

Saint Louis University Journal of Health Law & Policy

Volume 3
Issue 1 *Living in the Genetic Age: New Issues,
New Challenges*

Article 5

2009

Social Networking in the Age of Personal Genomics

Sandra Soo-Jin Lee
Stanford Center for Biomedical Ethics, sandra.lee@stanford.edu

Follow this and additional works at: <https://scholarship.law.slu.edu/jhlp>



Part of the [Health Law and Policy Commons](#)

Recommended Citation

Sandra S. Lee, *Social Networking in the Age of Personal Genomics*, 3 St. Louis U. J. Health L. & Pol'y (2009).

Available at: <https://scholarship.law.slu.edu/jhlp/vol3/iss1/5>

This Symposium Article is brought to you for free and open access by Scholarship Commons. It has been accepted for inclusion in Saint Louis University Journal of Health Law & Policy by an authorized editor of Scholarship Commons. For more information, please contact [Susie Lee](#).

SOCIAL NETWORKING IN THE AGE OF PERSONAL GENOMICS

SANDRA SOO-JIN LEE*

The beginning of the 21st century has ushered in a much-heralded era of personal genomics that presents new challenges to the regulation of human genetic testing. Personal genomics builds upon human genetic variation research—the area of study that attempts to identify how genetic differences may be associated with the onset of disease or the expression of a human trait or condition.¹ Based upon initial results from genome-wide association studies, dozens of companies now offer “personalized” genetic tests for a widening range of complex conditions and traits, including, for example, the analysis of genetic ancestry, or the determination of relative risk for developing, for example, colon cancer.² Many within the scientific community have joined an active debate over the validity and utility of personal genomics for the individual consumer, with some expressing skepticism over the potential public health benefits of personal genomics.³

* Sandra Soo-Jin Lee, Ph.D., is a medical anthropologist and Senior Research Scholar at the Center for Biomedical Ethics at Stanford University Medical School. Funding for this article was provided by a grant from the National Human Genome Research Institute, National Institutes of Health (P50 #HG003389). Dr. Lee would like to thank the participants at the Saint Louis University Health Law Symposium, “Living in the Genetic Age: New Issues, New Challenges,” for their helpful comments and suggestions on the presentation on which this article is based.

1. See Elizabeth Pennisi, *Breakthrough of the Year: Human Genetic Variation*, 318 SCIENCE 1842, 1842 (2007). See also Jocelyn Kaiser, *It’s All About Me*, 318 SCIENCE 1843, 1843 (2007).

2. Sarah E. Gollust et al., *Direct-to-Consumer Sales of Genetic Services on the Internet*, 5 GENETICS MED. 332, 333 (2003); Katrina A.B. Goddard et al., *Awareness and Use of Direct-to-Consumer Nutrigenomic Tests, United States, 2006*, 9 GENETICS MED. 510, 510 (2007).

3. See, e.g., Deborah A. Bolnick et al., *The Science and Business of Genetic Ancestry Testing*, 318 SCIENCE 399, 399-400 (explaining that genetic ancestry tests often provide information about only a few of the customer’s ancestors); Wylie Burke, *Genetic Testing*, 347 NEW ENG. J. MED. 1867, 1871-72 (2002) (noting that because some disorders may have different causes, testing for all possible mutations may be prohibitively expensive); Sarah E. Gollust et al., *Limitations to Direct-to-Consumer Advertising for Clinical Genetic Testing*, 288 JAMA 1762, 1762-63 (2002) (arguing for increased regulation of advertisements for genetic tests); David J. Hunter et al., *Letting the Genome Out of the Bottle – Will We Get Our Wish?*, 358 NEW ENG. J. MED. 105, 106 (2008) (explaining that “even very small error rates per SNP,

Whether personal genomics will ultimately improve health outcomes remains to be seen, yet what is disturbingly clear is that the current infrastructure of regulation has not kept pace with capitalization of emerging technology for personal genetic services and products. As personal genomic testing is introduced to and taken up by the public, it is imperative to consider and anticipate long-term ethical concerns over genetic testing. It is equally important to consider novel uses of personal genomics that may include purposes outside of the realm of clinical issues as they may prove critical to the creation of new regulatory guidelines aimed at protecting both commercial innovation and public health.

Since the completion of the Human Genome Project, the unexpected precipitous decline in the cost of genetic sequencing has resulted in a proliferation of companies which now market products and services that provide personal genetic information directly to consumers.⁴ The development of increasingly efficient high-throughput genetic sequencing technologies in concert with ubiquitous Internet use by the public has laid the foundation for these commercial developments.⁵ This combination of factors may foreshadow several paradigm shifts in how the public consumes personal genetic information.

The direct-to-consumer (DTC) marketplace articulates these shifts as stemming from changes in public desire for personal genomics.⁶ The first of

magnified across the genome, can result in hundreds of misclassified variants for any individual patient"); Linda L. McCabe & Edward R.B. McCabe, *Direct-to-Consumer Genetic Testing: Access and Marketing*, 6 GENETICS MED. 58, 58-59 (2004) (explaining that consumers are not able to adequately analyze direct-to-consumer marketing); Roxanne Mykitiuk, *Caveat Emptor: Direct-to-Consumer Supply and Advertising of Genetic Testing*, 27 CLINICAL & INVESTIGATIVE MED. 23, 25-26 (2004) (noting how the misunderstanding of genetic information can lead to improper and unhealthy lifestyle adjustments); Christopher H. Wade & Benjamin S. Wilfond, *Ethical and Clinical Practice Considerations for Genetic Counselors Related to Direct-to-Consumer Marketing of Genetic Tests*, 142C AM. J. MED. GENETICS 284, 285-86 (2006) (noting that "the literature on risk factors for common diseases is often inconsistent due to the publication of gene-disease associations that turn out to be spurious"); Adam J. Wolfberg, *Genes on the Web – Direct-to-Consumer Marketing of Genetic Testing*, 355 NEW ENG. J. MED. 543, 543-44 (2006) (noting critics' concern that the companies are exploiting consumers' anxiety in order to sell them unnecessary tests).

