic...
including...
ations, diet...
Despite continued doubts a...
have sent away tubes full o...
number of early adopters a...
can be. **Elie Dolgin** reports

Three years ago, the DNA technol...
llumina teamed up with the comp...
to develop genotyping chips fo...
direct-to-consumer gene test kits...
the partnership, Illumina emplo...
rare opportunity to order discount...
for just \$249—a low cost compare...
price tag at the time.

Raymond McCauley, a senior bio...
at Illumina's Northern Californi...
Hayward, jumped on the opportu...
about his family's DNA, order...
himself, his partner, his twin so...
other members of his family. "It's...
instead of Christmas sweaters," M...
The three generations of genetic...
through the tests refuted the fami...
McCauley's grandmother was ha...
It also helped the family find dis...
who had posted their details onlin...
importantly, says McCauley, learn...
genetic predispositions to diabetes

...that Genomera's model is...
democratic. 23andMe's mo...
to some exte...
company is...
makes the...
which pro...
pursuing," h...
providers, su...
California-b...
which is...
academic...
using per...
testing as a...
discovery t...
even less pa...
Genomera...
says, "the...
be different...
will decide...
pursuing"

Biggers e...
With Genom...
locus of co...
and distributed. There a...
investigators and subjects

Greg Biggers

“The locus of control is different and distributed.”
— Greg Biggers

W I F E
C O N T R I B U T O R

COVER STORY
Max Butler, a \$100-an-hour online-security expert, had an alter ego: "Iceman". Using this identity, Butler crowned himself king of a global online fraud network.

NATURE MEDICINE VOLUME 16 | NUMBER 9 | SEPTEMBER 2010



Raymond McCauley, the citizen scientist using a map of his DNA to tailor-make his healthcare

All Studies

Create New Study

Processing Reality: Impact of Dopamine Modulation on Memory Filtering

To determine if genetic variants related to dopamine processing in the brain impact the processing of memories according to their relation with ongoing reality

Variants: rs1076560, rs1800497, rs27048, rs27072, rs40184, rs4680

Tags: dopamine, memory

Organizers



Vitamin B-9 and MTHFR variants IN PROGRESS

Do common variations in the MTHFR gene keep vitamin B from working? Can a group of ordinary people come together to find out? And maybe find a

What would you like to contribute?



rwmccauley I got emails from LabCorp with a personal/medical folder, but I made a copy of my MTHFR folder, so I could easily find the original all of my homocysteine levels. What are you going to have a tool automatically extract your levels?

23 days ago



timferis joined as a data participant. about a month ago



rwmccauley Folks, note that the instrument is now included in the study. See the right column on this link http://genomera.com/instrument for editing and download capabilities soon.

I just entered the homocysteine levels from my blood test. I have a chance to do the same thing. Thanks! 5 months ago

Participants

Data Participants



Enter your blood test lab results:

Date & Time Collected *

01/18/2011 10:20 am

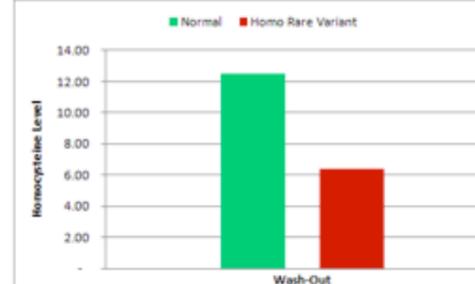
Intervention *

- Wash-out (no supplements)
- Inactive B-9 / Standard multivitamin (400 mcg of Folic Acid daily)
- Active B-9 (100 mcg of L-Methylfolate daily)
- Both (multivitamin and L-Methylfolate)
- Other

Homocysteine Level (umol/L) *

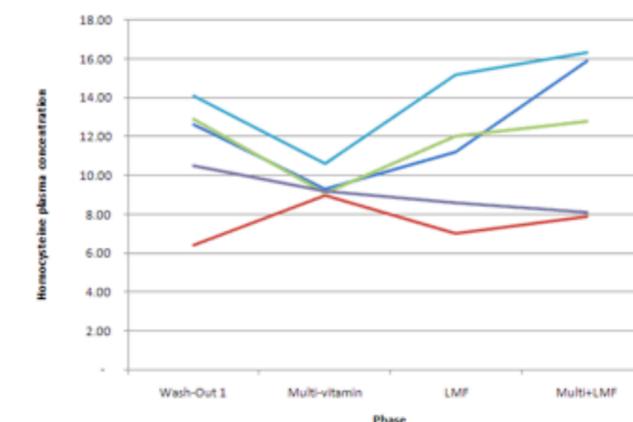
4.3 0 15

Results: Vitamin B-9 and MTHFR variants



Study Phase	Wash-Out 1	Multi-vitamin	LMF	Multi+LMF
Citizen 1 (AV)	12.60	9.30	11.20	15.90
Citizen 2 (RM)	6.40	9.00	7.00	7.90
Citizen 3 (MS)	12.90	9.10	12.00	12.80
Citizen 4 (KH)	10.50	9.20	8.60	8.10
Citizen 5 (CH)	14.10	10.60	15.20	16.30

Homozygous Rare Variants			
	GG	AG	AA
TT	GG/TT	AG/TT	AA/TT
GT	GG/GT	AG/GT	AA/GT
GG	GG/GG	AG/GG	AA/GG



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Enlarging 'Patient' Roles

- Unwitting subject
- Willing subject
- Participant
- Collaborator
- Shareholder

Who is 'scientist?'

