REDEEMING THE GENETIC GROUPON: EFFICACY, ETHICS, AND EXPLOITATION IN MARKETING DNA TO THE MASSES

Jessica D. Gabel[*]

[*] Assistant Professor of Law, Georgia State University College of Law. I thank Leslie Wolf and Paul Lombardo for their ongoing advice and support. I also owe debts of gratitude to my talented research assistant, Ashley Champion, for her superb research and dedicated editing and to Michelle Williams for her FDA expertise.

INTRODUCTION: ANOTHER BRICK IN THE WALL

Have you ever wondered whether you are related to a famous historical figure? Do you have questions about your ancestral lineage or family tree? Would you like to know if you are at risk for a serious disease? As advertised, genetic testing holds the key to unlocking those questions. From mild curiosities to very sober considerations, more Americans have taken steps to crack open their genetic codes and obtain information on everything from global origins to drug interactions and inherited illness mutations.[1] The idiosyncrasies and unique characteristics revealed by these tests lend more validation to the notion that we are more than just another brick in the wall.

Until recently, this need-to-know consumer attitude largely remained an untapped corner of the genetic marketplace. The staple genetic tests—paternity and forensic DNA testing[2]—dominated the field and occasionally garnered the interest of the American public.[3] A few health care providers began to shine some light on this unused corner of the marketplace by using genetic tests to offer their patients insight into current or future illnesses and even discover potential maladies awaiting unborn

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[1] *See* 23ANDME, https://www.23andme.com (last visited Jan. 2, 2012) [hereinafter 23ANDME].

[2] Forensic genetic testing is used in criminal cases to identify offenders and victims based on DNA evidence. MICHAEL NEWTON, THE ENCYCLOPEDIA OF HIGH-TECH CRIME AND CRIME-FIGHTING: FROM AIRPORT SECURITY TO THE ZYX COMPUTER VIRUS 92 (2004).

[3] The cases of O.J. Simpson and Anna Nicole Smith serve as prime examples. The genetic issues presented in both the Simpson case (whether O.J. Simpson's DNA was left at the crime scene by O.J. or planted by scheming LAPD detectives) and the Smith case (the paternity of her child revealed after her death) captured the nation's attention. Ironically, Simpson and Smith crossed paths when it was rumored that Simpson was among the possible candidates who could have fathered Smith's child. *See* Richard Johnson, Paula Froelich & Corynne Steindler, *O.J. A Smith Dad Candidate*, N.Y. POST, Mar. 7, 2007, http://www.nypost.com/p/pagesix/item_CPsHhDua3ibqh4CW6ym2gP.

children.[4] What was once the exclusive province of the legal system (paternity, forensic DNA) and health care providers, however, has now become as easy as buying a book on Amazon.com.

Indeed, the availability of direct-to-consumer genetic testing has skyrocketed in comparison to its non-existence only a decade ago. No longer in its infancy, these commercially available genetic tests offer a wide range of services to consumers beyond disease prediction, including intelligence measurements,[5] compatible mate matching,[6] and "DNA Tribe" identification, a growing number of individuals send their DNA samples to these companies with little understanding of the scope of their consent or whether they maintain any rights or interest in their DNA.[7] Moreover, the accuracy and reliability of such services largely remains untested.[8]

To be sure, the amenities these companies offer—to know the unknown and be empowered with one's own crystal ball—are appealing. Yet, in addition to considering the easy questions at the outset of this Article, I submit that most consumers do not consider that these companies are first-and-foremost, for-profit enterprises that essentially go unregulated by law or medical guidelines. In order to stay in business, direct-to-consumer genetic testing outfits must continuously attract more customers, often by offering flashy services.[9] Profits and survivability dictate the need for mass appeal, and to achieve a consumer attitude that seeks

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[4] Jonathan M. Gitlin, *Direct to Consumer Genetic Testing Raises Concerns*, ARS TECHNICA, Apr. 4, 2008, http://arstechnica.com/science/news/2008/04/direct-to-consumer-genetic-testing-raises-concerns.ars.