4. See Kaiser, *supra* note 1, at 1843. See also Gollust et al., *supra* note 3, at 1762.

5. See generally, Gollust et al., *supra* note 2, at 332 (discussing the availability of direct-to-consumer genetic services); Mykitiuk, *supra* note 3, at 23 (discussing issues of direct-to-consumer genetic tests in Canada).

6. Amy L. McGuire et al., *Social Networkers' Attitudes Toward Direct-to-Consumer Personal Genome Testing*, AM. J. BIOETHICS, June 2009, at 3, 4-5 (noting that sixty-four percent of respondents to a survey "indicated that they would consider using [personal genome tests] in the future" and that forty percent of respondents found personal genome tests appealing because they can "learn about their genetic make-up without having to go through a physician").

these claims is that knowledge of a person's genetic code is "empowering" and will enable individuals to make better decisions about lifestyle, health, and medical care.⁷ The second is that a new era of "openness" challenges traditional approaches to genetic testing, requiring a different ethical framework towards public protection.⁸ This position suggests a new attitude towards personal information and individual privacy. And, the third claim argues that in a context where large population-based DNA collections are needed to fuel genomic research, industry will play a critical role in scaling-up the collection of genotypic and phenotypic information needed for large cohort genetic studies.⁹ Although these predictions have yet to be validated as only time will tell, it is imperative to consider what questions these putative shifts may generate in anticipating effective and timely regulation of the capitalization of emerging genomic technologies.

I. THE RISE OF DTC PERSONAL GENOMICS

Two years after the company 23andMe, Inc. launched in 2006,¹⁰ *Time Magazine* named 23andMe's DNA-testing service "Time's 2008 Invention of the Year."¹¹ Anita Hamilton, an author for *Time Magazine* wrote, "We are [only] at the beginning of a personal-genomics[sic] revolution that will transform not only how we take care of ourselves but also what we mean by personal information."¹² The California-based *23andMe*, which was founded by Linda Avey and Anne Wojcicki, has become a leader in a burgeoning industry aimed at offering genetic testing directly to consumers over the Internet.¹³ Funded by Google, Inc., Genentech, Inc., and New

7. See Bryn Williams-Jones, 'Be Ready Against Cancer, Now': *Direct-to-Consumer Advertising for Genetic Testing*, 25 NEW GENETICS & SOC'Y 89, 91 (2006).

8. See generally Katherine Wasson et al., *Direct-to-Consumer Online Genetic Testing and the Four Principles: An Analysis of the Ethical Issues*, 22 ETHICS & MED. 83, 83, 90 (2006) (discussing how uncertainty regarding the accuracy and reliability of direct-to-consumer genetic tests raises moral and ethical considerations). See also Williams-Jones, *supra* note 7, at 89 (discussing "[t]he social, ethical and policy implications of the commercialization of genetic testing for health related [sic] conditions . . .").

9. See Henry T. Greely, *The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks*, 8 ANN. REV. GENOMICS & HUM. GENETICS 343, 344-49 (2007).

10. 23andMe, Inc., 23andMe, Inc. Fact Sheet [hereinafter 23andMe, Inc. Fact Sheet], <https://23andme.https.internapcdn.net/res/4843/pdf/factsheet.pdf> (last visited Jan. 09, 2010).

11. Anita Hamilton, *TIME's Best Inventions of 2008*, TIME, Oct. 29, 2008, http://www.time.com/time/specials/packages/article/0,28804,1852747_1854493,00.html.

12. *Id.*

13. 23andMe, Inc. Fact Sheet, *supra* note 10.

Enterprise Associates, 23andMe is emblematic of a growing category of companies that actively seek to make genetic testing ubiquitous.¹⁴

Under the heading “Genetics Just Got Personal,”¹⁵ 23andMe offers tests that reveal patterns of hundreds of thousands of single-nucleotide polymorphisms (SNPs) across an individual’s genome.¹⁶ 23andMe tests for over 600,000 SNPs through the Illumina HumanHap 550+ BeadChip¹⁷ and makes the results—both the raw data and their analyses—available to customers through a password-protected website.¹⁸ The company offers two main categories of products: a genetic ancestry edition, and a health edition.¹⁹ The company provides several portals through which to interpret genetic results, including an application where customers learn about their SNP patterns (genotypes) and their associations with different ethnic populations.²⁰

23andMe is similar to other companies, including Bay area neighbor Navigenics, Inc. and the Icelandic company deCODE genetics.²¹ These companies use the same sequencing technology to offer similar tests,²² though they distinguish themselves by price and test offerings. In contrast to 23andMe’s current fee of \$399 (the lowest in the current market), Navigenics charges its customers \$999 for individualized information on genetic risk for twenty-eight different complex diseases and syndromes, and promises to update customers with new information as genomic research advances.²³ Navigenics “believe[s] that [it] can fundamentally improve

14. 23andMe, Inc., 23andMe Corporate Info, <https://www.23andme.com/about/corporate/> (last visited Jan. 09, 2010).

15. 23andMe, Inc., Home Page, <https://www.23andme.com> (last visited Jan. 09, 2010).

16. 23andMe, Inc., Frequently Asked Questions, How Does 23andMe Genotype My DNA?, <https://www.23andme.com/you/faqwin/chip/> (last visited Jan. 09, 2010).

17. 23andMe, Inc., Genotyping Technology, <https://www.23andme.com/more/genotyping/> (last visited Jan. 09, 2010).

18. 23andMe, Inc., Help FAQ, Who Can Access My Account?, <https://www.23andme.com/you/faqwin/accountaccess/> (last visited Jan. 09, 2010).

19. See 23andMe, Inc., Store [hereinafter 23andMe Store], <https://www.23andme.com/store/> (last visited Jan. 09, 2010).

20. 23andMe, Inc., Help FAQ, What does the Odds Calculator Show?, <https://www.23andme.com/you/faqwin/whatisincidence/> (last visited Jan. 09, 2010).

21. See Navigenics, Inc., Home Page, <http://www.navigenics.com> (last visited Jan. 09, 2010); deCODE genetics, Home Page, <http://www.decode.com> (last visited Jan. 09, 2010).

