

Personal genomics: consumer genomics companies and their rhetoric

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Consumer genomics companies

- Since the completion of the Human Genome Project, 100+ consumer genomics companies have emerged
- The most recent wave take advantage of recent developments in genome-wide scanning in order to provide “personalized” genetic profiles



Personal genomics: personal DNA information direct-to-consumer

The “me-companies”

- The signature mark of some of these new companies has been the inclusion of first person pronouns in their company names:
 - deCODEme
 - 23andMe
 - Knome
 - Mycellf
 - Mygenome

Genetic services (1)

- health-related DNA information:
 - relative genetic disease risk: risk compared with someone of the same age or gender in the general population (23andMe, deCODEme)
 - absolute genetic disease risk: risk to develop the disease over a time-period (DNA Direct)
 - pharmacogenetic info: drug response (DNA Direct)
 - nutrigenetic info: nutritional needs, “DNA fitness” (Mycellf)

Genetic services (2)

- **non-health-related DNA information:**
 - traits
 - genetic ancestry tracing: haplogroup membership, and
 - ethnicity analysis: statistical biogeographical origin, admixture (23andMe, deCODEme, DNA Worldwide)

Rhetoric

- **The appeal to personal identity:**
DNA information direct-to-consumer provides knowledge pertinent to personal identity
- **The appeal to personal empowerment:**
DNA information direct-to-consumer empowers the consumer

The appeal to personal identity



Examples (1)

- **DNA Worldwide:**
“For thousands of years mankind has always wanted to know; who are we? Where do we come from? And what makes us unique? Now thanks to advances in DNA and genetics we can start to answer some of these questions”.
- **Knome:**
“Know Thyself!”

Examples (2)

- **deCODEme:**
“deCODE yourself: your genes – your health – your ancestry”
- **23andMe:**
“By tapping into advances in DNA analysis and offering education, tools, and expertise, we at 23andMe want to help others take a bold, informed step toward self-knowledge”

Personal identity (1)

- Individualistic and communitarian visions of personal identity: who am I?
- Individuals are unique (a unique DNA fingerprint)
- Individuals are also part of a very long chain that lasts thousands of years back in time (genetic ancestry tracing)
- Individuals share their basic features with many others (customers are encouraged to discuss their DNA information with other people as a social-networking tool)

Personal identity (2)

- Health-related identity, e.g., “I am a person at risk of developing the disease x” (disease risk testing)
- Non-health-related identity, e.g., “I am the father of A”, “I am an African-American” (paternity testing, ethnicity analysis)

How important is DNA to personal identity?

- The company names and the content of their web-sites indicate that the appeal to personal identity is in fact an appeal to “genetic essentialism” – the view that our genomes do intrinsically define our personal identities, as secular substitutes for the “soul”
- BUT one of the lessons from the last two decades of ELSI research is the need to avoid investing too much personal meaning in DNA information
- AND most companies stress gene/environment interaction and “genes in context”

Why appeal to personal identity? (1)

- **WITH THIS IN MIND**, the appeal to “genetic essentialism” might seem surprising
- **HOWEVER**, this appeal is probably an important factor behind the companies’ business success

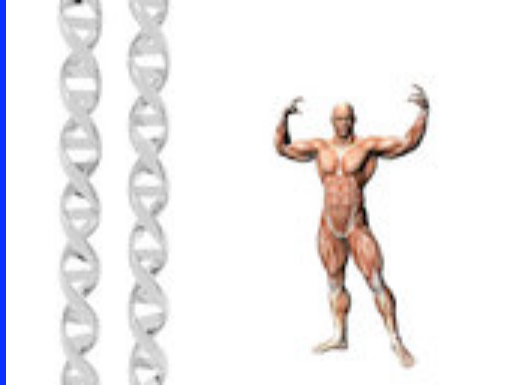
Why appeal to personal identity? (2)

Three cultural currents appears to be at work:

- a pre-modern interest in a naturalistic account of personal identity,
- a modern enthusiasm for science, and
- a post-modern emphasis on radical individual self-determination and an attitude of amused self-objectification with respect to our increasingly “online” lives

(see Nordgren & Juengst (submitted))

The appeal to personal empowerment



Examples (1)

Ryan Phelan, CEO, DNA Direct:

“At DNA Direct, we believe that testing is about empowerment – your body and your health are ultimately your responsibility, and your genes offer tremendous insight into personal, medical and lifestyle choices... Genes are a valuable part of the equation, and they must be interpreted in context and in privacy. We have set a unique service that does just that – while providing individuals with knowledge and insight to take control of their personal health.”

Examples (2)

23andMe:

“23andMe was founded to empower individuals and develop ways of accelerating research.”

deCODEme:

“We need to empower people. If a genetic test prompts patients to do what is right for them, then we have accomplished our goal.”

What is empowerment?

