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# PGTandMe: Social Networking-Based Genetic Testing and the Evolving Research Model

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# PGTandMe: SOCIAL NETWORKING-BASED GENETIC TESTING AND THE EVOLVING RESEARCH MODEL

*Valerie Gutmann Koch*<sup>†</sup>

## ABSTRACT

The opportunity to use extensive genetic data, personal information, and family medical history for research purposes may be naturally appealing to the personal genetic testing (PGT) industry, which is already coupling direct-to-consumer (DTC) products with social networking technologies, as well as to potential industry or institutional partners. This article evaluates the transformation in research that the hybrid of PGT and social networking will bring about, and—highlighting the challenges associated with a new paradigm of “patient-driven” genomic research—focuses on the consequences of shifting the structure, locus, timing, and scope of research through genetic crowd-sourcing. This article also explores potential ethical, legal, and regulatory issues that arise from the hybrid between personal genomic research and online social networking, particularly regarding informed consent, institutional review board (IRB) oversight, and ownership/intellectual property (IP) considerations.

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#### INTRODUCTION: BLOOD, SWEAT, TEARS . . . AND SPIT

Lorenzo Odone’s struggle with adrenoleukodystrophy (ALD), a rare incurable genetic disorder that results in brain damage, failure of the adrenal glands and, eventually, death, was memorialized in the Oscar-nominated film *Lorenzo’s Oil*. The 1992 movie tells the story of Lorenzo’s parents’ mission to find a cure on their own, after failing to find a doctor who could treat their son’s illness.<sup>1</sup> They reviewed studies and experiments, questioned doctors, organized an international symposium about ALD, and sought out a chemist to distill the oil that, in the movie, stopped the progression of Lorenzo’s disease. The moral of the story is that if the medical world fails to help us, we must help ourselves, even if it means contributing our own blood, sweat, and tears to find the treatments or cures we seek.

Today, genetic technology holds the promise of better and more frequent treatments and cures. It is also being used for more recreational purposes—allowing customers to glean personal health and ancestral data for informational and nonmedical reasons. Most per-

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<sup>1</sup> LORENZO’S OIL (1992); Roger Ebert, *Lorenzo’s Oil*, ROGEREBERT.COM (Jan. 15, 1993), <http://rogerebert.suntimes.com/apps/pbcs.dll/article?AID=/19930115/REVIEWS/301150303/1023>.

sonal genome testing (PGT) kits require the consumer to send in a DNA sample—often a spit sample or cheek swab—which is analyzed by a U.S. government-certified laboratory.<sup>2</sup> The company then notifies the consumer of the results by telephone, mail, or, more recently, online. Now that some PGT companies have coupled their direct-to-consumer (DTC) products with social networking technologies,<sup>3</sup> consumers can communicate and share their information—including extensive personal information, genetic data, and family history—with others.

The opportunity to use such a wealth of information for research purposes is naturally appealing to the PGT companies and their potential industry or institutional partners. Sourcing research participants from social networking sites is often referred to as “crowd-sourcing” or “open-source research.” PGT companies such as 23andMe have heralded the advantages of what they refer to as the “democratization of research,” or “patient-driven research.”<sup>4</sup> Often referred to as “collaborative,” consumers/participants are purportedly involved in choosing the focus of the research and contributing their own genetic and personal data.

Genomic research arising out of PGT and social networking could produce a number of transformations in the model for clinical research. Recruitment and enrollment problems could be lessened as patient pools become larger and more diverse. Data shortages or gaps could be eliminated as participants could share every aspect of their personal and genetic information. Doubts about the validity of the results and uncertainty about conclusions could be reduced, as investigators could more easily reproduce each others’ research.<sup>5</sup> The combination of DTC genomic testing services with online social networking promises the advancement of research across entire populations as well as for personalized medicine, or pharmacogenomics,

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<sup>2</sup> See CTRS. MEDICARE & MEDICAID SERVS., *Clinical Laboratory Improvement Amendments (CLIA)*, <http://www.cms.gov/CLIA/> (last updated July 12, 2011).

<sup>3</sup> Generally, online social networking involves sharing and communicating information over the internet. Online communities provide a forum for people with similar interests, activities, or goals.

<sup>4</sup> See, e.g., Rob Waters, *Google-Backed 23andMe Seeks Parkinson’s Patients Spit (Update 1)*, BLOOMBERG (Mar. 12, 2009) (quoting Ann Wojcicki, who stated, “We also believe we are really democratizing research in a new way.”), <http://www.bloomberg.com/apps/news?pid=newsarchive&refer=home&sid=akLbmqiB1ISw>.

<sup>5</sup> One early example of patient-driven medical advances using social networking technology is Flu Wiki, which is used to generate epidemiological maps of illness outbreaks. FLUWIKI, <http://www.fluwiki.info/> (last visited Sept. 17, 2009).

shifting both the focus and locus of research and revealing challenges that are not addressed by our current regulatory framework.

This article focuses on the potential ethical, legal, and regulatory issues that arise from bringing together personal genomic research and online social networking, and highlights the challenges associated with a new paradigm of “patient-driven” genomic research. Part II includes a summary of the PGT/social networking products currently on the market—with respect to both the testing services available and the companies’ intentions to use data for research purposes. Part III considers the evolving PGT/social networking hybrid for clinical research. Part IV discusses the implications of social networking-based genetic research in terms of shifting the structure, locus, timing, and scope of human subjects research. Part V explores the implications this evolving research model may have on a number of ethical, legal, and policy dimensions related to informed consent and institutional review board (IRB) oversight. Finally, Part VI addresses ownership and intellectual property (IP) considerations for the contributions or products of the techno-social hybrid of PGT and social networking.

#### **I. PERSONAL GENOMIC TESTING: WHAT’S ON THE MARKET NOW?**

The market for PGT continues to expand, with a test to match the needs of almost any consumer. There are services that provide genealogical information to fill in a family tree (e.g., deCODE Genetics or 23andMe) and tests focused on disease and trait prediction (e.g., 23andMe, Navigenics, Pathway Genomics, or Interleukin Genetics). There are tests based on single-nucleotide polymorphisms (SNPs) or specific genetic markers (e.g., 23andMe, Navigenics, or Pathway Genomics), and tests that conduct genome-wide scans (e.g., Knome). There are options for individuals who are concerned with privacy (e.g., Knome) as well as for those who want the opportunity to share and discuss their test results with others (e.g., 23andMe). Some companies require customers to sign “informed consent” forms prior to purchasing a service or participating in genetic research while others do not. Some disclose the potential use of the data gleaned from their websites in future research—either by internal investigators or by those who have purchased rights to the databases of information—while others currently have no intent to conduct any research at all. Each company’s offerings vary by price, services, and policies, and new companies and products seem to enter the market daily. Although Interleukin Genetics, Knome, Navigenics, deCODE Genetics, Pathway Genomics, TruGenetics, and 23andMe all provide some form of PGT service, not all of them intend to pursue research agendas util-

izing the information to identify tests, diagnostics, or treatments. However, the collection of genomic data, often coupled with other personal information, renders a discussion of their services and policies useful.

Knome (pronounced “know me”) is a private PGT company that interprets human genomes for pharmaceutical and clinical researchers.<sup>6</sup> The company, founded in 2007, was the first of its kind to commercially offer complete genomic sequencing. To meet the needs of the research community, Knome established KnomeDISCOVERY to deliver data and analysis for complete human genome and exome sequencing.<sup>7</sup> Unlike some of the other companies that offer social networking opportunities, Knome has emphasized privacy.<sup>8</sup>

deCODE Genetics’ service provides disease-specific genetic tests, as well as a genealogy service.<sup>9</sup> deCODE Genetics’ services include a full forty-seven disease and trait scan (including ancestry information), a “Cardio” scan, and a “Cancer” scan.<sup>10</sup> The conditions covered by deCODE Genetics’ complete scan, which captures over a million SNPs, include breast cancer, risk of heart attack, obesity, psoriasis, Alzheimer’s disease, asthma, eye color, and restless leg syndrome.<sup>11</sup> Results of the genetic analysis, performed in deCODE Genetics’ labo-

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<sup>6</sup> *FAQs*, KNOME, <http://knome.com/company/faqs/> (last visited Apr. 12, 2011). In July 2011, scientists used Knome’s services to aid in the discovery of a mutation associated with an inherited form of Parkinson’s disease. Carles Vilariño-Güell et al., *VPS35 Mutations in Parkinson Disease*, 89 AM. J. HUMAN GENETICS 162, 162 (2011).

<sup>7</sup> *KnomeDiscovery*, KNOME, <http://knome.com/solutions/knomediscovery/> (last visited Oct. 24, 2011).

<sup>8</sup> David P. Hamilton, *The Nitty-Gritty on Knome: How it Works*, VENTUREBEAT (Nov. 29, 2007), <http://venturebeat.com/2007/11/29/the-nitty-gritty-on-knome-how-it-works/>. Formerly, the FAQs section of the Knome website explained that consumers will own their genomic information, and that they are under no obligation to continue using the company’s services or to maintain their genome with Knome. *FAQs*, KNOME, <http://web.archive.org/web/20091129101404/http://www.knome.com/about/faqs.html> (last visited Sept. 17, 2009) (accessed by searching for the URL on Internet Archive database).

<sup>9</sup> DECODEME, <http://www.decodeme.com/> (last visited Apr. 12, 2011). deCODE is an Icelandic company that endeavored to set up an Icelandic Health Sector Database (HSD) containing the medical records and genealogical and genetic data of all Icelanders. David E. Winickoff, *Genome and Nation: Iceland’s Health Sector Database and its Legacy*, INNOVATIONS, Spring 2006, at 80, 80.

<sup>10</sup> *deCODEme Complete Scan*, DECODEME (June 8, 2011), <http://www.decodeme.com/complete-genetic-scan>; *deCODEme Cancer Scan*, DECODEME (Feb. 8, 2010), <http://www.decodeme.com/cancer-scan>; *deCODEme Cardio Scan*, DECODEME (Feb. 8, 2010), <http://www.decodeme.com/cardio-sca>

<sup>11</sup> *Conditions We Cover*, DECODEME, <http://www.decodeme.com/conditions-covered> (last updated Feb. 18, 2010).

ratory in Reykjavik, Iceland, are made available through a genome browser tool that gives users access to the variant information on the SNPs analyzed in the scan. The company also offers genetic counseling through a network of certified genetic counselors, but does not require counseling prior to or after using its services. The company states that, as the account owner, the consumer owns the genetic data within the deCODE Genetics account, and he or she can choose to make the information private or public to all users or only to a list of selected “friends.”<sup>12</sup> deCODE may also contact users to invite them to participate in research studies.<sup>13</sup> In fact, the CEO of deCODE, Kari Stefansson, has stated that the company has conducted studies involving more than 10,000 people with the same disease.<sup>14</sup> deCODE Genetics also maintains a blog, heralding discoveries by the company and announcing the benefits of its tests and products.<sup>15</sup>

Although it has not stated its intent to conduct research, one of the most recent entries onto the PGT market, Pathway Genomics, has a significant social networking component. Pathway “provides physicians and their patients with genetic testing reports on diet and exercise, drug response, carrier status, and complex health conditions.”<sup>16</sup> Genetic counselors are available for consultation. Pathway also maintains a blog, which addresses genetic news, innovations, and discoveries, in addition to company-focused announcements.<sup>17</sup>

On its website, the company TruGenetics previously claimed that the company would scan 500,000 SNPs for approximately 200 traits and illnesses and would provide access to genetic counselors.<sup>18</sup> To

<sup>12</sup> *deCODEme Privacy Policy*, DECODEME, <http://www.decodeme.com/privacy-policy> (last updated June 7, 2011).

<sup>13</sup> *deCODEme Genetic Scan Service Agreement and Informed Consent*, DECODEME, <http://www.decodeme.com/service-agreement> (last updated June 7, 2011).

<sup>14</sup> Andrew Pollack, *Google Co-Founder Backs Vast Parkinson’s Study*, N.Y. TIMES, Mar. 12, 2009, at B1, B9.

<sup>15</sup> DECODEYOU, <http://decodeyou.com/> (last visited Apr. 12, 2011).

<sup>16</sup> PATHWAY GENOMICS, <http://www.pathway.com/> (last visited Apr. 12, 2011). Pathway, which initially sold its test kits as direct-to-consumer products over the internet (and at one point intended to sell its kits at Walgreens and CVS stores), now markets its services only to physicians. Turna Ray, *FDA on Pathway’s Class I Spit Kit Determination: ‘Registration is Not Classification’*, PHARMACOGENOMICS REP. (Oct. 5, 2011), <http://www.genomeweb.com/mdx/fda-pathways-class-i-spit-kit-determination-registration-not-classification>.

<sup>17</sup> See *DNAAction Blog*, PATHWAY GENOMICS, <http://blog.pathway.com/> (last visited Apr. 12, 2011).