[5] *See* 23ANDME, *supra* note 1.

[6] Catherine Holahan, *So I Married an Avatar,* BUSINESSWEEK (Feb. 14, 2008, 4:38 PM), http://www.businessweek.com/technology/content/feb2008/tc20080214_131079.htm

[7] *See* Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990).

[8] Judy Foreman, *You Can Buy a DNA Test, But Beware*, BOS. GLOBE, Aug. 7, 2006, http://www.boston.com/news/science/articles/2006/08/07/you_can_buy_a_dna_test_but_beware/ (noting the law regulates the laboratories doing the testing, but doesn't address the clinical validity of the tests themselves).

[9] For example, 23andMe offers services purporting to allow you to "grow your family tree," "explore the world of your early ancestors," *Ancestry*, 23ANDME, https://www.23andme.com/ancestry (last visited Jan. 2, 2012), and "be on the lookout now" for health risks. *Health*, 23ANDME, https://www.23andme.com/health (last visited Jan. 2, 2012).

answers through DNA, the costs have become more affordable. Affordability essentially gives rise to a "Genetic Groupon"[10] of sorts—easily accessible by signing up online and sending in a swab of your own DNA on a Q-tip.[11]

Perhaps lost in the glitz and glamour of obtaining a personalized genetic report card is the larger process that engulfs the purchased product and generally operates without the consumer's full knowledge or cognizance. This intricate process runs much like any other commercial transaction: attractive advertising, the purchase of a product, delivery of results, online consumer account activity, and the sales-related research.[12] There is nothing inherently suspect with this—a process that is axiomatic to our almost ubiquitous free market system.[13] After all, if someone wanted to buy a book titled *To Test or Not To Test: A Guide to Genetic Screening and Risk*[14] on Amazon, the method would be much the same: advertising, purchase, delivery, and the use of sales information for market research.[15]

The difference, however, is that paying for a genetic test is more than merely buying your body's instruction manual. It is a deeply personal chronicle of who a person is and who he or she might become. But is it an accurate biography or a work of fiction?[16] Because of this, genetic profiteering runs the risk of generating genetic *misinformation*. Does the provider equip the consumer with enough information to discern whether results are

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[10] Groupon is a portmanteau derived from "group coupon" and also a website which sells discounted gift certificates, emulating a group rate discount. Here it is used to describe the boom in business created by newly affordable at home genetic testing kits.

[11] *See, e.g.*, THE GENETICS AND PUBLIC POLICY CENTER, DTC GENETIC TESTING COMPANIES (2010), http://www.dnapolicy.org/resources/AlphabetizedDTCGenetic TestingCompanies.pdf.

[12] *See Help: Privacy Notice*, AMAZON.COM, http://www.amazon.com/gp/help/customer/display.html/ref=hp_468496_conditions?nodeId=468496&#gather (last visited Jan. 2, 2012).

[13] *Id.*

[14] DORIS TEICHLER ZALLEN, TO TEST OR NOT TO TEST: A GUIDE TO GENETIC SCREENING AND RISK (2008).

[15] *See* AMAZON.COM, *supra* note 12 ("We use the information that you provide for such purposes as responding to your requests, customizing future shopping for you, improving our stores, and communicating with you.").