- Empowerment as a goal:
 - control (gaining mastery of one's own health or life)
 - internal resources (obtaining knowledge, becoming more autonomous, changing one's self-image)
- Empowerment as a process or approach:
 - involving the participants in problem formulation, decision-making and action in a way that makes the experts having to withdraw some of their control and power

(Source: Tengland 2007)

Two versions of the appeal

- **Health-related DNA information direct-to-consumer empowers the consumer (in the above senses)**
- **Non-health-related DNA information direct-to-consumer empowers the consumer (in the above senses)**

Health-related information and empowerment (1)

Empowerment as a goal may be accomplished by DNA information direct-to-consumer:

- **about disease risks, because this may lead consumers to start taking certain helpful drugs or change lifestyle**
- **about drug response, because this may lead the consumers to take certain drugs but avoid others**
- **about nutritional needs, because this may lead consumers to make certain changes concerning diet and lifestyle**

Health-related information and empowerment (2)

Empowerment as a process or approach may be accomplished by DNA information direct-to-consumer:

- because there are very few genetic counselors and medical geneticists available, which has the consequence that most people don't have access to genetic testing and its benefits.

Non-health-related information and empowerment (1)

(Re)constructed arguments:

Empowerment as a goal can be accomplished by DNA information direct-to-consumer:

- that supports the consumer's self-image and subjectively experienced social identity
- that change the self-image in a way that is experienced as positive

These insights might have profound practical consequences and are not merely a matter of subjective experience (or recreation)

Non-health-related information and empowerment (2)

(Re)constructed argument:

Empowerment as a process or approach may be accomplished by DNA information direct-to-consumer:

- because earlier there was no possibility to get to know these things even through genetics experts; the consumer gets involved in something that he/she could never be involved in before.

Why appeal to personal empowerment?

- Empowerment can be understood in many different ways and this ambiguity in combination with its positive connotation makes it very useful in the rhetoric of the consumer genomics companies

Criticism of the two appeals

- **The information may be much less informative than advertised**
- **A risk for misinterpretation**
- **Inadequate or premature science: unvalidated tests**
- **No mandatory genetic counselling regarding health-related DNA information**

The GAO Report 2006 (US Government Accounting Office)

- **14 “different” DNA samples, which actually came from only two individuals (two from a male (48 years) and 12 from a female (9 months)), were sent to four companies offering nutrigenetic testing.**
- **The recommendations from three of the companies simply mirrored the fictitious additional information that was given: those who were smokers were told to quit smoking etc.**
- **The companies stated that the results would not contain any medical predictions, however all 14 results did contain predictions that might be interpreted as diagnoses.**

The GAO Report (continued)

- Sometimes the information from the companies was quite meaningless. For example, some tests reported that people “may” be “at increased risk” for developing certain diseases. This would hold true for each and everyone.
- The GAO Report concluded that none of the results from the companies contained scientific support.

New CoE regulation (1)

**Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes
CETS 203, 27.XI.2008**

New CoE regulation (2)

Article 5

“Parties shall take the necessary measures to ensure that genetic services are of appropriate quality. In particular, they shall see to it that: genetic tests meet generally accepted criteria of scientific validity and clinical validity...”

Article 6

“Clinical utility of a genetic test shall be an essential criterion for deciding to offer this test to a person or a group of persons.”

New CoE regulation (3)

Article 8:2

“For predictive genetic tests as referred to in Article 12 of the Convention on Human Rights and Biomedicine, appropriate genetic counselling shall also be available for the person concerned.

The tests concerned are:

- tests predictive of a monogenic disease,
- tests serving to detect a genetic predisposition or genetic susceptibility to a disease,
- tests serving to identify the subject as a healthy carrier of a gene responsible for a disease.”

To what extent does this new CoE regulation apply to the services of consumer genomics companies?

Two types of services:

- **Testing of absolute genetic risk: the regulation applies**
- **Providing information about relative genetic risk: this is not genetic disease risk testing in the strict sense but merely provision of health-related DNA information in a more general sense, and therefore the regulation does not apply, OR...?**
(cf. disclaimers by 23andMe and deCODEme)

Disclaimer: 23andMe

“The genetic information provided by 23 andMe is for research and educational use only..... The Services Content is not to be used, and is not intended to be used, by you or any other person to diagnose, cure, treat, mitigate, or prevent a disease or other impairment or condition, or to ascertain your health.”

Disclaimer: deCODEme

“Risk estimates are only as accurate as the data used in the risk model. You acknowledge your understanding of genetic risk as a statistical measure that has implications derived from a large group of people with characteristics equivalent to yours but does not determine your chances for getting the corresponding disease, the disease severity or the disease outcome.”

Practical implications of the new CoE regulation

- **Validation and clinical utility:**
For example, some nutrigenetic tests appear to be scientifically premature
- **Genetic counselling mandatory:**
The policies of deCODEme (to recommend the customer to seek advice from her physician or other qualified health provider) and DNA Direct (to offer it at no extra cost although the initiative must come from the customer) are not sufficient

The need for national legislation

- The home of most consumer genomics companies – the US – lacks national regulation (but some states do not permit their residents to obtain certain information about genetic risk unless a qualified health provider is involved in the ordering and the delivery of the results).
- The new CoE regulation will only affect countries that have signed the *European Convention on Human rights and Biomedicine* (Council of Europe 1997). The UK, for instance, has not signed it.
- Even for those European countries that have signed it, it is still optional and needs to be implemented into national legal regulation for full effect.

**Can genomics tell me who I am?
Can genomics empower me?
Yes, to some extent and on certain
conditions.....**