<sup>18</sup> *TruGenetics Services*, TRUGENETICS, <http://www.trugenetics.com/services/index.htm> (last visited Apr. 12, 2011); *TruGenetics Process*, TRUGENETICS, <http://www.trugenetics.com/process/> (last visited Apr. 12, 2011).

receive the service, participants would be required to take a personalized risk assessment survey and to store their genetic risk results, survey results, and other information with TruGenetics. The company also intended to add a social networking element, called TruCommunities. On its website, TruGenetics disclosed that “[o]ne of the main goals of TruGenetics™ is to develop a unique research database for conducting genetic studies.”<sup>19</sup> In early 2009, TruGenetics declared that its genome scanning services would be free to its first 10,000 customers.<sup>20</sup> However, on August 21, 2009, it announced that its funding sources had fallen through, and that, for the time being, it would not be offering genome scanning services.<sup>21</sup> Although the company maintains its website, complete with privacy policy and terms and conditions, it is not accepting new registrations at this time.<sup>22</sup>

23andMe is probably the most popular of the PGT companies on the market today,<sup>23</sup> as much for its approach to genetic testing as its relationship to Google (Anne Wojcicki, the co-founder of 23andMe, is

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<sup>19</sup> The company stated that it may conduct research, or “may partner with another organization, including non-profit and commercial entities, to conduct research.” *Terms & Conditions for Genome Scanning Provided by TruGenetics*, TRUGENETICS, <http://www.trugenetics.com/about/terms.htm> (last visited Apr. 12, 2011) [hereinafter *TruGenetics Terms & Conditions*]. The Terms and Conditions continue: “[y]our decision to use TruGenetics™ services indicates that you are willing to contribute your questionnaire responses and genetic information to the TruGenetics™ research database. This research database will be free of any information that can be used to trace this data to you . . . . TruGenetics™ may charge a fee for conducting research using this database.” *Id.*

<sup>20</sup> *Money for Nothin’ and Your SNPs for Free?*, GENOMEBOY.COM (June 19, 2009), <http://genomeboy.com/2009/06/19/money-for-nothin-and-your-snps-for-free/> (linking potential customers to the then-current TruGenetics website: TRUGENETICS (June 21, 2009), <http://web.archive.org/web/20090621083424/http://www.trugenetics.com/?> (accessed by searching for the URL on Internet Archive database); the TruGenetics website has subsequently been changed to reflect the company’s revised policy).

<sup>21</sup> Dan Vorhaus, *10,000 Free Genome Scans too Good to be Tru? TruGenetics Announces Fundraising Difficulties*, GENOMICS L. REP. (Aug. 21, 2009), <http://www.genomicslawreport.com/index.php/2009/08/21/free-genome-scans-too-good-to-be-tru-trugenetics-announces-fundraising-difficulties/>.

<sup>22</sup> *Not Accepting New Registrations*, TRUGENETICS, <http://www.trugenetics.com/> (last visited Apr. 12, 2011).

<sup>23</sup> 23ANDME, <https://www.23andme.com/> (last visited Apr. 12, 2011); Dan Vorhaus, *A Thanksgiving Tradition: 23andMe Repackages Product, Raises Prices*, GENOMICS L. REP. (Nov. 23, 2010), <http://www.genomicslawreport.com/index.php/2010/11/23/a-thanksgiving-tradition-23andme-repackages-product-raises-prices/> (discussing repackaging and repricing by “23andMe, the most popular provider of direct-to-consumer (DTC) genetic testing products.”).

married to Sergey Brin, co-founder of Google).<sup>24</sup> 23andMe's innovation stems from its coupling of social networking elements with its testing service.<sup>25</sup>

23andMe posts genetic test results for approximately 100 traits and diseases, along with genealogy and ancestry information (the "recreational genetics" aspects of the product), on a password protected website.<sup>26</sup> 23andMe's blog, "The Spittoon," provides educational posts about genetics, along with a series entitled "SNPwatch," which highlights new research and ties it back to the consumer's raw data.<sup>27</sup> 23andMe customers are encouraged to become active members of the 23andMe community. One blogger, describing his experience with 23andMe, explained,

I get to join groups of fellow subscribers with whom I share some DNA commonalities, be they connected with health or haplotype. For some, these will be support groups of those said to share a significant risk of something awful. For others it will be a new way to forge genealogical links. New groups are formed, almost a parody of the idea of biosocial identity that I envisaged . . . .<sup>28</sup>

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<sup>24</sup> Katie Hafner, *Silicon Valley Wide-Eyed over a Bride*, N.Y. TIMES, May 29, 2007, at C1. Google, which created a business arm solely focused on venture-related activities in 2009, "invested in 23andMe and Navigenics, two companies offering consumer genetic testing." Andrew Pollack, *Google's Venture Arm Invests in Biotech Start-Up*, N.Y. TIMES (Oct. 1, 2009, 8:37 AM), <http://bits.blogs.nytimes.com/2009/10/01/googles-venture-arm-invests-in-biotech-start-up/>. Allegedly, Brin loaned 23andMe \$2.6 million in start-up fees that the company paid back when Google itself became a Series A investor. David Ewing Duncan, *The Glamorous Life of Web 2.0 Genetics*, CNNMONEY.COM (Sept. 25, 2009), [http://money.cnn.com/2009/09/25/technology/23andme\\_alzheimers\\_avey.fortune/index.htm](http://money.cnn.com/2009/09/25/technology/23andme_alzheimers_avey.fortune/index.htm). Other investors include Genentech and New Enterprise Associates. Luke Timmerman, *23andMe Brings Down the Price of Consumer Genetic Tests, Builds Up Relations with Big Pharma*, XCONOMY (May 24, 2011), <http://www.xconomy.com/san-francisco/2011/05/24/23andme-moves-beyond-simple-consumer-dna-sequencing-sets-sight-on-research/>.

<sup>25</sup> For a thorough description of the social networking aspects of 23andMe, see Sandra Soo-Jin Lee & LaVera Crawley, *Research 2.0: Social Networking and Direct-to-Consumer (DTC) Genomics*, AM. J. BIOETHICS, June 2009, at 35, 35.

<sup>26</sup> 23ANDME, <https://www.23andme.com/> (last visited Oct. 23, 2011).

<sup>27</sup> See THE SPITTOON, <http://spittoon.23andme.com/> (last visited Apr. 12, 2011).

<sup>28</sup> Ian Hacking, *Commercial Genome Reading*, NAT'L HUMANITIES CTR. (Mar. 30, 2009), <http://onthehuman.org/2009/03/current-controversies-ian-hacking/>.

23andMe engaged Informed Medical Decisions, Inc. (InformedDNA), a nationwide network of board-certified genetics experts, to offer independent genetic counseling services to its customers.<sup>29</sup> Linda Avey, co-founder of the company with Wojcicki, has spoken out against a “paternalistic” approach to genetic testing, but has acknowledged that genetic counseling might be required in certain situations.<sup>30</sup>

23andMe has devoted its resources to conducting research utilizing genetic and phenotypic information gathered through its services. According to reports, nearly 90 percent of its 125,000 genotyped customers have opted to participate in research approved by the company’s IRB.<sup>31</sup> 23andMe’s research arm, 23andWe, was the company’s first attempt to obtain detailed trait information via online surveys of customers.<sup>32</sup> The service evolved into more targeted recruitment of specific “research communities” for larger association studies for Parkinson’s disease,<sup>33</sup> sarcoma,<sup>34</sup> and pregnancy.<sup>35</sup> The first initiative was launched March 7, 2009, and is an effort to recruit 10,000 participants for Parkinson’s disease research. It is funded by Brin, who allegedly found out through his wife’s company’s test that he was predisposed to the disease.<sup>36</sup> Participants receive all 23andMe’s services for free and are given access to Parkinson’s disease community forums. As of January 26, 2010, more than 3,500 people with Parkinson’s disease had submitted saliva samples for genetic analysis

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<sup>29</sup> Press Release, 23andMe, 23andMe Enlists Informed Medical Decisions to Make Independent Genetic Counseling Services Available to Customers (June 3, 2010), available at <https://www.23andme.com/about/press/20100603/>.

<sup>30</sup> In September 2009, Avey left 23andMe to start an Alzheimer’s disease foundation. *DNA Test Firm Founder to Start Research Foundation*, N.Y. TIMES (Sept. 4, 2009), available at [http://www.nytimes.com/2009/09/05/technology/startups/05bizbriefs-DNATESTFIRMF\\_BRF.html?\\_r=1](http://www.nytimes.com/2009/09/05/technology/startups/05bizbriefs-DNATESTFIRMF_BRF.html?_r=1).

<sup>31</sup> Bruce V. Bigelow, *23andMe Identifies Possible Protective Gene Against Parkinson’s Disease*, XCONOMY (Oct. 25, 2011), <http://www.xconomy.com/san-diego/2011/10/25/23andme-identifies-possible-protective-gene-against-parkinsons-disease/>.

<sup>32</sup> *Research*, 23ANDME, <https://www.23andme.com/research/> (last visited Apr. 12, 2011).

<sup>33</sup> *23andMe Parkinson’s Community: Strength in Numbers*, 23ANDME, <https://www.23andme.com/pd/> (last visited Apr. 12, 2011); *On Our Way to 10,000: 23andMe Welcomes First Members of Parkinson’s Disease Community*, THE SPITTOON (Apr. 13, 2009), <http://spittoon.23andme.com/2009/04/13/on-our-way-to-10000-23andme-welcomes-first-members-of-parkinsons-disease-community/>.

<sup>34</sup> *23andMe Sarcoma Community: A Patient-Driven Revolution in Sarcoma Research*, 23ANDME, <https://www.23andme.com/sarcoma/> (last visited Aug. 9, 2011).

<sup>35</sup> *Pregnancy Community: See Your Pregnancy in a Whole New Light*, 23ANDME, <https://www.23andme.com/pregnancy/> (last visited Apr. 12, 2011).

<sup>36</sup> See Pollack, *supra* note 14, at B9.

and answered over 30,000 online surveys.<sup>37</sup> In addition, more than 8,000 people without Parkinson's disease have taken 23andMe's surveys as control subjects.<sup>38</sup> Likewise, individuals who have been diagnosed with sarcoma are encouraged to "take an active role in research that may benefit you and others living with a similar diagnosis" and to "[t]ake action against this disease," by providing a saliva sample for genetic analysis, completing online surveys about their sarcoma experience and response to treatment, and participating in the "community."<sup>39</sup>

In the summer of 2009, 23andMe unveiled Research Revolution, where anyone—those with the disease to be studied or healthy volunteers who would serve as controls—could participate.<sup>40</sup> The principles of the Research Revolution were as follows: participants who purchased the spit test would then "vote" on a predetermined list of common diseases on which they would like the company to focus research.<sup>41</sup> For the first wave of votes, from July 7 through September 30, 2009, the diseases and traits on which participants could vote in-

<sup>37</sup> Nick Eriksson & Lizzie Dorfman, *23andMe Parkinson's Research Initiative Progress Update*, THE SPITTOON (Jan. 26, 2010), <http://spittoon.23andme.com/2010/01/26/23andme-parkinsons-research-initiative-progress-update/>. By March 2011, the study had enrolled more than 5,000 participants with Parkinson's disease and gathered more than 40,000 data points about their experiences with the disease. *An Update on Our Parkinson's Research Community*, THE SPITTOON (Mar. 21, 2011), <http://spittoon.23andme.com/2011/03/21/an-update-on-our-parkinsons-research-community/>.

<sup>38</sup> *Id.*

<sup>39</sup> *23andMe Sarcoma Community: A Patient-Driven Revolution in Sarcoma Research*, *supra* note 34.

<sup>40</sup> Linda Avey, *Introducing a Do-It-Yourself Revolution in Disease Research*, THE SPITTOON (July 7, 2009), <http://spittoon.23andme.com/2009/07/07/introducing-a-do-it-yourself-revolution-in-disease-research/> (linking readers to a now defunct website, *The 23andMe Research Revolution*, 23ANDME (Jan. 8, 2010), <http://web.archive.org/web/20100108012414/https://www.23andme.com/researchrevolution/> (accessed by searching for the URL on Internet Archive database). For the first phase of Research Revolution, participants could purchase a limited version of its testing service at a reduced rate of \$99, but 23andMe discontinued offering the service at this rate because, as Andro Hsu, then the Manager of Regulatory & Governmental Affairs at 23andMe, stated, "we found that consumer interest is focused on our complete product and those users can still pledge to support the program." Mark Henderson, *Personal Genomics: 23andMe's Research Revolution is Over...For Now*, TIMESONLINE (Jan. 7, 2010), <http://web.archive.org/web/20100417152440/http://timesonline.typepad.com/science/2010/01/personal-genomics-23andmes-research-revolution-is-over-for-now.html> (accessed by searching for the URL on Internet Archive database).

<sup>41</sup> Jason Kincaid, *23andMe Launches \$99 Kit to Spur its 'Research Revolution'*, TECHCRUNCH (July 8, 2009), <http://techcrunch.com/2009/07/08/23andme-launches-99-kit-to-spur-its-research-revolution/>.

cluded epilepsy, migraines, psoriasis, rheumatoid arthritis, and severe food allergies.<sup>42</sup> Participants then submitted online surveys and questionnaires related to their “physical traits, health history and behaviors.”<sup>43</sup> Any diseases that garnered 1,000 or more votes would become the subject of an association study performed by the company’s scientists and outside researchers, using the genetic data from the assembled patients and controls. The company called this collaborative, democratizing research: “research of, by and for the people, directed and advanced by you.”<sup>44</sup> Although Research Revolution itself was discontinued due to unprofitability, 23andMe’s customers were informed that they could still participate in research by purchasing the company’s full services.<sup>45</sup>

In June 2010, a principal investigator at 23andMe, Nicholas Eriksson, and his colleagues published the first genome-wide association studies (GWAS) on multiple traits ascertained by self-reported information provided through the internet. The article stated that the company’s research framework “takes advantage of the interactivity of the Web both to gather data and to present genetic information to research participants, while taking care to correct for the population structure inherent to this study design.”<sup>46</sup> Wojcicki, a coauthor, explained, “[i]n this paper, we confirm that self-reported data from our customers has the potential to yield data of comparable quality as data

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<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Research Revolution—23AndMe*, PHARMA STRATEGY BLOG (Aug. 20, 2009), <http://pharmastrategyblog.com/2009/08/research-revolution-23andme.html/> (citing the now defunct “Research Revolution” page of the 23andMe website, *The 23andMe Research Revolution*, 23ANDME (Jan. 8, 2010), <http://web.archive.org/web/20100108012414/https://www.23andme.com/researchrevolution/> (accessed by searching for the URL on Internet Archive database)).

<sup>45</sup> Andro Hsu maintained that research will continue to be a fundamental aspect of 23andMe’s business model: “Research has always been a fundamental part of our platform. 23andMe is focused on providing a great experience for consumers while also allowing them to contribute meaningfully to scientific research. We designed our web service to allow customers to participate in research surveys and to be engaging enough that they will want to return to our site and continue taking new surveys. We’re seeing more and more active involvement of individuals in the management of their health. 23andMe is part of this shift in focus as far as genetics is concerned; but we take individuals a step farther by allowing them to be involved in research.” Henderson, *supra* note 40.