22. Like 23andMe, Navigenics and deCODE genetics both offer single nucleotide polymorphism (SNP) genotyping. See 23andMe, Inc., Help FAQ, How Does 23andMe Genotype My Data?, <https://www.23andme.com/you/faqwin/chip/> (last visited Jan. 09, 2010); deCODE genetics, Scientific Services, <http://www.decode.com/genotyping/index.php> (last visited Jan. 09, 2010); Navigenics, Inc., The Science Behind the Navigenics Service, <http://www.navigenics.com/static/pdf/Navigenics-TheScience.pdf> (last visited Jan. 09, 2010).

23. 23andMe Store, *supra* note 19; Navigenics, Inc., Conditions We Cover, http://www.navigenics.com/visitor/what_we_offer/conditions_we_cover/ (last visited Jan. 09,

health outcomes across the population by empowering people to act based on an understanding of their genetic predisposition for certain medical conditions.”²⁴ This premise is central to the business of DTC personal genomic companies and it maintains that individuals are not only empowered by this form of self-knowledge, but that they are also expected to use their genetic risk profiles in the prevention of disease.²⁵ 23andMe builds on this emerging ethos, but in addition, offers a broader array of services, including non-medical information, or what the company provides in its “ancestry edition” product (e.g. tests for genetic lineage and traits such as wet or dry earwax).²⁶ The success of 23andMe depends in part on creating a new class of ‘recreational genomics’. Framing it with the pleasures of hobbies and entertainment, personal genome companies recast the weighty enterprise of genetic testing for disease—traditionally overseen by healthcare professionals—into a private matter between the consumer and the company from which she or he has purchased the information.²⁷

II. LACK OF CONSENSUS ON DTC GENOMICS

Personal genomics promises to leverage prognostic and predictive tools toward achieving personalized prevention and treatment of complex diseases,²⁸ but despite the growing number of risk alleles reported in genome-wide association studies,²⁹ some scientists are now skeptical about whether these DNA variants have clinical utility.³⁰ One of the challenges of genome-wide association studies is the need for improved study designs that will ensure sufficient power to detect genes of modest risk while minimizing the potential of false-association signals from the testing of large numbers of

2010); Navigenics, Inc., Our Genetic Testing, http://www.navigenics.com/visitor/what_we_offer/our_tests/ (last visited Jan. 09, 2010).

24. Navigenics, Inc., Our Mission, http://www.navigenics.com/visitor/about_us/mission (last visited Jan. 09, 2010).

25. Fred Ledley, *A Consumer Charter for Genomic Services*, 20 NATURE BIOTECHNOLOGY 767, 767 (2002).

26. See 23andMe, Inc., Ancestry, <https://www.23andme.com/ancestry/lineage/> (last visited Jan. 09, 2010); 23andMe, Inc., Earwax Type – Sample Report, <https://www.23andme.com/health/Earwax-Type/> (last visited Jan. 09, 2010).

27. See Catherine Nash, “Recreational Genetics”, *Race and Relatedness*, 24 L’OBSERVATOIRE DE LA GENETIQUE 1, 1-7 (2005).

28. See, e.g., Dimitrios H. Roukos et al., *Molecular Genetic Tools Shape a Roadmap Towards a More Accurate Prognostic Prediction and Personalized Management of Cancer*, 6 CANCER BIOLOGY & THERAPY 308, 311 (2007) (discussing the use of personalized treatments for cancer).

29. Pennisi, *supra* note 1, at 1842-43 (2007) (noting that in 2007 alone, “researchers linked variants of more than 50 genes to increased risk for a dozen diseases”).

30. See Hunter et al., *supra* note 3, at 105-106.

markers.³¹ Currently, there is a dearth of available sample sets, which has led to particular problems in the control of factors related to population substructure and false positive results.³²

With genome-wide association studies yielding few definitive results and many unknowns concerning the contribution of genomic information to relative risk for complex traits and diseases, several scholars, scientists, and health professionals have expressed concern that personal genomic products and services offer little value.³³ These concerns have prompted scholars to suggest that personal genomic information needs to be interpreted and contextualized by clinicians and counselors in order to be meaningful to individuals.³⁴ Even when an association between genetic variation and disease is statistically significant, this does not mean that it is clinically meaningful.³⁵ “Moreover, simply knowing genetic risks and disease predispositions may not lead to better health decisions. For some, it might lead to fatalism and reduced compliance with healthy choices.”³⁶ Some have argued that providing information directly to consumers without the help of experienced health professionals increases the chance that consumers will misinterpret their information and apply it inappropriately to their decisions regarding the management of their health.³⁷ Therefore, the complexity of the concepts of risk, significance, validity, replication, and gene/environment interaction increase the likelihood that personal genomic information may lead to misunderstandings among consumers on how they should respond to their own results.³⁸

31. *See id.* at 106.

32. *See id.*

33. *See supra* note 3.

34. *See, e.g.,* Gollust et al., *supra* note 3, at 1764 (noting that consumers may not have the requisite knowledge to be able to understand the results and limitations of genetic tests).

35. Amy L. McGuire et al., *The Future of Personal Genomics*, 317 SCIENCE 1687, 1687 (2007).

36. *Id.* *See also* Wolfberg, *supra* note 3, at 545 (citing the chief of the Cancer Genetics Clinic at Baylor College of Medicine: “My biggest concern is that members of the public are getting tests that they don’t understand, and their physicians may not understand, and they may be making big decisions that are ill-informed”).

37. *See, e.g.,* Gail H. Javitt, *Policy Implications of Genetic Testing: Not Just for Geneticists Anymore*, 13 ADVANCES CHRONIC KIDNEY DISEASE 178, 179-80 (2006); David Magnus et al., *Genetic-Test Firms Must Follow Law*, SAN JOSE MERCURY NEWS, July 11, 2008, at 19A (noting that individuals can easily allow misinterpretations of their test results influence their health decisions).

38. *See, e.g.,* Javitt, *supra* note 37, at 178-79 (noting that genes’ interactions with environmental factors are largely unknown and that associations between genetic variations and disease are not necessarily clinically significant); Gollust et al., *supra* note 3, at 1763-64; Wasson et al., *supra* note 8, at 85 (noting throughout the danger that consumers may not understand their genetic test results and will make inappropriate health choices based upon erroneous notions).