[16] *See, e.g.*, Jason Kincaid, *23andMe Sends Wrong DNA Test Results to 96 Customers*, TECHCRUNCH, June 7, 2010, http://techcrunch.com/2010/06/07/23andme-sends-wrong-dna-test-results-to-96-customers/.

uncertain or inevitable?[17] When the news may impact the consumer's quality of life (such as the decision to have children or have preventative surgery), does the provider offer genetic counseling or steer the consumer to those who can offer those services?[18]

Although primary, these immediate considerations do not include issues regarding the downstream uses of the genetic information. In addition to collecting DNA samples and processing the biological material to generate an end product for the consumer, companies may also collect additional information that includes self-reported data that the consumer provides, such as health, ethnic, and other personal facts.[19] The provider may also keep records of a person's usage patterns of the company's website.[20] Third parties may also receive some of the information—ostensibly stripped of identifying indicators—to use for undisclosed research purposes.[21] Of course, each company has

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[17] *See* Gaia Bernstein, *Direct-to-Consumer Genetic Testing: Gatekeeping the Production of Genetic Information*, 79 UMKC L. REV. 283, 291 (2010) (pointing out that a positive test result may be given more weight than is merited).

[18] For example, 23andMe's "Terms of Service" expressly state:

> Once you obtain your Genetic Information, the knowledge is irrevocable. You should not assume that any information we may be able to provide to you, whether now or as genetic research advances, will be welcome or positive. You should also understand that as research advances, in order for you to assess the meaning of your DNA in the context of such advances, you may need to obtain further services from 23andMe or from your physician or other health care provider. . . . You may learn information about yourself that you do not anticipate. This information may evoke strong emotions and has the potential to alter your life and worldview. You may discover things about yourself that trouble you and that you may not have the ability to control or change (e.g., your father is not genetically your father, surprising facts related to your ancestry, or that someone with your genotype may have a higher than average chance of developing a specific condition or disease). These outcomes could have social, legal, or economic implications.

Terms of Service, 23ANDME, https://www.23andme.com/about/tos/ (last visited Jan. 2, 2012).

[19] *See, e.g.*, *Consent Document*, 23ANDME, https://www.23andme.com/about/consent/ (last visited Jan. 2, 2012) ("By participating in this study, you are agreeing to allow us to use your genetic data, survey responses and any other non-identifying data for research on genetic markers associated with traits, disease and other physical conditions.").

[20] *Id.*

[21] *Id.*

a detailed consent page with numerous conditions and clauses that legally protect the company. But who protects the consumer?

As the industry currently stands, Genetic Groupons over promise and under deliver. In this Article, I will discuss the ethical implications of marketing DNA to the masses and the need for balanced regulatory oversight. First, I follow the evolution of genetic services, from the educational and medical mainstays to the current regulatory scheme that applies to them. Second, this Article considers the predictive and predatory capabilities of "DIY DNA,"[22] where customers collect and mail in their own DNA swabs for various services. In this Section, I consider the seemingly incongruous dynamic between the consumer's interests in knowledge, convenience, privacy, and accuracy and the corporate interest in profit and productivity. In the final Section, I discuss the regulatory scheme that must be considered with Genetic Groupons. Although currently untouched by the FDA and ignored by the FTC, there is room for regulation that encourages innovation, protects privacy, delivers scientifically defensible results, and of course, allows profit. Genetic information may seem like numbers on a license plate, but as the industry grows so must the education and safeguards that accompany it. When new technology develops at an astonishing pace, the law is often slow (and even ill-equipped) to respond. But when that technology involves private genetic information, the law cannot afford to be either lethargic or ignorant.

I. COMFORTABLY NUMB: ACCEPTING THE GENETIC REVOLUTION

Going off to college promises a host of new experiences—independence, ramen noodles, and communal bathrooms are classic elements of this coming of age event. Admittedly, late night fast food runs and drinking too much also come with the territory for many coeds. With this newfound independence and responsibility, however, come the realities of autonomy: dealing with roommates, splitting bills, and sharing a space built for one with three other people. In some ways, college demands that you

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[22] Marcus Wohlsen, *Do It Yourself DNA: Amateurs Trying Genetic Engineering At Home*, HUFFINGTON POST (Dec. 25, 2008, 9:38 PM), http://www.huffingtonpost.com/2008/12/25/do-it-yourself-dna-amateu_n_153489.html.