<sup>46</sup> Nicholas Eriksson et al., *Web-Based, Participant-Driven Studies Yield Novel Genetic Associations for Common Traits*, 6 PLOS GENETICS 1, 1 (June 2010), <http://www.plosgenetics.org/article/fetchObjectAttachment.action?uri=info%3Adoi%2F10.1371%2Fjournal.pgen.1000993&representation=PDF>.

gathered using traditional research methods.”<sup>47</sup> The article’s publication was delayed for almost six months, while the editors of the journal considered issues related to ethical review, consent, and data access.<sup>48</sup>

The public sector has responded to the private sector’s move into genetic research by offering alternative research initiatives.<sup>49</sup> The

<sup>47</sup> Press Release, 23andMe, 23andMe Makes New Discoveries in Genetics Using Novel, Web-based, Participant-driven Methods (June 24, 2010), available at <https://www.23andme.com/about/press/20100624/>.

<sup>48</sup> Greg Gibson & Gregory P. Copenhaver, *Consent and Internet-Enabled Human Genomics*, 6 PLOS GENETICS 1, 1 (June 2010), <http://www.plosgenetics.org/article/fetchObjectAttachment.action?uri=info%3Adoi%2F10.1371%2Fjournal.pgen.1000965&representation=PDF>. On June 23, 2011, 23andMe published its second research paper, discovering two novel associations with Parkinson’s disease using the largest single Parkinson’s cohort to date, in addition to replicating 20 previously identified genetic associations with the disease. See Chuong B. Do et al., *Web-Based Genome-Wide Association Study Identifies Two Novel Loci and a Substantial Genetic Component for Parkinson’s Disease*, 7 PLOS GENETICS 1, 1 (June 2011), <http://www.plosgenetics.org/article/fetchObjectAttachment.action?uri=info%3Adoi%2F10.1371%2Fjournal.pgen.1002141&representation=PDF>.

<sup>49</sup> Some public databases and software for genomic information are already being developed or are available to non-profit organizations, academic medical centers, and other entities devoted to public research. For example, the International HapMap Project was established in 2002 as a partnership of scientists and funding agencies from Canada, China, Japan, Nigeria, the United Kingdom and the United States to develop a public resource that will help researchers find genes associated with human disease and drug responses. *About the International HapMap Project*, INT’L HAPMAP PROJECT, <http://hapmap.ncbi.nlm.nih.gov/thehapmap.html.en> (last visited Apr. 12, 2011). The information produced by the Project will be made freely available. *Id.* In phase I, “over 1.1 million SNPs were genotyped in 270 individuals from 4 worldwide populations.” Gudmundur A. Thorisson et al., *A User’s Guide to the International HapMap Project Web Site*, INT’L HAPMAP PROJECT 1 (2005), [http://snp.cshl.org/downloads/presentations/users\\_guide\\_to\\_hapmap.pdf](http://snp.cshl.org/downloads/presentations/users_guide_to_hapmap.pdf). Likewise, the 1000 Genomes Project was established in January 2008, as an international effort to sequence the genomes of approximately 1,200 people from around the world in order to create the most detailed and medically useful picture to date of human genetic variation. *Project Overview*, 1000 GENOMES PROJECT, <http://www.1000genomes.org/about> (last visited Oct. 23, 2011). Until recently, the collected data were available to the worldwide scientific community through freely accessible public databases. See *First Data Release: SNP Data Downloads and Genome Browser Representing Four High Coverage Individuals*, 1000 GENOMES PROJECT (Dec. 23, 2008), <http://www.1000genomes.org/announcements/first-data-release-snp-data-downloads-and-genome-browser-representing-four-high-covera> (“The first set of SNP calls representing the preliminary analysis of four genome sequences are now available to download through the EBI FTP site and the NCBI FTP site.”). See also *About Us*, THE RARE GENOMICS INSTITUTE, <http://www.raregenomics.org/about.php> (last visited Oct. 26, 2011). In December 2011, the National Human Genome Research Institute announced that would give approximately \$300 million to three institutes to continue work on the 1000 Genomes

Personal Genome Project (PGP) is a public interest, nonprofit response to companies like 23andMe and deCODE Genetics, with the intention of placing research results in the public domain.<sup>50</sup> The PGP aims to recruit 100,000 participants to share their genome sequences, related health and physical information, and regularly report their experiences. Participants will also receive online access to their genome sequences for their own use. To enroll in the project, participants must take an entrance exam, which covers genetics, regulation, and the risks and benefits of genetic technologies.<sup>51</sup> The second phase of the project has enrolled over 1,000 individuals whose profiles (both genetic and phenotypic) are made public on the PGP website.<sup>52</sup> Each subsequent phase will encompass larger and larger numbers of people. The PGP does not provide genetic counseling.

Despite concerns regarding the inadequacy of DTC genomic tests to explain the complexity of genetic information in combination with environmental and lifestyle information,<sup>53</sup> the questionable clinical validity or utility of the tests,<sup>54</sup> and the lack of genetic counseling as-

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Project. Susan Young, *Funds Dedicated to Personalized Genetics: NIH Aims to Push Genome-Sequencing into Mainstream Medicine*, NATURE NEWS (Dec. 6, 2011), <http://www.nature.com/news/funds-dedicated-to-personalized-genetics-1.9565>.

<sup>50</sup> See PERSONAL GENOME PROJECT, <http://www.personalgenomes.org/> (last visited Apr. 12, 2011); see also *Newsletter #1*, PERSONAL GENOME PROJECT (Apr. 2009), <http://www.personalgenomes.org/newsletter/01.html>.

<sup>51</sup> See Kathleen Page et al., PERSONAL GENOME PROJECT STUDY GUIDE, <http://www.pgpstudy.org/index.htm> (last visited Apr. 12, 2011).

<sup>52</sup> *PGP-1K*, PERSONAL GENOME PROJECT, <http://www.personalgenomes.org/pgp1k.html> (last updated Mar. 30, 2011).

<sup>53</sup> A blogger paid by 23andMe through its pregnancy initiative noted, “[t]he geneticist said that over at 23andMe, they were worried that people would just see the number and stop reading. That there’d be all these worried people out there, who might need to be a bit careful—but didn’t need to go and start pricking their fingers and swearing off chocolate bars, either.” *What? Me Worry? My 23andMe Results*, 23ANDME (Apr. 16, 2009), <http://agelessbodytimelessmom.wordpress.com/2009/04/16/what-me-worry-my-23andme-results/>. Most identified risk-marker alleles confer incredibly small risks, between 1.1—1.5. Peter Kraft & David J. Hunter, *Genetic Risk Prediction—Are We There Yet?*, 360 NEW ENGL. J. MED. 1701, 1701 (2009).

<sup>54</sup> See Gail Javitt et al., *Developing the Blueprint for a Genetic Testing Registry*, 13 PUB. HEALTH GENOMICS 95, 96 (2009) (“While the number of genetic tests continues to grow, publicly accessible information about the analytic and clinical validity of such tests is lagging,” and supports the HHS Secretary’s Advisory Committee on Genetics, Health and Society’s 2008 recommendation to develop a clinical registry, for “a more transparent, quality-centered system of oversight that will better inform and protect the public.”). Based on a white paper issued by 23andMe, Navigenics, and DeCODE Genetics that described how the companies calculate genetic risk, using voluntary industry standards they had developed with the help of the Personalized Medicine Coalition, Muin Khoury, Director of CDC’s Office of Public Health Genomics, stated that companies still diverge on clinical validation issues

sociated with DTC genetic testing,<sup>55</sup> such tests have been proliferating.<sup>56</sup> Among the most visible are those provided by companies such as Navigenics,<sup>57</sup> Inherent Health,<sup>58</sup> 23andMe, deCODE Genetics, Knome, and Pathway Genomics, all of whom promise consumers knowledge and control over their genetic destinies—and, in many cases, the opportunity to participate in, or even drive, genetic research.<sup>59</sup>

Although companies like deCODE Genetics and TruGenetics have floundered in the recent economic environment, the opportunity

critical to protecting consumer health. Turna Ray, *More Work Needed to Standardize Consumer Genomics Offerings*, *Top US Health Official Says*, GENOMEWEB.COM (Apr. 15, 2009), <http://www.genomeweb.com/dxpgx/more-work-needed-standardize-consumer-genomics-offerings-top-us-health-official?page=show>; see also Eline Bunnik et al., *How Attitudes Research Contributes to Overoptimistic Expectations of Personal Genome Testing*, AM. J. BIOETHICS, June 2009, at 23, 24. Recent studies have emphasized the “recreational” nature of genomic testing, focusing on the limited predictive capacity of current tests to determine risk. See Kraft & Hunter, *supra* note 53, at 1701-03; see also David B. Goldstein, *Common Genetic Variation and Human Traits*, 360 NEW ENGL. J. MED. 1696, 1698 (2009).

<sup>55</sup> See NAT’L INST. HEALTH, HANDBOOK: HELP ME UNDERSTAND GENETICS, 111 (Nov. 7, 2011), available at <http://ghr.nlm.nih.gov/handbook.pdf>.

<sup>56</sup> For excellent overviews and descriptions regarding genetics, genomics, and genetic testing, see Gail H. Javitt et al., *Direct-to-Consumer Genetic Tests, Government Oversight, and the First Amendment: What the Government Can (and Can’t) Do to Protect the Public’s Health*, 57 OKLA. L. REV. 251, 255-56 (2004); Lori Andrews & Erin Shaughnessy Zuiker, *Ethical, Legal, and Social Issues in Genetic Testing for Complex Genetic Disease*, 37 VAL. U. L. REV. 793, 798 (2003).

<sup>57</sup> Founded in 2006, Navigenics’ PGT service does not offer genealogy services or a social networking component, but does maintain a blog that gives lifestyle tips, provides updates on the company, and discusses genes for which Navigenics tests. See NAVIGENICS, <http://www.navigenics.com/> (last visited Apr. 12, 2011); *The Navigator-Navigenics Blog*, NAVIGENICS, <http://blog.navigenics.com/> (last visited Apr. 12, 2011).

<sup>58</sup> Interleukin Genetics markets a number of “Inherent Health™” genetics tests. *About Interleukin Genetics*, INTERLEUKIN GENETICS, <http://www.ilgenetics.com/content/about-interleukin/index.jsp> (last visited Apr. 12, 2011). Inherent Health genetics tests require a consent form for all consumers of their tests, specifically “to document that the person providing their DNA sample to Inherent Health for analysis has done so voluntarily.” *Frequently Asked Questions*, INHERENT HEALTH, <http://www.inherenthealth.com/faq.aspx> (last visited Apr. 12, 2011). Inherent Health informs its clients that “[y]ou own your genetic data. As a result, only you are able to access and download your genetic data and test results. Furthermore, you cannot be forced to reveal the results of your genetic test to anyone else.” *Id.*

<sup>59</sup> Almost all of these companies state in some form that their products are not designed to diagnose, prevent, or treat any condition or disease but are intended for educational, informational, and research purposes only. See, e.g., *Consent Document*, 23ANDME, <https://www.23andme.com/about/consent/> (last visited Apr. 12, 2011).

for PGT companies to contribute to and transform the model for research is still very real. The success or failure of one company cannot predict the success or failure of the industry as a whole. David Altschuler, a medical geneticist at the Massachusetts General Hospital, cautioned, “[i]t would be a mistake to draw any connection between the medical promise of the human genome and the success of a specific company and business model.”<sup>60</sup>

## II. A NEW RESEARCH PARADIGM?: TOWARD A PERSONAL GENOMIC TESTING/SOCIAL NETWORKING HYBRID

As the number of clinical trials in the United States multiply and studies require greater numbers of participants, recruitment of research participants becomes increasingly difficult.<sup>61</sup> By March 2009, there were approximately 50,000 clinical trials underway, of which 80 percent were delayed at least a month due to low enrollment.<sup>62</sup> Consequently, researchers and sponsors of research are seeking access to potential research populations in new and different ways.

At the same time, more and more individuals are seeking health information from the internet. A 2006 Pew Research Center study found that 80 percent of internet users in the United States obtain health information online,<sup>63</sup> a statistic that is likely to increase as online communities and social networking sites continue to multiply. And a more recent study found that one in four internet users living with high blood pressure, diabetes, heart conditions, lung conditions, and cancer have gone online to find others with similar health concerns.<sup>64</sup> The PatientsLikeMe Genetics Search Engine<sup>65</sup> allows pa-

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<sup>60</sup> Nicholas Wade, *A Genetics Company Fails, Its Research Too Complex*, N.Y. TIMES, Nov. 18, 2009, at B2.

<sup>61</sup> Susan Gilbert, *Trials and Tribulations*, 38 HASTINGS CTR. REP. 14, 14 (2008); Kenneth A. Getz et al., *Assessing the Impact of Protocol Design Changes on Clinical Trial Performance*, 15 AM. J. THERAPEUTICS 450 (2008).

<sup>62</sup> Sarah Kliff, *Pharma’s Facebook: Research 2.0: How Drug Companies are Using Social Networks to Recruit Patients for Clinical Research*, DAILY BEAST (Mar. 9, 2009), <http://www.thedailybeast.com/newsweek/2009/03/10/pharma-facebook.html>.

<sup>63</sup> Susannah Fox, *Online Health Search 2006*, PEW INTERNET & AMERICAN LIFE PROJECT 4 (Oct. 29, 2006), [http://www.pewinternet.org/~media/Files/Reports/2006/PIP\\_Online\\_Health\\_2006.pdf](http://www.pewinternet.org/~media/Files/Reports/2006/PIP_Online_Health_2006.pdf).