Discussion of the ethical and social concerns over the validity and transparency of DTC genetic tests has focused primarily on products related to health.³⁹ A body of literature on DTC marketing for breast cancer has generated calls for increasing scrutiny of corporate practices.⁴⁰ Several professional organizations have produced position statements urging for greater oversight of DTC genetic testing, including the National Society of Genetic Counselors,⁴¹ the International Society of Nurses in Genetics,⁴² and the Secretary's Advisory Committee on Genetics, Health and Society.⁴³ In January 2007, the American Society of Human Genetics released a statement on DTC genetic testing in the U.S. urging: 1) greater transparency regarding information that consumers may require in order to make informed decisions about genetic testing; 2) increased education of health personnel regarding the clinical validity of DTC genetic tests; and 3) greater governmental oversight over both the validity of DTC tests and the use of commercial information concerning the value and limitations of the DTC tests.⁴⁴ The trend in the scientific and bioethics literature seems to be that the majority of genetic tests currently marketed to the public may not meet minimum standards for clinical utility.⁴⁵

39. See, e.g., Gollust et al., *supra* note 3, at 1762 (specifically focusing only on medical uses of genetic tests, and avoiding analyses concerning "paternity, identity, genealogy, and DNA banking").

40. See, e.g., J. Mouchawar et al., *Genetic Testing for Breast and Ovarian Cancer Susceptibility: Evaluating Direct-to-Consumer Marketing — Atlanta, Denver, Raleigh-Durham, and Seattle, 2003*, 53 MORBIDITY & MORTALITY WKLY. REP. 603, 606 (2004) (arguing that "[c]ollaboration among public health agencies, health-care providers, the clinical laboratory/biotechnology industry, and professional organizations" is necessary "as genomics becomes more integrated into health promotion and disease prevention").

41. See Position Statement, Nat'l Soc'y of Genetic Counselors, Direct to Consumer Genetic Testing (2007), <http://www.nsgc.org/about/position.cfm>.

42. See Position Statement, Int'l Soc'y of Nurses in Genetics, Provision of Quality Genetic Services and Care: Building a Multidisciplinary, Collaborative Approach Among Genetic Nurses and Genetic Counselors (Nov. 1, 2006), http://www.isong.org/about/ps_multi_disciplinarygeneticcare.cfm.

43. See Letter from Reed V. Tuckson, Chair, SACGHS, to Tommy G. Thompson, Sec'y of Health & Human Serv. (Dec. 8, 2004), available at <http://oba.od.nih.gov/oba/sacghs/reports/DTCletter.pdf>.

44. Kathy Hudson et al., *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, 81 AM. J. HUM. GENETICS 635, 636-37 (2007).

45. See, e.g., Javitt, *supra* note 37, at 178-79 (highlighting the lack of oversight and transparency, which make it difficult to gauge validity and reliability); Wasson et al., *supra* note 8, at 84 (stating that the reliability and validity of DTC genetic tests are difficult to ascertain); Magnus et al., *supra* note 37, at 19A (noting that the tests do not take into account such risk factors as diet, medication, and exercise).

III. BIOSOCIALITY AND THE SHARING OF PERSONAL GENOMIC INFORMATION

Despite concerns over the utility of personal genomics, DTC personal genomic companies have expanded their services by essentially claiming that the public desires direct access to personal genomic information and that the industry fills that gap by providing expert knowledge and leadership in research on personalized medicine. This expansion has led to the development of online sharing tools, collaborations with social networking platforms, and the creation of online, company-sponsored research communities. In considering the ethical and regulatory implications of social networking around personal genomic information, it will be important to consider not only the benefits (and risks) applicable to individual consumers as described above, but their impacts on larger social groups formed by the sharing of personal genomic information.

In its commitment to connecting individuals around genomics, 23andMe encourages its consumers to share their results with family members, friends, and others via their website.⁴⁶ Towards this end, 23andMe has created online tools allowing its consumers to instantaneously compare their genes with others who likewise agree to share information.⁴⁷ This exchange may occur through one-to-one comparisons or through the establishment of groups.⁴⁸ For example, a 23andMe customer may want to connect with a friend who also has a 23andMe account in order to share their individual risks for stomach cancer. To do so, she would only need to send a request to share to her friend using the 23andMe platform, and upon consent, they may discover that they have a 95.2% similarity in the hundreds of SNPs that are associated with this disease.⁴⁹ If the two friends wanted to create a group of friends with which to share information, they would only need to make the requests and designate their “friends” as sharers and 23andMe will provide graphics that will allow them to see the relative percent similarity or dissimilarity within the group.⁵⁰

The potential for social networking is amplified through other company-provided online tools such as blogs and dedicated community webpages, where consumers with similar genomic profiles may congregate in virtual space to meet and carry on online discussions.⁵¹ For example, individuals who show a higher genetic predisposition to Parkinson’s disease may

46. 23ANDME, INC., GETTING STARTED GUIDE 8 (2008) (noting that members can choose to share their genomes with other members through 23andMe’s “Genome Sharing” application).

47. *Id.*

48. *Id.* at 12.