relinquish some personal space—in addition to fees, tuition, room and board—for this degree-fetching experience. But what if students also have to provide a DNA sample when registering? Recently, the University of California, Berkeley asked its incoming freshmen to submit their DNA (in addition to tuition, room and board) so that the school could analyze those samples for three genes that regulate alcohol, lactose, and folate metabolization.[23]

The unusual request was made as part of a "mass genetic testing" project engineered by Berkeley scientists.[24] The project targeted those specific genes not to determine health risks, but to use "nutritional genomics" to help students (in a somewhat Orwellian fashion) "lead healthier lives by drinking less, avoiding dairy products or eating more leafy green vegetables."[25] Framed as a "common intellectual experience" that could be shared by new students, the testing of the incoming 2010 freshman class—termed "Bring Your Genes to Cal"—was both voluntary and confidential, and students under the age of 18 were required to obtain parental consent before submitting their DNA.[26] The results would then be delivered through a campus-wide lecture to discuss the three genetic markers.[27] Berkeley sweetened the testing by creating a contest whereby students could "submit creative entries on the theme" for the opportunity to win genetic testing from 23andMe.[28]

Despite the promise of confidential results reporting and the use of informed consent documents, the project received more criticism than praise.[29] Some assailed the testing for its lack of

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[23] Tamar Lewin, *College Bound, DNA Swabs in Hand*, N.Y. TIMES, May 19, 2010, at A14, *available at* http://www.nytimes.com/2010/05/19/education/19dna.html?sq=College%20bound,%20dna%20swab%20in%20hand&st=cse&adxnnl=1&scp=1&adxnnlx=1305832168-2ozR3CkIu9b3h2APlvG/1Q.

[24] *Id.*

[25] *Id.*

[26] *Id.* The DNA testing offered at Berkeley was part of a program—On the Same Page—which normally provided incoming freshmen and transfer students with the same book or DVD once they matriculated so that it could be discussed after the start of classes in the fall. Robert Sanders, *UC Berkeley Alters DNA Testing Program*, BERKELEY NEWS CTR. (Aug. 12, 2010), http://newscenter.berkeley.edu/2010/08/12/dna_change/.

[27] Lewin, *supra* note 23.

[28] *Id.*

[29] *Id.*

counseling support subsequent to receiving results.[30] Berkeley professors attempted to mitigate the rising discontent by labeling the testing to be a "relatively harmless" endeavor, but critics posited that all genetic knowledge carries risk.[31] Indeed, one bioethicist noted that testing for the presence of an alcohol tolerance gene is anything but innocuous information: "What if someone tests negative, and they don't have the marker, so they think that means they can drink more?"[32]

Amid these concerns, roughly 600 of the 5000 incoming students offered up a saliva sample before the California Department of Public Health effectively shut the project down.[33] The CDPH determined that if students were to receive access to their own test results, the "academic exercise" must comply with laws that required "accuracy and quality of diagnostic tests used in providing medical care to patients."[34] At CDPH's request, Berkeley made the decision to limit the research to a macro-analysis and not provide individual results to the students.[35] The university still held its discussion of personalized medicine in the fall of 2010.[36] Not surprisingly, the project's organizers focused the program "on the politics of genetic testing and whether individuals, rather than physicians and public agencies, ultimately control their own genetic information . . . ."[37]

Whether this brand of personalized medicine/vulnerability assessment will be attempted at other universities remains unknown. It certainly would have given students some common ground as the largest mass direct-to-consumer genetics testing endeavor. But Berkeley's concession might best be summed up by

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[30] *Id.*

[31] *Id.*

[32] *Id.*

[33] Sanders, *supra* note 26.