<sup>64</sup> Susannah Fox, *Peer-to-Peer Healthcare*, PEW INTERNET & AMERICAN LIFE PROJECT 2 (Feb. 28, 2011), [http://pewinternet.org/~media/Files/Reports/2011/Pew\\_P2PHealthcare\\_2011.pdf](http://pewinternet.org/~media/Files/Reports/2011/Pew_P2PHealthcare_2011.pdf). Very few internet users check the source and date of the information they find. Fox, *supra* note 63, at iii.

tients to “share genetic information and find others like them by the gene (and even the specific mutation in that gene) causing their condition.”<sup>66</sup> The co-founder of PatientsLikeMe described the system as helping to “realiz[e] the goals of personalized medicine today,”<sup>67</sup> and the company emphasizes the democratization of data and research enabled by its “openness philosophy.”<sup>68</sup>

Likewise, pharmaceutical companies have begun to take advantage of the research recruitment opportunities afforded by social networking. Online networking sites like Inspire.com and PatientsLikeMe allow users to receive targeted information from pharmaceutical companies who use the site as a recruiting tool for drug studies.<sup>69</sup> In 2008, a partnership between Novartis and PatientsLikeMe led to the first effort to recruit research participants for a study (in this case, for a multiple sclerosis drug) through a social network.<sup>70</sup> In a similar effort, Pfizer announced its intention to create an online community to increase clinical trial participation, in collaboration with Private Access, a health information technology company.<sup>71</sup>

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<sup>65</sup> PATIENTSLIKEME, [www.patientslikeme.com](http://www.patientslikeme.com) (last visited Sept. 17, 2009). PatientsLikeMe allow registrants to record, monitor, and share symptoms, severity, progression, and treatment (including drug regimens and dosages) on the site. *See id.* In April 2011, it opened its online community to people with all types of illnesses, rather than restricting it to patients with particular chronic diseases. *PatientsLikeMe Calls All Patients with Any Condition to Join*, PATIENTSLIKEME (Apr. 11, 2011), <http://blog.patientslikeme.com/2011/04/11/patientslikeme-calls-all-patients-with-any-condition-to-join/>.

<sup>66</sup> Press Release, PatientsLikeMe, *PatientsLikeMe Launches Genetics Search Engine for ALS Patients* (Apr. 22, 2009), available at <http://www.patientslikeme.com/press/20090422/15-patientslikeme-launches-genetics-search-engine-for-als-patients>.

<sup>67</sup> David S. Williams III, *Our Philosophy*, PATIENTSLIKEME, <http://www.patientslikeme.com/about/openness/> (last visited Sept. 26, 2011) (“PatientsLikeMe enables you to [a]ffect a sea change in the healthcare system. We believe 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. Will you add to our collective knowledge... and help change the course of healthcare?”).

<sup>68</sup> David S. Williams III, *The Value of Openness*, PATIENTSLIKEME (Dec. 13, 2007, 3:50 PM), <http://blog.patientslikeme.com/2007/12/13/the-value-of-openness/>.

<sup>69</sup> Kliff, *supra* note 62.

<sup>70</sup> *Id.* “In May 2008, the site sent out a message to the 8,000 members of their multiple-sclerosis community, alerting them to the Novartis trial. From that e-mail, nearly 1,500 members visited the Novartis website. After recruiting through PatientsLikeMe.com, Novartis saw a boost in registrations for the study, although they did not track which or how many individuals enrolled because of the campaign—due to patient privacy concerns.” *Id.*

<sup>71</sup> The site will “focus on patient privacy rights to connect patients, physicians and researchers with tailored information, tools and technology that will lead to

Even before PGT companies entered the fray, commentators had already begun considering the pros and cons of online targeted recruitment.<sup>72</sup> The proliferation of social networking sites offers researchers and research sponsors the opportunity to access databases of personal, genetic, and health-related information. Crowd-sourcing enables pharmaceutical companies to “get easy online access to highly engaged populations with specific medical conditions.”<sup>73</sup> Online recruitment allows potential participants who might never have heard about such studies otherwise, due to geography or other reasons, to decide whether enrollment is right for them. Social networking aids recruitment, as participants enlist others from among their connections within their network.<sup>74</sup>

Although many of the features of research resulting from PGT and social networking are new, a number of the underlying issues have been discussed at length in the context of biobanks.<sup>75</sup> Biobanks serve as repositories of biological specimens, which can be analyzed to identify gene variations associated with human diseases. Typically, samples are collected during routine clinical and surgical procedures<sup>76</sup>

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more informed decisions about patient care, including clinical trial participation industry-wide.” *Pfizer and Private Access Announce Plans to Develop Online Community to Accelerate Clinical Research*, BUSINESS WIRE (Aug. 19, 2009), <http://www.businesswire.com/news/home/20090819005806/en/Pfizer-Private-Access-Announce-Plans-Develop-Online>.

<sup>72</sup> In an in-depth piece in August 2009, the New York Times examined the practice of collecting patient data and genetic information online to use in recruiting patients for clinical trials, conducting research internally or to sell to drug and biotechnology companies. Sarah Arquist, *A Research Trove: Patients’ Online Data*, N.Y. TIMES, Aug. 25, 2009, at D1; see also Editorial, *Calling All Patients*, 26 NATURE BIOTECHNOLOGY 953 (2008).

<sup>73</sup> Kliff, *supra* note 62.

<sup>74</sup> Dan O’Connor, *Apomediation and the Significance of Online Social Networking*, AM. J. BIOETHICS, June 2009, at 25, 26.

<sup>75</sup> For comprehensive considerations of the legal and ethical issues as they relate to biobanks, see, e.g., Karen J. Maschke, *Biobanks: DNA and Research, in FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS* 11, 12-13 (Mary Crowley ed., 2008), available at [http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing\\_Book/biobanks%20dna%20and%20research.pdf](http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/biobanks%20dna%20and%20research.pdf); The National Bioethics Advisory Commission, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance* (Aug. 1999), available at <http://bioethics.georgetown.edu/nbac/hbm.pdf>; THE ETHICS OF RESEARCH BIOBANKING (Jan Heldge Solbakk, Soren Holm & Bjorn Hofmann, eds., 2009); ROBERT F. WEIR & ROBERT S. OLICK, *THE STORED TISSUE ISSUE: BIOMEDICAL RESEARCH, ETHICS, AND LAW IN THE ERA GENOMIC MEDICINE* (2004).

<sup>76</sup> Maschke, *supra* note 75, at 11 (citing ELISA EISEMAN & SUSANNE B. HAGA, *HANDBOOK OF HUMAN TISSUE SOURCES: A NATIONAL RESOURCE OF HUMAN TISSUE SAMPLES* (1999)).

or by research initiatives that collect, store, and distribute samples and data to researchers.<sup>77</sup> Recently, biotech companies have begun to build biobanks for the sole purpose of selling or licensing samples and data to researchers.<sup>78</sup> The circumstances by which samples are collected and obtained may shed new light on the gaps in regulation and law as they relate to these issues.

The move toward online collaboration and the “democratization” of data can be seen in the greater context of the transformation of the “networked information economy.”<sup>79</sup> The “basic change in the material conditions of information” due to the increase in electronic information sharing has been credited with shifting the role of the participant and rendering information communication collaborative instead of a single-direction endeavor.<sup>80</sup>

Ultimately, many of the PGT companies’ business models do not focus on profits from the sale of genetic tests, but from gathering the genetic and personal data that can be licensed and sold to institutions, academic researchers, or drug companies.<sup>81</sup> Thus, these companies’ mission statements, websites, and advertisements are potentially misleading, convincing PGT consumers that they are either (1) purchasing a recreational service to track ancestry or predisposition to genetic conditions, or (2) driving in-house research efforts to find cures and benefit society.

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<sup>77</sup> *Id.* For example, the author cites the Children’s Hospital of Philadelphia project to collect blood samples from more than 100,000 children as part of a genetic research initiative to study the most prevalent childhood diseases.

<sup>78</sup> See, e.g., Anita Huslin, *Firm Carves New Model in Biotech Research*, WASH. POST, Dec. 17, 2007, at D1.

<sup>79</sup> For example, intellectual property scholar Yochai Benkler is an advocate of collaborative research and peer production on the internet and discusses the networked information economy. See, e.g., Yochai Benkler, *Freedom in the Commons: Towards a Political Economy of Information*, 52 DUKE LAW J. 1245, 1246, 1251, 1255-56 (2003).

<sup>80</sup> *Id.* at 1250 (discussing the decentralizing of the distribution of information function). Benkler describes the “commons-based peer production” as “a process by which many individuals, whose actions are coordinated neither by managers nor by price signals in the market, contribute to a joint effort that effectively produces a unit of information or culture.” *Id.* at 1256.

<sup>81</sup> David P. Hamilton, *23andMe’s Price Cut: The End of Commercial Personal Genomics?*, BNET HEALTHCARE (Sept. 9, 2008), <http://industry.bnet.com/healthcare/1000151/23andmes-price-cut-the-end-of-commercial-personal-genomics/>. However, many companies’ business models focus on the money to be made from genetic genealogy and ancestry testing. Daniel MacArthur, *Cheap Personal Genomics: The Death-Knell for the Industry?*, WIRED.COM (Sept. 10, 2008, 11:58 AM), [http://scienceblogs.com/geneticfuture/2008/09/cheap\\_personal\\_genomics\\_the\\_de.php](http://scienceblogs.com/geneticfuture/2008/09/cheap_personal_genomics_the_de.php)

### III. SHIFTS IN RESEARCH STRUCTURE, TIMING, LOCUS, AND SCOPE

The concerns related to genome-wide research resulting from the PGT/social networking hybrid require thoughtful consideration, particularly in light of transformations in the way that research is done and how participants are recruited. The *where*, *when*, *who*, and *how* of research is shifting, intensified by the fact that all interactions between research participant and investigator occur online. Some of these shifts are considered below.

#### A. Shift in the Scope of Use of Genomic and Personal Data

Under the typical model for recruitment for clinical research, participants are enrolled in studies with an established and IRB-approved protocol, and when that study ends, they are no longer research participants. However, once a PGT company has access to one's genomic data and the results of surveys revealing physical, behavioral, and other personal information, it could ostensibly utilize that data in studies *ad infinitum*. Thus, potential participants will most likely not be signing on for a single, targeted test. Instead, participants' genetic and phenotypic data might be used for any number of studies, focused on any number of genetic traits or illnesses, and overseen and conducted by any number of investigators. As with biobanked data, the use of an individual's genomic and/or phenotypic information in innumerable studies that were not identified at the time of enrollment challenges current expectations of how research protocols are defined and what it means to participate in research.<sup>82</sup>

#### B. Shift in the Role of the Participant: Patient-Driven Research?

Many commentators have applauded the model of participant-driven research—research that is spurred by and recruited from members of online social networks—as “novel and powerful,” exclaiming that it will “increasingly come to dominate the genomic research land-

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<sup>82</sup> Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS), 72 Fed. Reg. 49,290, 49,291 (Aug. 28, 2007).

scape.”<sup>83</sup> Scholars may welcome the idea of patient-driven research as part of the “commons-based peer production of information [and] knowledge . . .,” which permits the “emergence of . . . radically new roles that individuals play in the production process.”<sup>84</sup> If 23andMe’s research agenda is successful in recruiting large numbers of participants, the initiative could set the stage for progress in terms of recruitment and enrollment.<sup>85</sup> Wojcicki described the shift to patient-driven research as “patient empowerment,” explaining that “[t]wenty years ago doctors had tight control over all medical information. We want that power to shift to individuals.”<sup>86</sup>

However, it is unclear that customers who contribute genetic and personal information for research purposes are “driving” research. Under 23andMe’s Research Revolution model, collaboration consisted of a simple “vote” for the disease on which research would be focused—a vote purchased with both cash and release of information including genetic data, physical traits, health history, and behavior. Thus, beyond contribution of genetic and phenotypic information, it is questionable that participants would truly be directing research. They did not have a say in the contours of the research or selection of the investigators who would conduct the studies. The power to make all these decisions remained in the hands of the research sponsor (in this case, 23andMe and its partners). Significantly, the fact that the research participants may never know how their information is being used in a particular study directly conflicts with the notion that participants are driving research. Thus, it is unclear whether this approach to genetic research is truly democratizing, or is simply an illusion of collective production.

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<sup>83</sup> Daniel MacArthur, *The Future of Participant-Driven Genomic Research*, WIRED.COM (Mar. 12, 2009, 1:10 PM), <http://www.wired.com/wiredscience/2009/03/The-future-of-participant-driven-genomic-research>.

<sup>84</sup> Benkler, *supra* note 79, at 1254-55.

<sup>85</sup> Daniel MacArthur, *23andMe Launches New Effort to Recruit Patients for Disease Gene Studies*, WIRED.COM (July 7, 2009, 8:00 PM), [http://scienceblogs.com/geneticfuture/2009/07/23andme\\_launches\\_new\\_effort\\_to.php](http://scienceblogs.com/geneticfuture/2009/07/23andme_launches_new_effort_to.php) (“Modern genomics studies require mind-bogglingly large numbers of samples to achieve the power required to find subtle genetic associations, and recruiting those numbers of patients is far from easy.”).

<sup>86</sup> *Getting Personal*, THE ECONOMIST, Apr. 18, 2009, at 9.

### C. Shift in the Role of the Participant: Participant Self-Organization and Self-Identification

As patients organize into online communities and self-identify for participation in research, recruitment and enrollment practices in clinical research may begin to transform.<sup>87</sup> For example, although research arising out of the PGT/social networking hybrid may not be as collaborative as the companies claim, the notion of having patients self-organize into an online community for a study may still elevate the participant to a position of greater authority.<sup>88</sup>

Moreover, self-selection may cause the breakdown of the screening process which has developed over the years to ensure the safety of participants as well as the reliability of the resulting data. With no one to screen participants for eligibility, the possibility of selection and attrition bias and mis- or over-reporting of symptoms and traits will likely increase, undermining the integrity of the data generated from such studies.<sup>89</sup> In fact, despite deCODE Genetics' apparent entry into the field of research in 2009, its CEO had publicly stated that such research may not be useful, because self-reported phenotypes are, by and large, unreliable.<sup>90</sup> In addition, self-organizing might be problematic because, where participants are also providing personal information, "[u]ser-generated data is highly variable and poorly controlled."<sup>91</sup> The head of exploratory clinical development at Novartis, Trevor Mundel, stated, "[i]t's something which hasn't been worked through, how [social networks] might worsen the accuracy of adverse-event reporting."<sup>92</sup> These concerns about accuracy are compounded by the fact that, in research arising from the PGT/social networking

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<sup>87</sup> Eric S. Lander, the Founding Director of the Broad Institute of MIT and Harvard, has stated that the idea of having patients "self-organize" into an online community for a study, rather than be recruited, is "a Googley thing to do." Pollack, *supra* note 14, at B9.