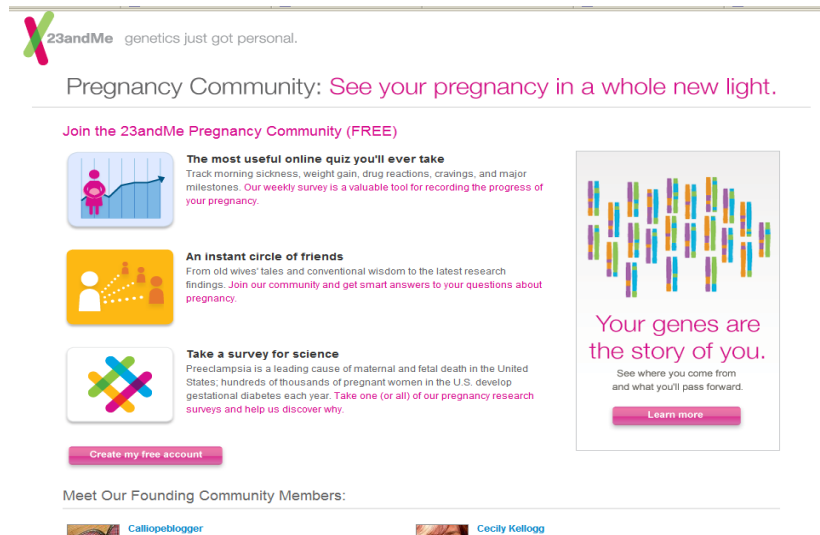
49. *See id.*

50. *See id.*

51. 23ANDME, INC., *supra* note 46, at 8-9.

converse online with others who have received similar information.⁵² For example, 23andMe recently announced the organization of their Pregnancy Community, as seen in Figure 1 below. Suggesting an “instant circle of friends,” 23andMe creates a dedicated portal for pregnant consumers to discuss questions they may have about their genetic profiles.⁵³

FIGURE 1. PREGNANCY COMMUNITY: A “CIRCLE OF FRIENDS”



Such online tools provide the infrastructure for new social formations through a process that has been referred to as “biopolitics.” Biopolitics describes the use of scientific understanding of life into the field of politics and governance.⁵⁴ Historically, this necessitated the inclusion of political authorities and scientific experts—such as physicians, urban planners, and others, who could administer, modify, control, and regulate individual behavior for the collective good.⁵⁵ The rise of genetics and the emerging coupling of genetic tests with “wellness programs” and self-care provide a powerful framework for what some have described as “biological

52. See, e.g., 23andMe, Inc., 23andMe Parkinson’s Community: Strength in Numbers, <https://www.23andme.com/pd/> (last visited Jan. 08, 2010).

53. 23andMe, Inc., Pregnancy Community, <https://www.23andme.com/pregnancy/> (last visited Jan. 09, 2010).

54. MICHEL FOUCAULT, THE HISTORY OF SEXUALITY: VOLUME I: AN INTRODUCTION 139-40 (1978).

55. See *id.* at 139-41.

citizenship.”⁵⁶ This framework merges with the narrative of DTC personal genomics in that knowing one’s genes and related risk profiles provides the basis for the modification of behavior and the adoption of preventative health despite the explicit rejection by the company in its customer agreements and informed consent forms that its genetic testing products constitute diagnostic or health-related information.⁵⁷ By creating virtual space for individuals to identify and connect through common genomic information, the company provides the architecture for self-governance of health that promotes engagement with and management of genomic risk.⁵⁸

In the emerging era of DTC personal genomics, social networking could potentially extend beyond any one individual to the creation of biosocial groups that demand a voice in shaping new genetic technologies. Scholars have already shown the power of technological developments in creating collective identity. An example is found in Benedict Anderson’s analysis of the impact of the printing press in creating “imagined communities” that no longer tethered groups by geographic proximity, but allowed the idea of community to be created through shared circuits of information flow.⁵⁹ Similarly, the Internet and the development of online tools have impacted the flow of personal genomic information between individual actors.⁶⁰ This will require serious consideration of what is at stake for consumers, companies, and the communities that are forged around the sharing of personal genomics. Personal genomic information must be understood in a framework of collective identity in order to identify fundamental ideals and values that operate in the coalescence of virtual communities. Building on

56. See generally Nikolas Rose & Carlos Novas, *Biological Citizenship*, in *GLOBAL ASSEMBLAGES: TECHNOLOGY, POLITICS, AND ETHICS AS ANTHROPOLOGICAL PROBLEMS* 439, 439-58 (Aihwa Ong & Stephen J. Collier, eds., 2005) (describing how scientific and technological advances are changing the concept of using biology as a classification of citizenship).

57. See 23andMe, Inc., Consent and Legal Agreement [hereinafter 23andMe Legal Agreement], <https://www.23andme.com/about/consent> (last visited Jan. 09, 2010) (noting that “the 23andMe Personal Genome Service is not a test or kit designed to diagnose disease or medical conditions, and it is not intended to be medical advice”).

58. See 23andMe, Inc., Core Values, <https://www.23andme.com/about/values> (last visited Jan. 09, 2010).

59. BENEDICT ANDERSON, *IMAGINED COMMUNITIES: REFLECTIONS ON THE ORIGIN AND SPREAD OF NATIONALISM* 54 (rev. ed. 1991).

60. See Matthew R. G. Taylor, Amy Alman & David K. Manchester, *Use of the Internet by Patients and Their Families to Obtain Genetics-Related Information*, 76 *MAYO CLINIC PROC.* 772, 775 (2001) (noting that “[t]he Web for [genetics-related information] provides physicians and patients equal access to information. Patients and their families can now rapidly and conveniently access information (and misinformation) about their genetic disorder with the click of a mouse”).

Gibbon's work on the "ethical value of community,"⁶¹ questions that probe the authority, flexibility, and the strategic co-construction of community by and through DTC genomic companies will be essential in order to fully consider the impact of the DTC personal genomic market on the trajectory of genomic medicine.

IV. THE BLURRING BOUNDARY BETWEEN CONSUMER AND RESEARCH PARTICIPANT

The use of social networking tools have been increasingly used by organizations interested in influencing the course of biomedical research. For example, in 2004 the non-profit company, PatientsLikeMe, was launched by three MIT engineers interested in using large-scale online commercial applications to create communities of patients, health professionals, and organizations.⁶² A fundamental goal of the company was to provide patients access to others who could provide information and share experiences about specific diseases of interest.⁶³ Under the motto of "patients helping patients live better everyday,"⁶⁴ the online site provides infrastructure for virtual communities organized around a broad range of diseases and conditions, including amyotrophic lateral sclerosis (ALS), HIV/AIDS, and post-traumatic stress disorder.⁶⁵ Undergirding PatientsLikeMe's approach is an "Openness Philosophy," that emphasizes that "openness is a good thing."⁶⁶ Asserting that transparency is critical for the greater good, the company states that "the Internet can democratize patient data and accelerate research like never before. Furthermore, we believe data belongs to you the patient to share with other patients, caregivers, physicians, researchers, pharmaceutical and medical device companies, and anyone else that can help make patients' lives better."⁶⁷

Echoing a similar goal to "dramatically accelerate the pace of genetics research," 23andMe unveiled its new research arm, 23andWe in the spring

61. See Sahra Gibbon, *Community, the Commons and Commerce: the Ownership of BRCA Genes and Genetic Testing*, in CONTESTING MORALITIES: SCIENCE, IDENTITY, CONFLICT 43, 54 (Nanneke Redclift ed., 2005) (analyzing the use of "moral communities" in a discussion of commercial genetic testing in the UK).