[34] *Id.* The CDPH pointed to the federal Clinical Laboratory Improvement Amendments (CLIA) and the California Business and Professions Code, both of which dictate that genetic testing performed in medical diagnostic laboratories be certified for accuracy and reliability. *Id.*

[35] *Id.*

[36] *See Events*, ON THE SAME PAGE, http://onthesamepage.berkeley.edu/archive/2010-genes/events.php (last visited Jan. 2, 2012). A video of one of the events, a lecture by Professor Jasper Rine, is also available. *See Looking for the Good News in Your Genome*, YOUTUBE (Sept. 18, 2010), http://www.youtube.com/watch?v=jycPMwbZwUw&feature=youtube_gdata_player.

[37] Sanders, *supra* note 26.

its website's candor: "Keep in mind that technology can advance faster than cultures respond."[38] Despite the project's rapid retreat under fire, it signifies a wider genetic liberation front. Opponents worry, among other things, about the erosion of privacy and the need for reliability and counseling with such programs.[39] Proponents would say that this is merely the logical extension of the work begun centuries ago.[40] Whether logic alone justifies such an extension and whether progress should be tempered by ethical considerations are whole other matters entirely.

A. The Early Years: From Peas to Genes

What is the risk of mainstreaming our genetic information? Although it seems that we break new genetic ground frequently, the science itself is well past its infancy stage. From Gregor Mendel's work in pea plant hybridization in the 1860s to Watson and Crick's discovery of the double-helix structure of the DNA molecule in 1953, the building blocks of life have spawned a vast array of research.[41] While the more familiar applications of genetics (i.e., those featured by the news media and in popular culture) include paternity testing and forensic DNA used in criminal investigations,[42] the field of genetics is robust and varied. Originally a discipline that focused on inheritance, genetics has now evolved to encompass routine applications such as human health research and disease epidemiology.[43] Genetics also

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[38] *Frequently Asked Questions*, ON THE SAME PAGE, http://onthesamepage.berkeley.edu/archive/2010-genes/faq.php (last visited Jan. 2, 2012).

[39] Larry Gordon, *U.C. Berkeley Adjusts Freshman Orientation's Gene-Testing Program*, L.A. TIMES (Aug. 13, 2010), http://articles.latimes.com/2010/aug/13/local/la-me-dna-20100813; Sanders, *supra* note 26.

[40] *See* Asad Ramzanali, Op-Ed., *Don't Attack UC Berkeley's Pursuit of Science*, DAILY BRUIN (May 26, 2010, 9:00PM), http://www.dailybruin.com/index.php/article/2010/05/dont-attack-uc-berkeleys-pursuit-science.

[41] James Watson & Frederick Crick, *A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737-38 (1953), *available at* http://www.nature.com/nature/dna50/watsoncrick.pdf.

[42] *See* Jessica D. Gabel, *Probable Cause From Probable Bonds: A Genetic Tattle Tale Based on Familial DNA*, 21 HASTINGS WOMEN'S L.J. 3, 5 (2010) (discussing the rising popularity of DNA, from forensic analysis and paternity testing to popular television shows).

[43] AN INTRODUCTION TO GENETIC EPIDEMIOLOGY 5-6 (Lyle J. Palmer et al. eds., 2011).

encompasses subspecialties such as pharmacogenetics, population genetics, and migration pattern analysis.[44]

Consequently, it is no wonder that science has been enamored with our genetic underpinnings for decades. The questions over what makes us tick resound on more than just a molecular level. It is an innate human condition to probe our individual origins and our personal peculiarities.[45] While the answers are often found in our cultural and historical records, they also exist in our genetic fiber, and scientists have long attempted to connect the dots biologically.[46] In 2003, the Human Genome Project (HGP) completed the map of the entire genome.[47] Launched in 1990, the U.S. Department of Energy and the National Human Genome Research Institute (part of the National Institutes of Health) coordinated the HGP along with the United Kingdom's Wellcome Trust and other international contributors.[48] "The international effort to sequence the [human genome's] 3 billion DNA letters . . . [constituted] one the most ambitious scientific undertakings of all time, even compared to splitting the atom or going to the moon."[49] Whether or not that claim holds up, the HGP's accomplishments are undeniable: identification of *all* the nearly 30,000 genes in human DNA.[50]

Although its primary objective has been met, the HGP's work is ongoing and uncovering new corridors at each turn.[51] Scientists hewed the new genomic data at an astonishing pace. For example, when the Human Genome Project began in 1990, scientists had

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[44] QUALITY ISSUES IN CLINICAL GENETIC SERVICES 206 (Ulf Kristoffersson et al. eds., 2010).