<sup>88</sup> It has been noted that investigators may not appreciate the "intrusion" of patients or patient advocates into their research. See *Do-it-Yourself Science*, 449 NATURE 755, 756 (2007).

<sup>89</sup> For example, as patients in the same study might communicate with and reveal significant information to one another on social networking sites, they could possibly deduce who is taking the test drug versus placebos. Kliff, *supra* note 62; see also Arnquist, *supra* note 72, at D6.

<sup>90</sup> Mark Henderson, *Cashing in on Your Genes: Will Personal DNA Testing Soon be Big Business and Will Our Genetic Data be Safe?*, TIMES (London) (Jan. 7, 2010), available at <http://www.timesonline.co.uk/tol/news/science/eureka/article6975520.ece?token=null&offset=0&page=1>.

<sup>91</sup> *Calling All Patients*, *supra* note 72.

<sup>92</sup> Kliff, *supra* note 62.

hybrid, research participants and investigators never meet, which may further transform how participants view their own role in the research and hinder investigators' ability to gauge the veracity of research subjects and the quality of the data.

#### D. Expectations of Care and Intensifying the Therapeutic Misconception

The marketing and promotion for initiatives like 23andMe's research agenda might mislead participants to think that, even if they may not benefit financially from their participation, they will benefit medically and therapeutically.<sup>93</sup> The promises of collaboration and democratization could exacerbate an already very real problem—the therapeutic misconception—that arises when research participants do not understand the distinction between treatment and research.<sup>94</sup> This is particularly relevant where companies have two primary and seemingly unrelated purposes: providing genetic and ancestry information to customers and developing research databases.<sup>95</sup> Currently, 23andMe, Pathway Genomics, TruGenetics, and even the PGP offer, or plan to offer, both genetic screening services *and* the opportunity to participate in genome-wide research. Critics of DTC genetic testing already point out that these companies may be overpromising the therapeutic advantages of these tests. When the therapeutic misconception is coupled with the promises of research—which is not intended to provide clinical benefits—participants may become further confused or misled as to the benefits of participation.

This confusion may intensify due to the lack of mandatory genetic counseling for participants. Only some PGT companies offer any genetic counseling services.<sup>96</sup> For many participants, there is no one to dispel the therapeutic misconception, particularly in the absence of

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<sup>93</sup> In the non-research context, most, if not all, PGT companies disclose the fact that customers should not expect medical benefits for their testing services, and that test results are no substitute for physician-provided medical care. However, in the research setting, the lines easily become more blurred.

<sup>94</sup> See Paul S. Appelbaum et al., *Therapeutic Misconception in Clinical Research: Frequency and Risk Factors*, 26 IRB: ETHICS & HUM. RES., Mar.-Apr. 2004, at 1, 1; Paul S. Appelbaum et al., *Correction and Clarification*, 26 IRB: ETHICS & HUM. RES., Sept.-Oct. 2004, at 18, 18.

<sup>95</sup> For example, TruGenetics declares that its services will “help you explore your genes.” *TruGenetics Process*, *supra* note 18. On a separate page, TruGenetics also states that “[o]ne of the main goals of TruGenetics is to develop a unique research database for conducting genetic studies.” *TruGenetics Terms & Conditions*, *supra* note 19.

<sup>96</sup> As of this writing, these companies include Navigenics, deCODE Genetics, Pathway Genomics, and 23andMe.

a physician-intermediary or investigator to explain test results, describe research protocols, and answer questions.

#### IV. LEGAL, ETHICAL, AND REGULATORY CONSIDERATIONS FOR RESEARCH

These shifts in *who*, *when*, *how*, and *where* give rise to a number of practical issues, and a thorough consideration of these shifts reveals gaps in the current regulatory and legal regime for protecting participants in research studies. In particular, the areas of concern include the informed consent process during recruitment and enrollment, lack of IRB oversight, and confused expectations related to therapeutic benefits. The regulatory checks and controls applied to other types of research may not be comprehensive or targeted enough to address the problems that arise out of social networking-based genetic research.

The well-known 2003 lawsuit between the Havasupai Tribe in Arizona and the Arizona Board of Regents and the University of Arizona and Arizona State University highlights some of the ethical issues related to the collection and use of DNA samples, even without the use of social networking technologies. Members of the tribe alleged that the defendants had used blood samples submitted solely for diabetes research for genetic research into schizophrenia, inbreeding, and ancient population migration.<sup>97</sup> Among a number of publications and research projects that relied on the misused data were four doctoral dissertations and a number of academic papers, many of which were completely unrelated to the research to which the Havasupai had agreed.<sup>98</sup> In April 2010, the University's Board of Regents settled, agreeing to pay \$700,000 to members of the tribe, return the blood samples obtained between 1990 and 1994, and provide other forms of assistance.<sup>99</sup>

Many of the ethical and legal considerations concerning the collection and use of genetic and phenotypic data—particularly those related to informed consent—become even more pronounced with

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<sup>97</sup> *Havasupai Tribe v. Ariz. Bd. of Regents*, 204 P.3d 1063, 1066 (Ariz. Ct. App. 2008). After the Arizona Court of Appeals ruled that the tribe could sue the Arizona Board of Regents and the Universities, the Arizona Supreme Court agreed to hear the appeal of one of the researchers. *Havasupai Tribe v. Ariz. Bd. of Regents*, No. CV-09-007-PR, 2009 Ariz. LEXIS 82 (Apr. 20, 2009).

<sup>98</sup> Of particular concern to the Havasupai Tribe was the fact that many of the papers related to theories about ancient human population migrations from Asia to North America, which is contrary to their belief that the tribe originated in the Grand Canyon. *Havasupai Tribe*, 201 P.3d at 1067.

<sup>99</sup> Amy Harmon, *Tribe Wins Fight to Limit Research of its DNA*, N.Y. TIMES, Apr. 22, 2010, at A1.

research conducted under genome-wide initiatives using online services. Some investigators have highlighted the implications of publishing and sharing aggregate genomic data, particularly considering that, despite aggregation, it may be possible to identify (or re-identify) an individual's genomic data within a large pool of data.<sup>100</sup> The authors of one article concluded that, “the policies and practices guiding genomic data sharing should continue to evolve in order to promote quality science, minimize duplicative research and merit the ongoing trust of the research subjects who consent to participate in scientific studies.”<sup>101</sup>

### A. Current Human Subjects Recruitment and Enrollment Law as it Applies to Social Networking-Based Genetic Research

Commentators have noted confusion about when the federal rules and regulations governing research with humans apply to research with biospecimens and the associated data.<sup>102</sup> Concerns about informed consent for participants in research arising from PGT databases are particularly acute, since empirical literature indicates that most people are willing to grant consent for genetic studies.<sup>103</sup> But, investigators are often not able—or not required—to obtain consent for use of collected or stored samples.

The Common Rule, the law governing human subject research in the United States for research conducted or supported by any of eighteen federal departments or agencies, regulates informed consent.<sup>104</sup>

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<sup>100</sup> Nils Homer et al., *Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays*, PLOS GENETICS 1, 2, 7, 9 (Aug. 2008), <http://www.plosgenetics.org/article/fetchObjectAttachment.action?uri=info%3Adoi%2F10.1371%2Fjournal.pgen.1000167&representation=PDF>; Kevin B. Jacobs et al., *A New Statistic and Its Power to Infer Membership is a Genome-Wide Association Study Using Genotype Frequencies*, 41 NATURE GENETICS 1253, 1253 (2009); Sriram Sankararaman et al., *Genomic Privacy and Limits of Individual Detection in a Pool*, 41 NATURE GENETICS 965, 965 (2009).

<sup>101</sup> Jacobs, *supra* note 100, at 1257.

<sup>102</sup> Maschke, *supra* note 75, at 11, 12-13 (“Some rules conflict with each other, and there are differences in how the rules define ‘research,’ ‘human subjects,’ and ‘identifiable’ personal information. How these terms are defined determines whether IRBs must approve biospecimen research, and whether individuals must give consent for use of their stored biospecimens or their identifiable genetic and other medical information.”).

<sup>103</sup> David Wendler, *One Time General Consent for Research on Biological Samples*, 332 BRIT. MED. J. 544, 547 (2006).

<sup>104</sup> See 45 C.F.R. § 46 (2010).

The Common Rule defines research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”<sup>105</sup> It requires that investigators explain to participants the purposes of their research, the mechanisms to ensure confidentiality, the existence of IRB oversight of the research protocol and consent process, and the risks of the research.<sup>106</sup> In terms of risk, there may be little individual physical risk in social networking-related genetic research because of the lack of clinical implications for the participant. However, individual informational risks and group harms are a very real possibility.<sup>107</sup> Population-based genomic research could lead to further stigmatization or discrimination against racial or ethnic groups.

Whether research utilizing biospecimens collected as part of a PGT service constitutes human subjects research under the Common Rule is unsettled.<sup>108</sup> Although, in some cases, even filling out a basic paper survey falls under the umbrella of research, survey procedures are exempt from the Common Rule, unless the information is directly or indirectly identifiable and any disclosure outside the research could reasonably place the subjects at risk of liability or be damaging to the subject’s financial standing, employability, or reputation.<sup>109</sup> However, contribution of biological samples and genetic information goes beyond simple survey procedures, and the revelation of personal behavioral and physical information as well as family history could easily affect employability and reputation. Guidance issued by the Office of Human Research Protections (OHRP) suggests that studies using samples that were not collected for the purpose of research “through an interaction or intervention with living individuals,” and for which “the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain,” do not constitute human subjects research.<sup>110</sup> However, com-

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<sup>105</sup> *Id.* § 46.102(d).

<sup>106</sup> *Id.* § 46.116.

<sup>107</sup> Laura M. Beskow et al., *Informed Consent for Population-Based Research Involving Genetics*, 286 JAMA 2315, 2318 (2001); Marc D. Schwartz et al., *Consent to the Use of Stored DNA for Genetics Research: A Survey of Attitudes in the Jewish Population*, 98 AM. J. MED. GENETICS 336, 336 (2001) (“[P]articipants were significantly less willing to participate in research that examined stereotypical or potentially stigmatizing traits as opposed to research that examined medical or mental illnesses.”).

<sup>108</sup> See Christian M. Simon et al., *Active Choice but Not Too Active: Public Perspectives on Biobank Consent Models*, 13 GENETICS MEDICINE 821, 821 (2011).

<sup>109</sup> 45 C.F.R. § 46.101(b)(2).

<sup>110</sup> OHRP, *Guidance on Research Involving Coded Private Information or Biological Specimens* (Oct. 16, 2008), available at <http://www.hhs.gov/ohrp/policy/cdebiol.html>; see also Human Subjects Research

mentators have noted that it is generally recognized that informed consent is necessary before an individual contributes biological samples for research.<sup>111</sup>

Recently proposed revisions by the Department of Health and Human Services (HHS) and the Office of Science and Technology Policy would do much to clarify the extent and scope of the Common Rule for research conducted using biospecimens.<sup>112</sup> The Advance Notice of Proposed Rulemaking (ANPRM) recommends the most substantive changes to the Common Rule in approximately twenty years, in response to the transforming and expanding research enterprise. Generally, it proposes a series of modifications in order to increase protections of research participants while reducing burden, delay, and ambiguity for investigators.<sup>113</sup> First, the ANPRM would expand the scope of the Common Rule's authority, applying the protections contained therein to all studies, regardless of funding source, that are conducted at United States institutions that receive some federal funding for human subjects research from a Common Rule department or agency.<sup>114</sup> Notably, it would extend the informed consent requirements for research on biospecimens and require that an individual give consent, in writing, for research use of their biospecimens.<sup>115</sup> However, the ANPRM envisions that consent may be one-time and general, rather than study specific, and would cover all future research.<sup>116</sup> At donation, individuals may choose not to sign a

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Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512, 44,519 (July 26, 2011) (acknowledging that "the current rules... allow research without consent when a biospecimen is used for research under conditions where the researcher does not possess information that would allow them to identify the person whose biospecimen is being studied.").

<sup>111</sup> Wendler, *supra* note 103, at 547.

<sup>112</sup> See Human Subjects Research Projections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. at 44,512. The ANPRM was issued, in part, in response to allegations that "uncertainty about the regulations on biospecimens has impeded research." Ezekiel Emanuel & Jerry Menikoff, *Reforming the Regulations Governing Research with Human Subjects*, 365 NEW ENGL. J. MED. 1145, 1148 (2011).

<sup>113</sup> See Human Subjects Research Projections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. at 44,512.

<sup>114</sup> *Id.* at 44,528.

<sup>115</sup> *Id.* at 44,515.

<sup>116</sup> In a comment addressing the ANPRM, the Secretary's Advisory Committee on Human Research Protections (SACHRP) advised against general consent for all future uses of biospecimens as a way to protect participants from harm. See Letter from Barbara E. Bierer, Chair, Secretary's Advisory Committee on Human Research Protections, to the Honorable Kathleen Sebelius, Secretary of Health and Human

standardized general consent form granting open-ended consent; in such cases, they may prohibit the use of their biospecimens for future research. Further, the proposed modifications would eliminate the distinction between research on biospecimens collected for research and nonresearch purposes.<sup>117</sup> This last point directly implicates research conducted on biospecimens collected through social networking PGT sites, as often these samples are not collected for the purpose of research, although the companies may then seek to use and share the data for that reason.