62. PatientsLikeMe.com, About Us, <http://www.patientslikeme.com/about> (last visited Jan. 09, 2010).

63. *Id.*

64. *Id.*

65. PatientsLikeMe.com, Home Page, <http://www.patientslikeme.com/> (last visited Jan. 09, 2010).

66. PatientsLikeMe.com, Openness Philosophy, <http://www.patientslikeme.com/about/openness> (last visited Jan. 09, 2010).

67. *Id.*

of 2008.⁶⁸ This program focuses on the company's well-publicized goal to actively engage with consumers who wish to participate in population-based genetic research. Stating that "23andMe isn't just about you," the company explains that 23andWe "gives customers the opportunity to leverage their data by contributing it to studies of genetics."⁶⁹ The company states that "[w]ith enough data [it] can produce revolutionary findings that will benefit us all."⁷⁰

In Figure 2 below, 23andMe highlights a personalized page which contains an individual's genetic data in the context of muscle performance.⁷¹ Describing what the company identifies as gene ACTN3, the page describes how variation in the presence or absence of this SNP may contribute to whether a customer is more likely to be a sprinter or marathoner.⁷² With an account, the customer is able to see his own data in comparison with the "23andWe Community," as indicated in the inset box titled with the query, "Tortoise or Hare?"⁷³

When signing up for 23andMe services, consumers are informed that their samples will become part of an anonymized database controlled by the company.⁷⁴ To participate in the 23andWe community, consumers are asked to sign up.⁷⁵ Consenting consumers are able to share their results with others and may be asked to participate in studies sponsored in collaboration with various researchers through collaborative relationships between 23andMe and other institutions and organizations.⁷⁶

68. Press Release, 23andMe, Inc., "23andWe" Mission: To Dramatically Accelerate the Pace of Genetics Research, (May 29, 2008), *available at* <https://www.23andme.com/about/press/20080529/>.

69. 23andMe, Inc., 23andWe Research [hereinafter 23andWe Research], <https://www.23andme.com/research> (last visited Jan. 09, 2010).

70. *Id.*

71. 23andMe, Inc., Muscle Performance—Sample Report, <https://www.23andme.com/health/Muscle-Performance/> (last visited Jan. 09, 2010).

72. *Id.*

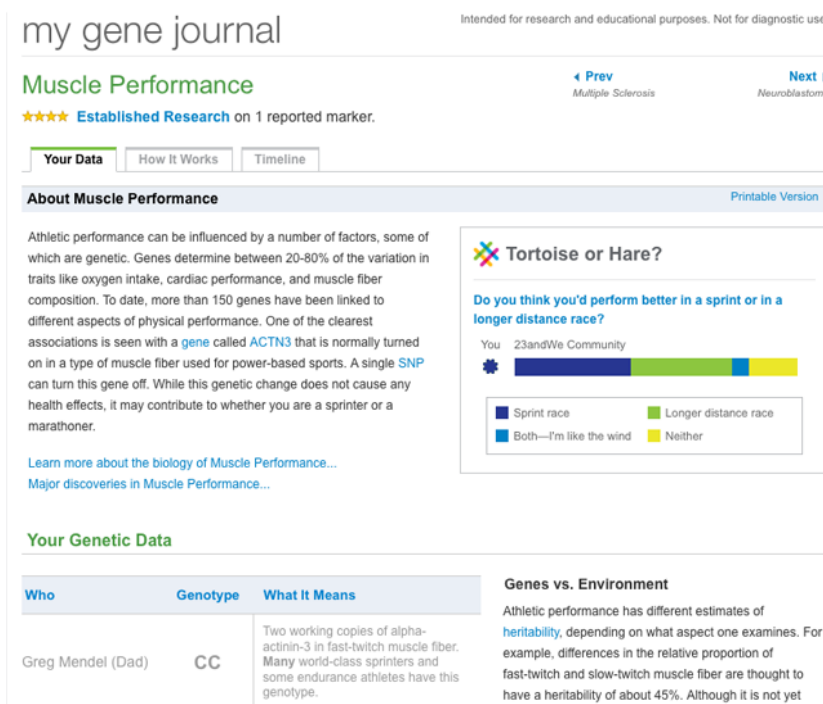
73. 23andWe Research, *supra* note 69 (from Research page, click on "view slideshow"; go to slide number 5).

74. *See* 23andMe Legal Agreement, *supra* note 57.

75. *See* 23andWe Research, *supra* note 69.

76. 23andMe Legal Agreement, *supra* note 57.

FIGURE 2. 23ANDWE PARADIGM FOR GENOMIC RESEARCH



Although the DTC personal genome companies emphasize that genetic data collected will never be sold, several have said they might consider partnerships with academic researchers or nonprofit drug developers in the future as a way of recruiting subjects for clinical trials and collecting additional information for research. For example, 23andMe and PatientsLikeMe have announced a collaboration focused on research on Parkinson's Disease through which PatientsLikeMe will recruit individuals to be genotyped by 23andMe and then participate in company-sponsored research.⁷⁷ 23andMe even has its own Facebook page.⁷⁸ Such social networking opportunities allow for instantaneous and pervasive sharing of personal genomic information in the course of routine, day-to-day socializing practices and demands research on the possible implications of these new social circuits.

77. See Press Release, PatientsLikeMe.com, PatientsLikeMe Teams Up With 23andMe to Help Parkinson's Patients (June 9, 2009), http://www.patientslikeme.com/press/20090609/17-patientslikeme-teams-up-with-23andme-to-help-parkinsons-patients?disease_tag=hiv.