[45] Tudor Parfitt & Yulia Egorova, GENETICS, MASS MEDIA AND IDENTITY: A CASE STUDY OF GENETIC RESEARCH ON THE LEMBA AND BENE ISRAEL 17 (2006).

[46] *Id.*

[47] *International Consortium Completes Human Genome Project*, HUM. GENOME PROJECT INFO. (Apr. 14, 2003), http://www.ornl.gov/sci/techresources/Human_Genome/project/50yr/press4_2003.shtml.

[48] *Id.*

[49] *Id.*

[50] *See generally* HUM. GENOME PROJECT INFO., http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml (last visited Jan. 2, 2012).

[51] *See The Science Behind the Human Genome Project: Basic Genetics, Genome Draft Sequence, and Post-Genome Science*, HUM. GENOME PROJECT INFO., http://www.ornl.gov/sci/techresources/Human_Genome/project/info.shtml#posthgp (last visited Jan. 2, 2012) (describing the new challenge as being to use the new "reservoir of data to explore how DNA and proteins work with each other").

only been able to isolate about 100 human disease genes.[52] Today, researchers have identified more than 4000 diseases that are caused by genetic variants.[53] Because what can best be described as a Genetic Revolution brought about such powerful information for individuals, families, and society at large, the impact of the Human Genome Project transcends laboratory analysis. In respect of the enormity of their responsibility, the HGP researchers took care to also study the impact that mapping our entire genome might have beyond its scientific significance.[54]

Under the guidance—and perhaps insistence—of Dr. Watson (yes, the Watson of Watson and Crick fame), the HGP broke new ground by dedicating a sizeable chunk of its budget for research regarding the ethical, legal, and social implications (ELSI) of this work.[55] Both the NHGRI and DOE each committed "3 to 5 percent of their genome budgets to study how the exponential increase in knowledge about human genetic make-up may affect individuals, institutions and society."[56] The research included more than just impact studies and anecdotal statistics. ELSI research also developed model legislation that would prohibit discrimination based on genetic information.[57] From that, more than forty states and the federal government have passed genetic non-discrimination bills.[58]

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[52] *International Consortium Completes Human Genome Project: All Goals Achieved; New Vision for Genome Research Unveiled*, NAT'L HUM. GENOME RES. INST. (Apr. 14, 2003), http://www.genome.gov/11006929.

[53] *About Genelink Biosciences*, GENELINK BIOSCIENCES, http://genelinkbio.com/about/ (last visited Jan. 2, 2012).

[54] *See Ethical, Legal, and Social Issues*, HUM. GENOME PROJECT INFO., http://www.ornl.gov/sci/techresources/Human_Genome/elsi/elsi.shtml (last visited Jan. 2, 2012).

[55] *Id.*

[56] NAT'L HUM. GENOME RES. INST., *supra* note 52.

[57] *Breaking News: GINA Becomes Law May 2008*, HUM. GENOME PROJECT INFO., http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml (last visited Jan. 2, 2012).

[58] Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. § 2000 (2008); ALA. CODE §§ 27-53-1 to -4 (1997); GA. CODE ANN. § 33-54-1 to -8 (1995). For a comprehensive listing of states which have enacted anti-discrimination statutes, see *Genetics and Health Insurance State Anti-Discrimination Laws*, NAT'L CONF. OF ST. LEGISLATURES (2008), http://www.ncsl.org/default.aspx?tabid=14374.