The Health Insurance Portability and Accountability Act (HIPAA) restricts how certain identifiable health information may be used and disclosed, including for research.<sup>118</sup> Genetic information is protected to some extent under HIPAA, after being amended by the Genetic Information Nondiscrimination Act (GINA) to include “genetic information” as “health information.”<sup>119</sup> However, anonymized biological material is not considered protected health information under HIPAA.<sup>120</sup> Because of the ease of re-identification

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Services 43-45 (Oct. 2011), [http://www.dfhcc.harvard.edu/fileadmin/DFHCC\\_Admin/Clinical\\_Trials/OPRS/Forms\\_Instructions/ANPRM/SACHRP\\_ANPRM\\_comment.pdf](http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/OPRS/Forms_Instructions/ANPRM/SACHRP_ANPRM_comment.pdf) (“[N]o researcher would have a reliable way of predicting, for purposes of informed consent adequate under the Common Rule, the full range of specific future uses of data and biospecimens that would be widely acceptable to American society in 25, 50, or 100 years; such a general future consent therefore could not be sufficient under the Common Rule to obviate the necessity, prior to a researcher’s undertaking a later specific study, of applying to an IRB for waiver of informed consent.”).

<sup>117</sup> Human Subjects Research Projections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. at 44,527.

<sup>118</sup> Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936, 2023. The HIPAA rules apply only to health plans, health-care clearinghouses, and certain health-care providers, and not all investigators are part of a covered entity. See Human Subjects Research Projections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. at 44,514. However, it has been argued that HIPAA is ineffective in protecting personally identifiable information (PII). See Arvind Narayanan & Vitaly Shmatikov, *Myths and Fallacies of “Personally Identifiable Information,”* COMM. ACM, June 2010, at 24, 26 (“PII has no meaning even in the context of the HIPAA Privacy Rule.”).

<sup>119</sup> Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, §1180, 122 Stat. 881, 904.

<sup>120</sup> In July 2010, the HHS proposed two new provisions to HIPAA intended to streamline the process for obtaining informed consent for clinical trial participation and authorization for use of protected patient data and biological materials. Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the HITECH Act; Proposed Rule, 75 Fed. Reg. 40,868 (proposed July 14, 2010) (to be codified at 45 C.F.R. pt. 164). The first provision allows for compound authorizations which would allow use of a single informed consent document for both enrollment in a

(and the “impossibility” of full de-identification) of biospecimens, the July 2011 ANPRM recommends adopting the HIPAA standards for purposes of the Common Rule regarding what constitutes individually identifiable information and de-identified information, and categorizing all research involving the collection of biospecimens as well as storage and secondary analysis of existing biospecimens as research involving identifiable information.<sup>121</sup>

To the extent they do not receive federal funds for research, companies like 23andMe are not covered by the Common Rule. If they intend to bring a product to market, however, PGT companies may be subject to the Food and Drug Administration (FDA) human subject protection requirements, which are similar to those enumerated in the Common Rule.<sup>122</sup> FDA regulations govern clinical studies submitted in marketing applications for new drugs and biological products and marketing applications and reclassification petitions for medical devices. Under FDA rules, there are eight basic elements of informed consent, including an explanation of the purposes of the research and the expected duration of participation, a description of the procedures to be followed, identification of any experimental procedures, a de-

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clinical trial and future research use of patient data and human tissue. *Id.* at 40,892. Under the proposed rule, HIPAA-covered entities could combine both conditioned and unconditioned authorizations, as long as the document clearly states that the individual may opt in to the unconditioned research activities. *Id.* The second provision would modify the HHS rule that authorization for future use of protected health information in research be study-specific. *Id.* at 40,893, 40,894. Moreover, in order to remain consistent with the Common Rule, SACHRP and the Institute of Medicine (IOM) have both recommended that HHS allow researchers to seek consent for future research if there is enough description of possible future uses in the document to allow for informed consent. Medical Research Law & Policy Report, *HIPAA Proposes Rule Change to Streamline Informed Consent, Authorization for Research*, 9 MRLR 441 (July 21, 2010).

<sup>121</sup> See Human Subjects Research Projections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. at 44,525. The ANPRM recognizes that advances in “genetic and information technolog[y] [have made] complete de-identification of biospecimens impossible and re-identification of sensitive health data easier.” See also Narayanan & Shmatikov, *supra* note 118, at 26 (“Unfortunately, advances in the art and science of re-identification, increasing economic incentives for potential attackers, and ready availability of personal information about millions of people (for example, in online social networks) are rapidly rendering [de-identification] obsolete.”). However, SACHRP does not endorse the assertion that biospecimens are inherently identifiable. Letter from Barbara E. Bierer to the Honorable Kathleen Sebelius, *supra* note 116 at 53.

<sup>122</sup> See 21 C.F.R. §§ 50, 56, 312, 812 (2011); see *Comparison of FDA and HHS Human Subject Protection Regulations*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationMaterials/ucm112910.htm> (last updated Mar. 10, 2009).

scription of foreseeable risk, appropriate alternative procedures or courses of treatment, and a statement of voluntariness.<sup>123</sup>

For example, the recruitment of research participants on social networking sites such as PatientsLikeMe, like in the case of Novartis' 2008 study for a multiple sclerosis drug, would be subject to FDA regulations.<sup>124</sup> The FDA considers direct advertising for study participants to be the start of the informed consent and recruitment/enrollment process, explaining that "[a]dvertisements should be reviewed and approved by the IRB as part of the package for initial review."<sup>125</sup> As noted above, however, in the studies proposed by companies like 23andMe, individuals may have been recruited, and have agreed to participate in hypothetical research, without any prior knowledge of how their genetic and phenotypic information will be used or who will be doing the research. Thus, they may already be "participating" in research (having submitted a biological sample and disclosed personal information and family history) *before* a protocol has been put in place. In those cases, there is no one to screen potential participants, no one responsible for the informed consent process, and personal data could presumably be used repeatedly in a number of different studies and scenarios.

Moreover, certain studies may not be subject to FDA oversight, as the agency's authority only covers trials relied upon to determine and establish a product's safety and efficacy<sup>126</sup>—not, for example, studies necessary for obtaining patent protections, Phase IV trials, or generally, where the company and/or sponsor are seeking to identify genetic predispositions to traits or illnesses but are not seeking to create

<sup>123</sup> 21 C.F.R. § 50.25.

<sup>124</sup> *A Safety and Efficacy Study of ELND002 in Patients with Relapsing Forms of Multiple Sclerosis*, PATIENTSLIKEME, [http://www.patientslikeme.com/clinical\\_trials/NCT01144351-MS-SPMS-RRMS-Relapsing-Forms-of-Secondary-Progressive-Multiple-Sclerosis-SPMS-or-Relapsing-Remitting-Multiple-Sclerosis-RRMS](http://www.patientslikeme.com/clinical_trials/NCT01144351-MS-SPMS-RRMS-Relapsing-Forms-of-Secondary-Progressive-Multiple-Sclerosis-SPMS-or-Relapsing-Remitting-Multiple-Sclerosis-RRMS) (last visited Sept. 17, 2009).

<sup>125</sup> *Recruiting Study Subjects—Information Sheet*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm> (last updated Oct. 18, 2010). FDA guidance makes clear that direct online advertising for potential clinical research participants is not per se objectionable: "IRB review and approval of listings of clinical trials on the internet would provide no additional safeguard and is not required when the system format limits the information provided to basic trial information, such as: the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information. Examples of clinical trial listing services that do not require prospective IRB approval include the National Cancer Institute's cancer clinical trial listing (PDQ) and the government-sponsored AIDS Clinical Trials Information Service (ACTIS)." *Id.*

<sup>126</sup> *Id.* § 54.2(e).

a drug or device that would require FDA approval.<sup>127</sup> Such gaps in the regulatory scheme are troubling.<sup>128</sup>

There is little relevant case law regarding informed consent and the donation of genetic data for research. It might be argued that sponsors of research have a duty to disclose the possibility that a customer's genetic information will be used for various and unpredictable research purposes which would lead to the inurement of the company. However, a federal district court declined to extend the duty of informed consent to cover disclosure of an investigator's financial interests in studies in which the participants' biological samples were used.<sup>129</sup>

### **B. Ensuring Informed Consent in Social Networking-Based Genetic Research**

In light of diverging and incomplete regulations, there is obvious disagreement regarding the method and structure of informed consent for genome-wide research, particularly research that originates from data collected via social networking by PGT companies. As noted above, the investigators, nature, purpose, and methods of future research may not be known or identified at the time samples are collected.<sup>130</sup> Even assuming that it is enough that participants sign an informed consent document, the issue of how far the consent can and should go still exists. To what may participants consent? Can they consent solely to research related to a specific illness? If so, should there be an opt-out option for certain types of research? Can participants give blanket consent covering all research utilizing their personal and genetic information? Or must participants be approached each time a new study is initiated? Empirical research suggests that, when participating in genetic studies, many people want to be asked to

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<sup>127</sup> See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-402, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 6 (2006), available at <http://www.gao.gov/new.items/d06402.pdf>.

<sup>128</sup> See Letter from Barbara E. Bierer to the Honorable Kathleen Sebelius, *supra* note 116 at 36 (providing a useful list of areas and types of research that are not currently subject to federal regulations that protect participants of research).

<sup>129</sup> *Greenberg v. Miami Children's Hosp. Research Inst.*, 264 F. Supp. 2d 1064, 1070 (S.D. Fla. 2003) (tissue and fluid donors accused the physician-investigator of failing to inform the donors that the hospital stood to benefit financially from the research on Caravan disease).

<sup>130</sup> See *id.* at 1069. For a thorough review of proposals for informed consent in data collection in biobanking, see also Elena Slavaterra et al., *Banking Together: A Unified Model of Informed Consent for Biobanking*, 9 EMBO REP. 307, 307-10 (2008).

be enrolled for each study or type of study.<sup>131</sup> However, re-contacting a large number of sample donors for consent may be impractical or even impossible.<sup>132</sup>

Commentators have noted the divergent informed consent practices in the United States for research conducted on biological samples.<sup>133</sup> Research reveals evidence that IRBs vary in their consent form requirements for genetic research.<sup>134</sup> A survey of thirty studies involving biospecimens determined that one-time general consent, with the requirement that an ethics committee reviews and approves future projects, is the “best option,” as it reflects the preference of most individuals.<sup>135</sup> Research has also demonstrated that potential participants would prefer a prospective opt-in consent approach, rather than an opt-out process.<sup>136</sup> Additionally, due to concerns about genomic privacy for those participating in research, commentators have advocated an open-consent framework.<sup>137</sup> At the very least, the

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<sup>131</sup> Darren Shickle, *The Consent Problem with DNA Biobanks*, 37 *STUD. HIST. & PHIL. BIOLOGICAL & BIOMEDICAL SCI.* 503, 513 (2006).

<sup>132</sup> See Paul S. Appelbaum, Professor, Columbia Univ., *Informed Consent: Recent Developments in Legal and Ethical Requirements for Data Collection and Use*, available at <http://www7.nationalacademies.org/cpop/Appelbaum%20Presentation.pdf> (last visited Sept. 17, 2009) (citing Shickle, *supra* note 131).

<sup>133</sup> Leslie E. Wolf & Bernard Lo, *Untapped Potential: IRB Guidance for the Ethical Research Use of Stored Biological Samples*, *IRB: ETHICS & HUM. RES.*, July-Aug. 2004, at 1, 1-2.

<sup>134</sup> See Mary T. White & Jennifer Gamm, *Informed Consent for Research on Stored Blood and Tissue Samples: A Survey of Institutional Review Board Practices*, 9 *ACCOUNTABILITY RES.* 1 (2002). The authors found greater attention to human subjects protection corresponding to the location of the IRB, the number of protocols evaluated each year, whether the IRB included a member with ethical expertise in genetics, and whether the IRB used both the IRB Guidebook and the National Bioethics Advisory Commission (NBAC) Report on Research Involving Human Biological Materials in its deliberations. *Id.* at 2, 13-15.

<sup>135</sup> Wendler, *supra* note 103, at 546. The author notes that although one-time general consent “does not allow people to control the projects for which their samples are used, there is no reason to think that they want to make such decisions.” *Id.* The author recommends six specific elements for the consent form and process: “request to obtain samples for future research; risks, if any; absence of direct benefits; information, if any, to be provided by individuals; reliance on ethics committees to review and approve future research provided it finds the research is ethical and poses no greater than minimal risk; and solicitation of individual questions.” *Id.* at 546-47. See also Simon, *supra* note 108, at 826 (finding that, in consenting to future research, participants prefer broad, research-unspecific consent over categorical and study specific consent models).

<sup>136</sup> Simon, *supra* note 108, at 826.

<sup>137</sup> See, e.g., Jeantine E. Lunshof et al., *From Genetic Privacy to Open Consent*, 9 *NATURE REV. GENETICS* 406, 409 (2008).

consent process, including consent forms, should address the possibility of data sharing.<sup>138</sup>

There is little evidence that PGT companies have devoted adequate time or energy to concerns regarding informed consent, and PGT companies seeking to collect and use individuals' genetic and phenotypic data have been reluctant to explicitly describe how consent to research would be ensured in all cases. Most of these companies' policies focus on the implications of testing and participating in the recreational aspects of their products, without considering, separately and thoroughly, the need for an informed consent process for research conducted as a result of an individual's participation in their services. In fact, it has been noted that the information provided in the PGT companies' documents "focus[es] on privacy protections, the corporate intent to give information but no diagnosis or health assessment, and the fact that data sharing is the responsibility of the individual," rather than focusing on the risks associated with the collection of data or the types of studies to be undertaken.<sup>139</sup> For example, users of deCODE Genetics' products are not required to sign a consent form, but are informed on the website that the "deCODEme genetic scan is for informational purposes only; it is not a medical test, and it is by no means a substitute for professional medical advice, genetic counseling, diagnosis, or treatment."<sup>140</sup> 23andMe does address informed consent for research,<sup>141</sup> albeit deficiently, by requiring that prior to having their sample processed, users must read and acknowledge an online "Consent and Legal Agreement" which discloses some, but not all, elements of informed consent (e.g., although it states that the company may enter into partnerships with both for-profit and nonprofit organizations for the purpose of scientific research, it does not provide a description of the research).<sup>142</sup> The Per-

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<sup>138</sup> See Susan Wallace et al., *Consent and Population Genomics: The Creation of Generic Tools*, IRB: ETHICS & HUMAN RES., Mar. 2009, at 15, 16.