78. Facebook, 23andMe, <http://www.facebook.com/23andMe?v=info> (last visited Jan. 09, 2010).

The coalescence of consumer groups around genomic information and disease is an emerging trend. Over the last several decades advocacy groups have proliferated⁷⁹ and provided critical funding for biomedical research. With the help of the Internet, public advocacy groups have created relationships with scientists and clinicians that have had a direct impact on the trajectory of research⁸⁰ by providing greater input in research questions and design, recruiting participants, and catalyzing studies responsive to patient experiences and needs.⁸¹ These patient groups have produced what some scholars have identified as “new forms of democratic participation.”⁸²

However, as the relationship between patient groups and industry partners has become more intertwined in recent years, there is concern over potential conflicts of interest. Stating the need for oversight, some have cautioned against adopting valueless or even harmful products or interventions that are promoted by industry through the use of patient voices.⁸³ In a context of population-based genomic research and the

79. See, e.g., Amy Dockser Marcus, *Advocacy Overload? Activists Seek to Unify Efforts of Groups Targeting Diseases; A Brain-Tumor Collaborative*, WALL ST. J., Oct. 10, 2006, at D1 (noting that for brain tumors, there are 141 different patient-advocacy groups for the 43,000 new diagnoses each year. That means there is roughly one advocacy group for every 305 new patients diagnosed with primary brain tumors).

80. See generally NIKOLAS ROSE, *THE POLITICS OF LIFE ITSELF: BIOMEDICINE, POWER, AND SUBJECTIVITY IN THE TWENTY-FIRST CENTURY* 148 (2007) (noting that today’s patient organizations are not simply focused on increased funding, but on actively “shaping the direction of science”); Sharon F. Terry et al., *Advocacy Groups as Research Organizations: The PXE International Example*, 8 NATURE REVIEWS GENETICS 157, 157-58 (2007) (noting that advocacy organizations are becoming more involved in research by becoming more active in areas like translational research); Nancy Tomes, *The Patient as a Policy Factor: A Historical Case Study of the Consumer/Survivor Movement in Mental Health*, 25 HEALTH AFF. 720, 720, 724 (2006) (analyzing the importance of consumer/survivor groups in the area of mental health); John W. Walsh et al., *A Review of the Alpha-1 Foundation: Its Formation, Impact, and Critical Success Factors*, 51 RESPIRATORY CARE 526, 526, 530 (2006) (discussing one specific patient advocacy organization and its influence on research and clinical care for its targeted community).

81. See Laura Landro, *The Growing Clout of Online Patient Groups*, WALL ST. J., June 13, 2007, at D1. See also Jean Cohen, *The Role of Patients’ Associations in Assisted Reproduction Treatment*, 13 REPROD. BIOMED. ONLINE 447, 447-48 (2006).

82. Deborah Heath, Rayna Rapp & Karen-Sue Taussig, *Genetic Citizenship*, in A COMPANION TO THE ANTHROPOLOGY OF POLITICS 152 (David Nugent & Joan Vincent eds., 2004).

83. See Ezekiel J. Emanuel, *Drug Addiction: Cancer in the Courts*, NEW REPUBLIC 9, 9-12 (2006) (discussing how allowing access to unproven treatments provides false hope to terminally ill patients).

ongoing challenges of recruitment of individuals into studies,⁸⁴ models of openness through social networking, as evident in companies like 23andMe and PatientsLikeMe, demand careful consideration. These conflicts are not addressed in the current arena of DTC personal genomics.

In the summer of 2009, 23andMe built on their efforts of 23andWe by unveiling a new program entitled, "The 23andMe Research Revolution."⁸⁵ The Research Revolution initiative is aimed at enrolling 1,000 consumers into ten studies that focus on the following diseases and conditions: migraines, psoriasis, rheumatoid arthritis, severe food allergies, celiac disease, lymphoma and leukemia, multiple sclerosis, amyotrophic lateral sclerosis (ALS), epilepsy, and testicular cancer.⁸⁶ At a discounted rate of \$99, consumers receive most of the genetic information on diseases and traits entitled to full price customers—except for ancestry information—and are able to share information using the company web site.⁸⁷ Also, unlike customers paying the \$399 price, Research Revolution participants do not have access to their raw genetic data.⁸⁸ As Figure 3 below from the Research Revolution webpage illustrates, customers are asked to take surveys that ask questions about lifestyle and behavior.⁸⁹ Rooting this product firmly in future societal benefit, 23andMe states that participating "could lead to better healthcare for everyone."⁹⁰ A challenge for DTC genomic research activities is the incongruous position of companies in that the genetic information they are providing is not "medical" or "health related," and yet, the same information is used as the basis for galvanizing the consumer base to participate in medical research.

84. See, e.g., Mark A. Hall, et al., *Concerns in a Primary Care Population about Genetic Discrimination by Insurers*, 7 GENETICS MED. 311 (2005) (analyzing public concerns about genetic discrimination and its influence on research participation).

85. 23andMe, Inc., The 23andMe Research Revolution Overview [hereinafter 23andMe Research Revolution Overview], <https://www.23andme.com/researchrevolution/overview/> (last visited Jan. 09, 2009).

86. 23andMe, Inc., The 23andMe Research Revolution, <https://www.23andme.com/researchrevolution/> (last visited Jan. 09, 2010).

87. 23andMe, Inc., Compare Services, <https://www.23andme.com/researchrevolution/compare/> (last visited Jan. 09, 2010).

88. *Id.*

89. See 23andMe Research Revolution Overview, *supra* note 85.

90. *Id.* (go to Overview page; click on "view slideshow"; go to slide 7, The Benefits of Participating in 23andMe Research).

FIGURE 3. "RACE TO 1000"



An important ethical question prompted by these new formations is whether DTC genomic consumers may also be considered research subjects. If so, the next question is whether companies must fulfill the same responsibilities and obligations to their consumers as would be expected in traditional contexts of genomic research. Are consumers ongoing vested partners in the research activities of 23andMe or are they "altruists," who are donating their samples and genetic data for the potential benefit of general knowledge? What type of assurances are there that the anonymity of genetic information will be safeguarded against genetic technologies aimed at identifying increasingly specific genetic variation where individual identity may be inferred even when personal information has been de-linked from samples? What obligations does the company have to its consumers to inform them of the type of research being conducted using consumer samples?