“In the 90s, patients were occasionally invited to the table. Today, we often control the table.”

What do we want (have)?

- **CONTROL** (of tissue, data, intent, outcomes)
- **Communities of TRUST** (consent —> governance)
- **ENGAGEMENT** (bi-di communication, new roles)
- **IMPACT** (what is at stake?)
- **SHAREHOLDERS** (in stakes & benefits)
- **EXPRESS rights** in addition to protecting

“You never change things by fighting existing reality. To change something, **build a new model** that makes the existing model obsolete.”

– Buckminster Fuller

“The best way to **predict the future**
is to **invent** it”

– Alan Kay

“The **future** is already here.

It’s just not **evenly distributed** yet”

–William Gibson

Appendix

DNA Warehousing – Newborn Screening



CNN Health

DNA Warehousing – Newborn Screening

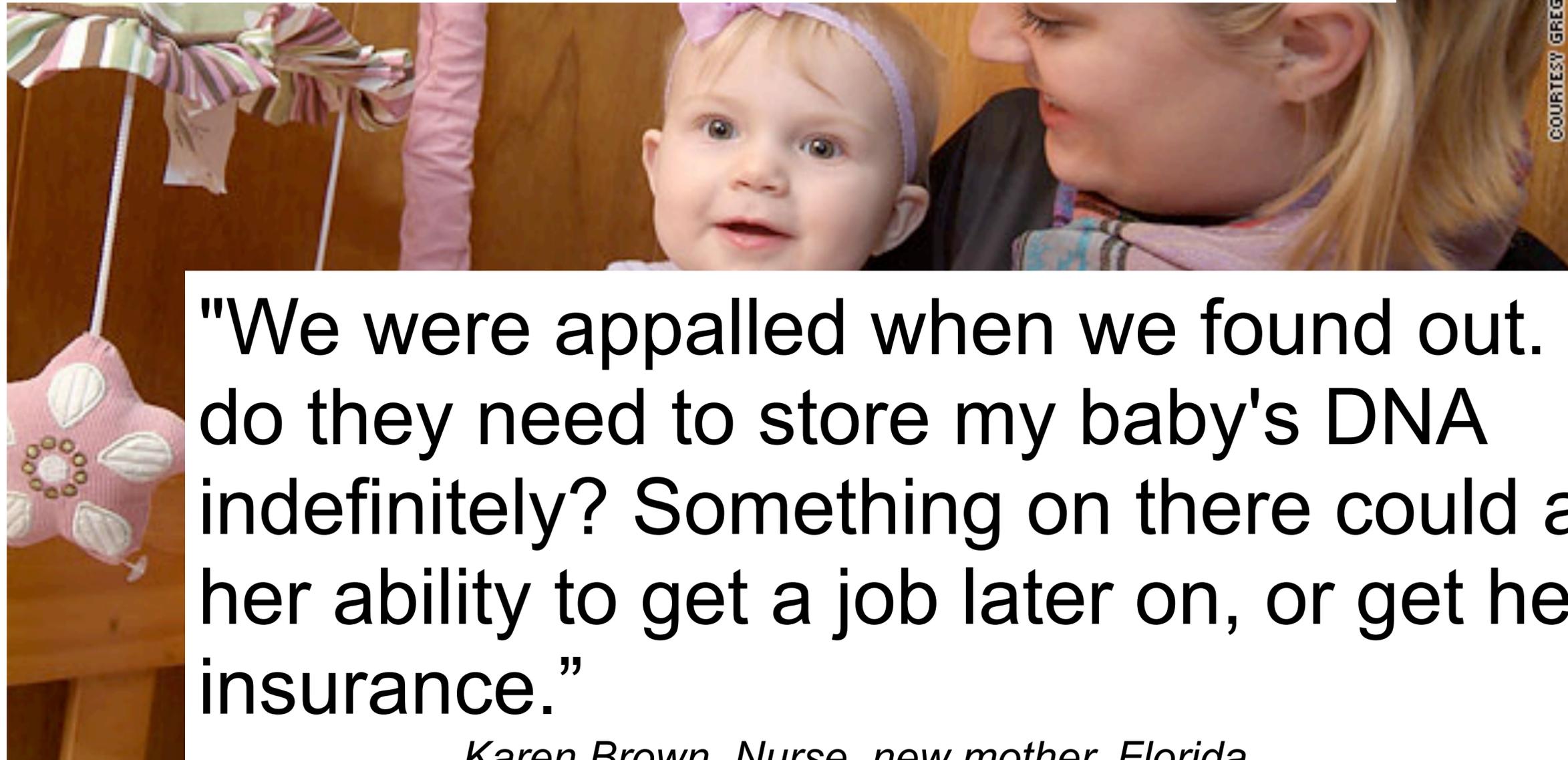


"We were appalled when we found out. Why do they need to store my baby's DNA indefinitely? Something on there could affect her ability to get a job later on, or get health insurance."

Karen Brown, Nurse, new mother, Florida

It is the moral imperative of every person on the planet to freely share their health information. ening

Paraphrase of Jamie Heywood, Co-founder, Patients Like Me



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Karen Brown, Nurse, new mother, Florida