<sup>139</sup> Karin Esposito & Kenneth Goodman, *Genethics 2.0: Phenotypes, Genotypes, and the Challenge of Databases Generated by Personal Genome Testing*, AM. J. BIOETHICS, July 2009, at 19, 20.

<sup>140</sup> *Frequently Asked Questions*, DECODEME, <http://www.decode.me/faq> (last visited Apr. 12, 2011).

<sup>141</sup> According to 23andMe, customers must agree to be involved in its 23andMe Research initiative. The "Consent and Legal Agreement" states that 23andMe will only provide individual level data to external researchers upon individual consent from each customer. *Consent Document*, *supra* note 59. In fact, a bill introduced in California, supported by 23andMe, would (among other things) require companies to obtain informed consent before using individuals' de-identified genetic data for research purposes. S.B 482, 2009-10 Reg. Sess. (Cal. 2009).

<sup>142</sup> *Consent Document*, *supra* note 59. Shortly before publication, 23andMe revised its privacy statement, with the support of a privacy-verifying consultant,

sonal Genome Project's two-step informed consent process involves detailed informed consent documents which are periodically updated; they include contact information for the primary investigator and others and more closely represent the framework for informed consent envisioned by the Common Rule.<sup>143</sup> Prospective participants must read, review, and electronically sign two different consent forms: (1) a "mini-consent" for eligibility screening procedures; and (2) the full consent for enrollment and ongoing participation.<sup>144</sup>

Even if PGT companies' forms and online policies made comprehensive disclosures as to the consequences of participation in research, the companies' approaches to informed consent would still be insufficient. Informed consent is best understood as a process, rather than a one-time occurrence where a simple form is read and signed, that obligates investigators to ensure that potential research participants appreciate and understand the risks, benefits, and alternatives to participating in research. Because informed consent often requires a meeting with a medical provider or someone involved in the research to explain the risks and implications of participation and answer ques-

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TrustE. *Privacy Highlights Page,* 23ANDME, <https://www.23andme.com/legal/privacy/> (last visited Dec. 9, 2011); *Summary of Changes to the 23andMe Privacy Statement,* 23ANDME, <https://www.23andme.com/you/faqwin/privacychanges/> (last visited Dec. 9, 2011). Of the substantive changes to the general privacy policy—as it applies to the collection and handling of personal information for recreational purposes, site use statistics, and customer testimonials—the company added one provision related to research, which allows third-party research consultants to do on-site research at 23andMe facilities, utilizing data from participants who have consented to 23andWe Research. *See also* Kashmir Hill, *Privacy Policy Changes Should be Crystal Clear, Especially When Your Genes are Involved*, FORBES.COM (Dec. 7, 2011, 12:05 PM), <http://www.forbes.com/sites/kashmirhill/2011/12/07/privacy-policy-changes-should-be-crystal-clear-especially-when-your-genetic-info-is-involved/>.

<sup>143</sup> *Current Consent Forms,* PERSONAL GENOME PROJECT, <http://www.personalgenomes.org/consent/> (last visited Oct. 23, 2011).

<sup>144</sup> *Participation Overview,* PERSONAL GENOME PROJECT, <http://www.personalgenomes.org/participate.html> (last updated Mar. 3, 2011); *see also Mini Consent Form,* PERSONAL GENOME PROJECT, [http://www.personalgenomes.org/consent/PGP\\_MiniConsent\\_Approved\\_02222011.pdf](http://www.personalgenomes.org/consent/PGP_MiniConsent_Approved_02222011.pdf) (last visited Oct. 23, 2011). The mini consent form discloses a principal investigator, and describes the purpose broadly, "to explore ways to connect human genetic information with human trait information (*i.e.*, human DNA sequence, medical information, tissue samples and physical traits) so that such data may be used for hypothesis-generating research and other scientific, clinical and commercial development efforts worldwide." *Id.* *Cf. Full Consent Form,* PERSONAL GENOME PROJECT, [http://www.personalgenomes.org/consent/PGP\\_Consent\\_Approved\\_02222011.pdf](http://www.personalgenomes.org/consent/PGP_Consent_Approved_02222011.pdf) (last visited Oct. 23, 2011).

tions,<sup>145</sup> only requiring participants to sign an online consent form before contributing to research may not be enough to meet the elements of the FDA regulations or the Common Rule. Most companies have not identified if and how they intend to follow up with participants (although TruGenetics has stated its intent to eventually share its discoveries),<sup>146</sup> how participants can ask questions or express concerns during the course of a study, or whether or when participants may withdraw from the research if they change their mind. Further consideration is needed to determine how best to disclose risks and benefits to customers so that they understand the implications and breadth of potential participation in research.

### C. IRB Oversight of Social Networking-Based Research: An “Unfortunate Loophole”

Where studies are subject to FDA regulations and the Common Rule, they must be approved by an IRB to assure that appropriate steps are taken to protect the rights and welfare of participants. However, many of the PGT companies have not publically identified an IRB for approval of their research protocols. Nor may companies be eager for IRB oversight; a bill supported by 23andMe that was introduced in the California legislature in April 2009 would explicitly not require companies to obtain IRB approval before conducting research using genetic data.<sup>147</sup> In cases where there is no IRB to oversee the informed consent process, there is little guarantee that research participants’ rights will be protected.

In March 2009, OHRP released its GINA Guidance<sup>148</sup> to clarify how GINA will affect genetic research that is conducted or supported

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<sup>145</sup> *Institutional Review Boards Frequently Asked Questions — Information Sheet*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm> (last updated Aug. 9, 2011) (“The entire informed consent process involves giving a subject adequate information concerning the study, providing adequate opportunity for the subject to consider all options, responding to the subject’s questions, ensuring that the subject has comprehended this information, obtaining the subject’s voluntary agreement to participate and, continuing to provide information as the subject or situation requires.”).

<sup>146</sup> *TruGenetics Terms & Conditions*, *supra* note 19.

<sup>147</sup> See S.B. 482, 2009-10 Reg. Sess. (Cal. 2009).

<sup>148</sup> GINA prohibits discrimination in health coverage and employment based on genetic information, with implications for disclosure and informed consent. Office for Human Research Prot., *Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards*, DEP’T HEALTH & HUMAN SERVS. 1-2 (Mar. 24, 2009), <http://www.hhs.gov/ohrp/policy/gina.pdf>. GINA

by HHS.<sup>149</sup> The Guidance provides nonbinding recommendations to researchers, emphasizing that investigators and IRBs should disclose reasonably foreseeable risks related to genetic research and not overstate the protections provided by GINA.<sup>150</sup> Investigators and IRBs must continue to vigilantly monitor how risks are described for genetic research, because GINA does not apply to life insurance, disability insurance, and long-term care insurance. For these types of insurance, providers may deny coverage or increase premiums based on known genetic predispositions. The Guidance recommends specific language for investigators and IRBs to include in informed consent documents. Further, the Guidance recommends that IRBs overseeing genetic research should also consider the provisions of GINA when assessing whether such research satisfies the criteria required for approval, keeping in mind that risks to subjects are minimized and reasonable in relation to anticipated benefits, and there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.<sup>151</sup>

When 23andMe sought publication of its GWAS on multiple traits using self-reported data via the internet, the journal *PLoS Genetics* delayed publication to consider the company's lack of IRB review.<sup>152</sup> 23andMe asserted that its study was exempted from review because it was not "human subjects research." In the same issue in which the final article appears, the journal's editors stated that, "[o]n the face of it, this seems preposterous, but on further review, this decision follows not uncommon practices by most scientists and institutional review boards, both academic and commercial, and is based on a guidance statement from [OHRP]."<sup>153</sup> The editors called this an "unfortu-

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went into effect for health insurance companies in May 2009 and for employers in November 2009. *Id.*

<sup>149</sup> GINA includes a "research exception" to the prohibition against requesting that an individual undergo a genetic test, which allows "a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan" to "request, but not require, and that a participant or beneficiary undergo a genetic test if" certain conditions are met. These conditions include that the research comply with the Common Rule, participation is voluntary, that the government is notified in writing of the research. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, §1180, 122 Stat. 881, 904.

<sup>150</sup> Office for Human Research Prot., *Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards*, DEP'T HEALTH & HUMAN SERVS. 5 (Mar. 24, 2009), <http://www.hhs.gov/ohrp/policy/gina.pdf>.

<sup>151</sup> *Id.*

<sup>152</sup> Gibson & Copenhaver, *supra* note 48.

<sup>153</sup> *Id.* (stating the two criteria that qualify research as human subject research: (1) "will the investigators obtain the data through intervention or interaction with the

nate loophole.”<sup>154</sup> The journal further required that the authors address their concerns about the consent process, and in response, 23andMe has fully engaged a formal IRB. In June 2010, 23andMe announced that it had received IRB approval for its research protocol and an accompanying revised consent document for its research intended for publication, although the company explicitly disavowed being required to do so.<sup>155</sup> In its announcement, the statement explained, “[b]ecause the 23andMe protocol excludes individual identifying information (e.g. name, email address, user ID, Password, payment information, etc.) and our analysts do not interact directly with customers during data collection, our research technically does not require IRB review.”<sup>156</sup>

## V. OWNERSHIP/INTELLECTUAL PROPERTY CONCERNS

Some of the policies listed on PGT companies’ websites are ambiguous as to ownership of the biospecimens or data collected for research.<sup>157</sup> For example, formerly, Pathway’s disclosures simply stated, “[y]our DNA and results belongs to you and no one else.”<sup>158</sup> Then, in what might have been a confusing switch for the consumer, the company asserted that it may use certain information that does not disclose the customer’s identity to conduct scientific and medical research, in collaboration with nonprofit or commercial organizations.<sup>159</sup>

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participants,” and (2) “will the identity of the subject be readily ascertained by the investigator or associated with the information.”) (citing Office for Human Research Prots., *Guidance on Research Involving Coded Private Information or Biological Specimens*, DEP’T HEALTH & HUMAN SERVS. 2 (Oct. 16, 2008), <http://www.hhs.gov/ohrp/policy/cdebiol.pdf>).

<sup>154</sup> *Id.* at 2.

<sup>155</sup> *23andMe Improves Research Consent Process*, THE SPITTOON (June 24, 2010), <http://spittoon.23andme.com/2010/06/24/23andme-improves-research-consent-process/>.

<sup>156</sup> *Id.* (alteration in original).

<sup>157</sup> The PGP, which has a different focus than the for-profit DTC genetic testing companies, clearly states, “[n]either you nor your heirs will gain financially from any discoveries, whether or not of a commercial nature, made using the information that you provide.” *Mini Consent Form*, *supra* note 144.

<sup>158</sup> Pascal Borry et al., *Preconceptional Genetic Carrier Testing: Direct-to-Consumers: The Appropriate Use of Existing Resources*, 26 HUM. REPROD. 972, 975 (2011) (linking readers to a since-modified website, *DNA Security*, PATHWAY GENOMICS, [http://web.archive.org/web/20100515174056/http://www.pathway.com/more\\_info/dna\\_security](http://web.archive.org/web/20100515174056/http://www.pathway.com/more_info/dna_security) (last visited Sept. 17, 2009) (accessed by searching for the URL on Internet Archive database)).

<sup>159</sup> *Privacy Policy*, PATHWAY GENOMICS, [http://web.archive.org/web/20090328011950/http://www.pathway.com/more\\_info/privacy](http://web.archive.org/web/20090328011950/http://www.pathway.com/more_info/privacy)

Generally, institutions have successfully claimed ownership of biospecimens. In the 1990 case *Moore v. Regents of the University of California*, the Supreme Court of California held that a patient with hairy cell leukemia had a cause of action against his physician based on a breach of fiduciary duty because the physician failed to disclose his intent to use portions of the plaintiff's spleen in research for which the physician hoped to benefit financially. However, the court even-

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vacuity\_policy (last updated Mar. 20, 2009) ("We may provide your Genetic Information and Survey-Based Information, unlinked from your name and Account Information, to research collaborators to conduct Pathway Genomics-authorized scientific research and development. *You cannot opt-out from this research.* We also may pass on to you a research collaborator's request that you volunteer additional information or participate in a study. No name or Account Information is shared with a research collaborator without your express consent.") (emphasis added) (accessed by searching for the URL on Internet Archive database). Later, the policy explained, "Pathway Genomics believes in furthering responsible scientific and medical research to improve our understanding of genetics and to assist physicians and other health-care professionals to provide better health care. Collaborations between Pathway Genomics and non-profit or commercial research organizations will be guided by a research advisory committee established by Pathway Genomics. Any research collaborator will first need to obtain permission from an appropriate Institutional Review Board." *Privacy Policy*, PATHWAY GENOMICS, [http://web.archive.org/web/20100405082115/http://www.pathway.com/more\\_info/privacy\\_policy](http://web.archive.org/web/20100405082115/http://www.pathway.com/more_info/privacy_policy) (last updated Dec. 21, 2009) (accessed by searching for the URL on Internet Archive database). This policy has subsequently been changed to what they refer to as an opt-in system, and now reads, "Pathway may want to work with other entities and organizations to conduct scientific research and other legitimate secondary purposes using the DNA obtained from your specimen. However none of your personal information will be shared for any secondary purpose outside the immediate control of Pathway, unless you expressly opt-in to authorize this.... We also may pass on to you a research collaborator's request that you volunteer additional information or participate in a study. No name or Account Information is shared with a research collaborator without your express consent and the research collaborator agreeing to comply with all appropriate privacy and information security laws and regulations to protect such personal information." *Privacy Policy*, PATHWAY GENOMICS, [https://www.pathway.com/more\\_info/privacy\\_policy](https://www.pathway.com/more_info/privacy_policy) (last updated Oct. 22, 2010). Similarly, 23andMe's privacy policy states, "[i]f you do not give consent for your Genetic and Self-Reported Information to be used in 23andWe Research, we may still use your Genetic and/or Self-Reported Information for R&D purposes... which may include disclosure of Aggregated Genetic and Self-Reported Information to third-party non-profit and/or commercial research partners who will not publish that information in a peer-reviewed scientific journal." *Privacy Highlights Page*, *supra* note 142. However, it continues, "[e]xcept as otherwise set forth herein, we will never release your individual-level Genetic and/or Self-Reported Information to a third party without asking for and receiving your explicit consent to do so, unless required by law." *Id.*

tually found that donors do not have an ownership interest in their cells after the cells have been removed from their bodies.<sup>160</sup>