Research now indicates that individual SNP profiles can be identified within pooled datasets.⁹¹ Homer et al. analyzed complex mixes of genomic DNA using high-density SNP genotyping microarrays.⁹² This allowed them to accurately identify individuals from aggregated genetic data, leading them to conclude that individuals can be identified in de-identified datasets

91. Nils Homer et al., *Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays*, 4 PLOS GENETICS 1, 1-2 (2008), available at <http://www.plosgenetics.org/article/info%3Adoi%2F10.1371%2Fjournal.pgen.1000167>.

92. *Id.* at 1.

of more than 1,000 people.⁹³ In response, the NIH and other institutions, including the Wellcome Trust Case Control Consortium in England and the Broad Institute of MIT and Harvard in Boston, removed previously publicly available aggregated data and have established a use policy that requires the protection of individual identity.⁹⁴ Such developments are salient to the creation of DTC personal genomics where DNA datasets may be distributed for genomic research. Ethical and social concerns over the security and confidentiality of personal information volunteered by consumers require greater scrutiny in order to ensure that consumers' genetic information is protected when it is shared for research.

V. THE NEED FOR EMPIRICAL RESEARCH

Despite the proliferation of companies that seek to bring personal genomic services and products to market, there is little consensus in the scientific literature over the clinical utility of many of the genome-wide study results published thus far. However, it is also evident that the once seemingly elusive \$1000 genome will be a reality in the near future and that routine whole genome sequencing may soon be ubiquitous. How meaning will be inferred to this abundance of personal genetic information and in what manner it will be understood will be critical to how genomic information becomes integrated into healthcare and social relationships. A serious challenge to efforts to fully understand the ethical and social implications of DTC personal genomics is a critical gap in empirical research on the perspectives and practices of two important stakeholder groups: the companies who provide genetic ancestry products and the individuals who consume them.

A 2007 study by Goddard et al., assessed consumer and physician awareness of genomic tests and consumer use of such tests via two national surveys.⁹⁵ They found that consumers who were aware of the tests tended to be young and educated with a high income.⁹⁶ Given the costs of personal genomic tests, it would seem that the test results reflect the population that would be the most likely to purchase the tests. However, as yet, there has been little research that reveals much more of who really are the consumers of DTC personal genomics tests. Studies that investigate not only who DTC personal genomic consumers are and perhaps more importantly, how individuals interpret and utilize their personal genomic information in daily decisions and everyday practice, will be essential.

93. *Id.* at 2.

94. NAT'L INST. OF HEALTH, NIH BACKGROUND FACT SHEET ON GWAS POLICY UPDATE 1-2 (2008), http://grants.nih.gov/grants/gwas/background_fact_sheet_20080828.pdf.

95. Goddard et al., *supra* note 2 at 511.

96. *Id.* at 513.

As social networking through online tools and platforms expands, it will be important to assess how consumers might be protected against potential discriminatory use of personal genomic information. In 2008, Congress passed the Genetic Information Nondiscrimination Act (GINA), which offers broad protections against genetic discrimination in the provision of health insurance and decisions regarding employment.⁹⁷ Although this statute fills an important and long-standing gap in legal protections against genetic discrimination, there remain several limitations to the legislation. Such limitations include cases where genetic information is obtained “through publicly-available information” or it is “inadvertently obtained” through general searches on the internet.⁹⁸

Focusing on genetic information as the unit of analysis, an examination of the life-course of personal genomic information as it is shared with family members, health professionals, online communities, and researchers, will illuminate the impact of DTC personal genomics on the current regulatory landscape. Questions that will be important to address are: Who are the people who are using online tools and platforms to share their personal genomic information, and what genetic information is being shared? What impact does sharing information have on the behaviors and decisions of primary and secondary actors? What are the similarities and differences among individuals who share their information and those who volunteer to participate in DTC-sponsored research efforts? Detailed analyses concerning how personal genomic information “travels” to different individuals and institutions through the web will be important in creating regulatory safeguards against potential abuse.

Another important area of research will be to investigate the prevailing assumptions that have ushered in this new era of personal genomics and served as rationale for emerging markets. Key questions will be to interrogate what “democratization of the genome” means for healthcare and what will be the future of large-scale population-based genetic research? Such a study would contribute a more informed assessment of the rights and responsibilities of companies and consumers who enter into research relationships. It will help contribute to the understanding of how regulations can address the broader ethical implications of consumer participation in DTC-sponsored research communities, and also explore the long-term significance of DTC genetic testing for the larger landscape of genomic medical research.

97. Genetic Information Nondiscrimination Act of 2008 (GINA), Pub. L. No. 110-233, 122 Stat. 881 (2008) (to be codified at 42 U.S.C. 2000ff et. seq. in scattered sections of 26 U.S.C., 29 U.S.C., and 42 U.S.C.).

98. § 202-205. *See also* Regulations Under the Genetic Information Nondiscrimination Act of 2008, 74 Fed. Reg. 9056, 9063 (proposed Mar. 2, 2009).

In an era of increasingly efficient genotyping technologies, DTC genomic companies have emerged as new regimes of biosociality where personal genetic information may reconstitute human identity and create new networks of social relationships. Personal genetic information and the practice of comparing one's own profile to others has the potential to create biosocial groups that ultimately serve to overcome the "nature/culture split" where biology becomes inherent to both our social identities and our positions in the world.⁹⁹ As personal genomic information is used in novel ways, it will be critical to put in place effective safeguards and policies. Successful translation of personal genomic information will depend on the adaptability of current models towards ethical oversight in considering new commercial, clinical, and research trajectories of the personal genome era.

99. Paul Rabinow, *Artificiality and Enlightenment: From Sociobiology to Biosociality*, in INCORPORATIONS, 234, 241-44 (Jonathan Crary & Sanford Kwinter eds., 1992).