ELSI also created a legal training program on the fundamentals of genetics for over 3000 judges.[59] In addition to the legislative and legal efforts, ELSI reached out to a wider research community to include minority and other groups that might receive increased scrutiny from the revelations brought about by the genetic revolution. [60] The HGP's innovative approach to ethical, legal, and social implications has been employed in other research projects,[61] but the adoption of such platforms like ELSI mostly occurs with respect to research housed in medical and educational institutions.[62]

B. Invasion of the Body Scrappers

While mapping the entirety of the human genome was a multi-billion dollar project,[63] the financial considerations in genetic research are not one-sided. As researchers continue work on deciphering the human code, the focus inevitably shifts to disease study and gene therapy for those conditions.[64] In order to foster the understanding necessary to develop treatments and cures for these conditions, it becomes necessary to isolate the specific genes connected with the diseases.[65] The routine procedures of battle—whether military or medical—demand that one knows as much as possible about the enemy.[66] In order to isolate those genes, scientists must seek samples for study; samples originate from human research subjects, many of whom either have developed or could develop the specific disorder.[67]

Of course, the use of such biological materials is not without controversy, particularly as it applies to questions of ownership

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[59] Francis S. Collins et al., *The Human Genome Project: Lessons From Large-Scale Biology*, 300 SCI. 286, 289 (2003).

[60] *Id*.

[61] *Id*. at 289-90.

[62] *Id*.

[63] *Human Genome Project Budget*, HUM. GENOME PROJECT INFO., http://www.ornl.gov/sci/techresources/Human_Genome/project/budget.shtml (last visited Jan. 2, 2012).

[64] Collins, *supra* note 59, at 290.

[65] TIMOTHY M. COX & JOHN SINCLAIR, MOLECULAR BIOLOGY IN MEDICINE 98 (1997).

[66] *Id*.

[67] *Id*.

and big profits.[68] Sourcing treatments from human tissue samples has been a routine research field for several decades.[69] Coupled with the gene sequencing capabilities generated by the HGP, it was only a matter of time before the two concepts merged.[70] As a result, thousands of patients volunteer to participate in clinical trials and treatments in any given year.[71] While many of these trials involve medications, medical devices, or both, a growing number of trials involve passive participation, whereby biological samples are taken and used for testing purposes and to extrapolate valuable data.[72] The road from human body to Petri dish varies from person to person, and the sample may come from leftover or unused tissue associated with a routine surgery[73] or it could be tissue specifically designated for tissue banking,[74] (additional tissue that the patient agreed to be removed for research purposes[75]), but the destination—hospital, university or research institution—generally remains the same.[76]

By its very nature, human tissue sampling requires some slicing and dicing of the human body in order to excise a specimen. By contrast, extracting a sample for genetic analysis is far less invasive and can be had by collecting a number of different bodily fluids: blood and saliva are the most common.[77] Nonetheless, the removal of unnoticed cells, tissue or genetic material still amounts to the collection of valuable individual data.[78] Medical researchers use the tissues and DNA to study and develop countless products,

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[68] *See* Leslie E. Wolf, *Advancing Research on Stored Biological Materials: Reconciling Law, Ethics, and Practice*, 11 MINN. J.L. SCI. & TECH. 99, 107 (2010).

[69] *Id.* at 128.

[70] *Id.* at 133-34.

[71] *Id.* at 142.

[72] *Id.* at 131.

[73] *Id.* at 107.

[74] Tissue bank refers to "a facility [used] for storing and maintaining a collection of tissues for future use in transplants." *Tissue Bank Definition*, MOSBY'S MEDICAL DICTIONARY, http://medical-dictionary.thefreedictionary.com/tissue+bank (last visited Jan. 2, 2012). Banked tissues include arteries, cornea, semen, skin, tendons, and veins. *Id.*

[75] STERILIZATION OF TISSUES USING IONIZING RADIATIONS 36 (John F. Kennedy et al. eds., 2005).