In 2008, in *Washington University v. Catalona*, the Eighth Circuit upheld the lower court's decision that tissue and serum samples donated to Washington University could continue to be used by the institution for cancer research, despite the donors' wishes to transfer ownership of the samples to another research institution. The Court of Appeals stated that the "pivotal inquiry in this dispute" was "whether individuals who make an informed decision to contribute their biological materials voluntarily to a particular research institution for the purpose of medical research retain an ownership interest allowing the individuals to direct or authorize the transfer of such materials to a third party."<sup>161</sup> The Court held that "[u]nder the facts of this case, the answer is no."<sup>162</sup>

It is not unprecedented for companies to prevent others from studying or testing a gene for which they hold a patent. An ongoing lawsuit against Myriad Genetics has highlighted the controversy surrounding the U.S. Patent & Trademark Office (USPTO)'s permissive attitude toward gene sequence patents. In March 2010, the Southern District of New York held that isolated human genes were unpatentable subject matter, and invalidated Myriad's patent claims relating to the BRCA1 and BRCA2 genes.<sup>163</sup> In July 2011, the Court of Appeals partially reversed the lower court's decision, holding that isolated DNA is patentable because it is markedly different from the DNA as it exists within the body and is therefore not simply a product of na-

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<sup>160</sup> *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 493 (Cal. 1990). However, *Moore* has questionable application, because the relationship between the testing companies and the participants in these cases is not a therapeutic one, and because these PGT companies disclose to participants that they will not benefit financially. *Id.* at 483. However, to the extent that PGT companies are not explicit in their intent, it implicates the court's belief that Moore's physician's behavior was particularly egregious, as he actively misled Moore by telling him that the research team was "engaged in strictly academic and purely scientific medical research" and "there was no commercial or financial value to his Blood and Bodily Substances." *Id.* at 486. See also *Greenberg v. Miami Children's Hosp. Research Inst.*, 264 F. Supp. 2d 1064, 1073 (S.D. Fla. 2003) (tissue and fluid donors alleged that hospital had fraudulently concealed that it: (1) would economically benefit from the research; (2) would patent the Canavan gene mutation; and (3) would license the testing under the patent).

<sup>161</sup> *Wash. Univ. v. Catalona*, 490 F.3d 667, 673 (8th Cir. 2007). See also Lori Andrews, *Who Owns Your Body? A Patient's Perspective on Washington University v. Catalona*, J. L. MED. & ETHICS 398, 298 (2006).

<sup>162</sup> *Wash. Univ.*, 409 F.3d at 673.

<sup>163</sup> Whether genetic tests and diagnostic tools are patentable is at issue in the ACLU suit against the PTO and Myriad Genetics for Myriad's screening tests for the breast cancer genes, BRCA1 and BRCA2. See *Ass'n for Molecular Pathology v. USPTO*, 702 F. Supp. 2d 181, 222 (S.D.N.Y. 2010).

ture.<sup>164</sup> The Court upheld, however, the invalidity of the patent claim over the analytic process for examining and comparing genes to identify the BRCA mutations because it involved “patent-ineligible abstract[] mental steps.”<sup>165</sup> The case is being appealed.

It is foreseeable that contributors of genetic and biological data might assert a property right in applications or products that arise out of research. However, patient-driven research does not correlate to patient-owned results and products. Throughout the process of collecting data, developing diagnostic tools and tests, and designing treatments, applications, pharmaceuticals, or biologics, a number of products may become ripe for patenting, licensing, and marketing.<sup>166</sup> Based on the fine print found on PGT websites, it is often clear that the participant/consumer will not financially gain from his or her participation.

Despite claims of democratization and collaboration, both public and private companies assert that they themselves will retain and exercise the right to any property interest created by the research. These companies may, however, negotiate ownership and IP rights with their commercial partners, or deal the rights away to other third parties.

However, recent USPTO actions have indicated that collaborating in genetic research may constitute inventorship.<sup>167</sup> Initiatives such as the PGP will likely spur nonscientist collaborators to ask the USPTO to consider granting them joint inventorship. The partnership of social networking and genetic testing projects will certainly lead to a demand to expand the concept of joint inventorship. Even to the extent that participants do not have a legal right to the intellectual property arising out of research, participants may still expect or seek access to tests developed from the results of their contribution for a discount.

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<sup>164</sup> *Ass’n for Molecular Pathology v. USPTO*, 653 F.3d 1329, 1333-34 (Fed. Cir. 2011).

<sup>165</sup> *Id.* at 1334.

<sup>166</sup> For a thorough consideration of the issues related specifically to gene patenting, an area itself rife with issues, see Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 *YALE J. HEALTH POL’Y L. & ETHICS* 403, 403-04 (2005).

<sup>167</sup> See Jordan Paradise, *Patient Advocacy Group Collaboration in Genetic Research and the Scope of Joint Inventorship Under U.S. Patent Law*, 3 *INT’L J. INTELL. PROP. MGMT.* 97, 100, 104 (2009) (stating that the USPTO named a non-science advocate as a co-inventor on a patent for a disease gene).

### CONCLUSION

As the story of Lorenzo Odone exemplifies, research driven by patients' preferences and needs is not unique to genetic research arising out of social networking. Recent history is rife with individual initiatives, foundations, and companies dedicated to spurring research and finding cures. In 2003, the daughter of Hugh Rienhof, the founder of DNA Sciences and an advisor to biotech companies, was born with undiagnosed congenital defects.<sup>168</sup> He had her genes sequenced and shared information about her conditions and portions of her genetic information on the internet. The founder of PatientsLikeMe started the online company after his brother, Stephen Heywood, was diagnosed with Lou Gehrig's disease (both brothers had previously founded ALS TDF, a nonprofit biotechnology company and ALS research center). Stephen spent the last three years of his life on an experimental drug developed by ALS TDF.<sup>169</sup>

Initiatives such as the PGP are poised to compete with efforts by for-profit companies such as 23andMe.<sup>170</sup> Such competition is remi-

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<sup>168</sup> Brandan Maher, *Personal Genomics: His Daughter's DNA*, 449 NATURE 772, 773 (2007).

<sup>169</sup> *Stephen Heywood, 37, Dies; Master-Builder/Architect Subject of the 2006 Major Motion Picture So Much So Fast*, PATIENTSLIKEME (Nov. 30, 2006), [http://www.patientslikeme.com/press/20061130/1-stephen-heywood-37-dies-masterbuilder-architect-subject-of-the-2006-major-motion-picture-so-much-so-fast?disease\\_tag=hiv](http://www.patientslikeme.com/press/20061130/1-stephen-heywood-37-dies-masterbuilder-architect-subject-of-the-2006-major-motion-picture-so-much-so-fast?disease_tag=hiv).

<sup>170</sup> The PGP is by no means the only non-profit initiative focused on using genomics and social networking to identify diseases and pursue treatments. The Rare Genomics Institute (RGI)'s initiative is perhaps the most patient-driven of its kind. RGI, a nonprofit organization founded in 2011 that aims to "empower[] patient communities to accelerate research by helping fund and creating personalized research projects based on individuals with rare diseases," provides three interrelated services: (1) a "micro-funding website," an "online fundraising platform and social network that helps patient community raise funds"; (2) a researcher network, which provides access to genomics researchers who will sequence and analyze the patients' information; and (3) a clinical network, which connects "patients with clinicians and genetic counselors who will help interpret and translate the individualized research findings." *About Us*, THE RARE GENOMICS INSTITUTE, <http://www.raregenomics.org/about.php> (last visited Oct. 26, 2011). Thus, a patient diagnosed with a rare disease that is considered a good candidate for sequencing-based research is invited to create an online profile, tell his or her story, and upload pictures in an effort to raise funds to support the research. *For Patients*, THE RARE GENOMICS INSTITUTE, <http://www.raregenomics.org/patients.php> (last visited Oct. 26, 2011). RGI will then coordinate the use of these community-raised funds and anonymized rare disease patient genomes in research. Researchers who conduct research utilizing data provided by RGI may publish results, together with the organization. By using a crowd-funding approach to raise money for whole genome sequencing and analysis in children with rare or orphan genetic diseases, the organization hopes to contribute to a

niscent of the “race” between Craig Venter and the Human Genome Project (HGP), where privately-funded researchers (who are subject to different and, often less, regulation) forced a publicly-funded institution to compete, resulting in increased effectiveness and productivity on both sides.<sup>171</sup> In an ideal world, the contest to recruit volunteers to contribute genetic and other personal information would encourage research and competition to create diagnostics and treatments that will benefit society.<sup>172</sup>

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better understanding of diseases and the development of new treatments. Currently, the organization’s website does not contain any information regarding privacy or consent, but does state that “RGI will ensure that patient information is kept in the strictest confidence according to government regulations.” It continues, “[s]equences will only be made available to the research community once they have been completely anonymized.” *For Patients*, THE RARE GENOMICS INSTITUTE, <http://www.raregenomics.org/patients.php> (last visited Oct. 26, 2011). Further, RGI’s website contains the following disclaimer: “[a]ll the genome sequencing projects are for research informational purposes only and are subject to change. No medical medical [sic] advice, diagnosis or treatment are provided.” *For Donors*, THE RARE GENOMICS INSTITUTE, <http://www.raregenomics.org/donors.php> (last visited Oct. 26, 2011).

<sup>171</sup> See *Getting Personal: The Promise of Cheap Genome Sequencing*, *ECONOMIST*, Apr. 18, 2009, at 9, 10. The HGP sequenced the genome for \$4 billion, while Venter did it for \$100 million. *Id.* at 10.

<sup>172</sup> In a novel approach to genetic research and social networking, openSNP, a non-profit, open-source project founded in September 2011, seeks to allow customers of direct-to-customer genetic tests—currently, deCODE Genetics and 23andMe—to publish their raw data test results and phenotypes, characteristics, and traits, find others with similar genetic variations, and search primary literature on their variations and “help scientists to find new associations.” OPENSNP, <http://opensnp.org/> (last visited Oct. 28, 2011). Participants make their full genotypic raw data available online, which may be accessed via a mass download-function “to enable everybody to perform crowd-sourced association studies,” thereby “making science more open and accessible.” *For Scientists*, OPENSNP, <http://opensnp.org/> (last visited Oct. 28, 2011); *About*, OPENSNP, <http://opensnp.wordpress.com/about> (last visited Oct. 28, 2011); *5 Days After Launch—Time for Some More Information*, OPENSNP (Oct. 3, 2011), <http://opensnp.wordpress.com/2011/10/03/5-days-after-launch-%E2%80%93time-for-some-more-information/>. Future features to be added include social media efforts and support for *Family Tree DNA*, another service that provides DTC-testing. The organization describes 23andMe’s policy of not sharing its datasets with other researchers outside of 23andMe and their collaborators, and explains its decision to make such information public: “[w]hile there may be many valid reasons not to publish those datasets, we feel that research projects all over the world and science in general would benefit from such a rich source of linked, genetic data that is freely available.” *Welcome to openSNP*, OPENSNP (Sept. 26, 2011), <http://opensnp.wordpress.com/2011/09/26/welcome-to-opensnp/>. openSNP’s “disclaimer” describes the “possible risks and side-effects that can occur by making... genetical and medical information available on this platform,” including challenges to privacy (“[a]lthough you can upload your data using a pseudonym, there is no way to anonymously submit data”), confidentiality, and the potential for genetic discrimination. *Disclaimer*, OPENSNP, <http://opensnp.org/disclaimer> (last visited Oct. 28, 2011).

However, PGT companies that utilize online social networking technologies are ushering in a new model for human subjects research, one which our current laws, regulations, institutions, and IRBs may not be prepared to handle. PGT companies, despite good intentions, may not be in the best position to protect the needs, desires, and rights of customers who choose to participate in research initiatives. These companies often blur the line between the recreational and the clinical, and individuals may not be fully informed of the risks and benefits of participating in research advanced by PGT companies. In fact, one of the most challenging aspects of the hybrid of PGT and social networking is the fact that customers may become research participants without full knowledge or understanding of the transformation of their roles. In order to ensure the appropriate use of PGT sites for recruiting purposes, transparency in partnerships between pharmaceutical companies and PGT providers is necessary, so that users understand the nature of the relationships and how they fit in.

A greater focus on regulation of the PGT/social networking hybrid model for research is essential. A deliberate evaluation of the application of existing laws and a consideration of new ones is needed in order to find a balance between efficient research using personal and genetic information with the long-term interests and values of individuals. Our first approach should be a reconsideration of how our current consent model applies to social networking-based genetic research. Recent publications of GWAS by PGT companies have intensified the need for a consistent and standardized informed consent process. Obtaining more adequate, honest, and complete consent from participants would be most effective at the time of initial contribution of information, although in some circumstances, re-consent may be required. Further, clarifying (and if necessary, extending, regardless of funding source) the reach of the Common Rule to crowd-sourced genetic research would help to ensure the protection of all participants.