[76] *Id.* at 27-29.

[77] SARDUL SINGH SANDHU, RECOMBINANT DNA TECHNOLOGY 43 (2010).

[78] *Id.*

including cancer treatments, flu vaccines, and pain relievers.[79] These samples are not collected just for medical diagnostic and treatment purposes either.[80] Scientists and researchers from non-profit research institutions and Fortune 500 companies alike expose the samples to a barrage of experiments—"radiation, drugs, cosmetics, viruses, household chemicals and biological weapons"—and then study reactions and damage.[81] Billions of dollars flow in and out of research based upon these biological samples.[82] No doubt, countless lives have been improved and even saved by the tests, vaccines, and treatments brought about by this research.[83]

Whatever the vehicle—tissue scraps, donated DNA, or solicited DNA—there seems to be consensus that biological samples are vital and necessary trappings for biomedical research.[84] The divide occurs over whether any intellectual property rights to such samples and their man-made progeny exist, and, if so, who owns them?[85] While an in-depth conversation on tissue and gene ownership is beyond the scope of this Article, a basic overview of property rights in body parts helps to frame the issues related to direct-to-consumer genetic testing. At least in the abstract, the use of tissue and genetic samples to conduct and benefit research is not something that many people lose sleep over.[86] It becomes deeply personal, however, when those same samples come from you; your medical or genetic information lay open for analysis, criticism, and possibly profit.[87] Of course, such information is not broadcast over the airwaves, but to some donors it may as well have been. Collectively, human beings "often have a strong sense of ownership when it comes to their bodies. . . . [e]ven tiny scraps of it."[88] Whether this attitude is misplaced or well-

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[79] Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES (Apr. 16, 2006), http://www.nytimes.com/2006/04/16/magazine/16tissue.html?adxnnl=1&pagewanted=all&adxnnlx=1312057723-dHFaoRER5kIA12vxRWJjGA.

[80] *Id.*

[81] *Id.*

[82] *Id.*

[83] *See id.*

[84] *See id.*

[85] *Id.*

[86] *See generally id.*

[87] *Id.*

[88] *Id.*

founded is a matter of perspective and whether a court views the issue as a question of property rights, informed consent, or something else altogether.[89] Moreover, those questions may not necessarily address the intellectual property (read: profit) issue.

1. Dibs on Tissue Scraps: The Ownership Question

To be sure, the ownership debate is not about absconding with vital or vestigial body parts. Courts have been reluctant to extend feelings of ownership into actual property rights.[90] After all, these are biological samples voluntarily donated or, in some cases, unwanted remnants of treatment, surgery or medical tests.[91] For the most part, research entities have free rein over the samples in tissue banks; scientists call the shots on the research conducted and which samples will be used.[92] Restrictions are few and far between, and efforts to curb the wide latitude afforded researchers have been less than successful.[93]

Personal property rights in genes, tissue, and other biological remnants are a murky legal concept.[94] The increase in biomedical research and development requires an inexhaustible supply of samples.[95] It is undisputed that the research conducted with such samples can lead to some incredibly valuable medical technologies and treatments.[96] Setting aside the pure ownership question, once money enters the picture, the debate may transform into a

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[89] Wolf, *supra* note 68, at 107.

[90] Skloot, *supra* note 79.

[91] *Id.*

[92] Some endeavors draw from a large pool of samples. The National Cancer Institute has a program that maps cancer genes using millions of tissue samples. Skloot, *supra* note 79. In addition, the Genographic Project is tracking human migration patterns by following genetic ties. *Id.*

[93] TRANSPLANTING HUMAN TISSUE: ETHICS, POLICY, AND PRACTICE 29 (Stuart J. Youngner et al. eds., 2004) (explaining that only four states have any kind of tissue bank regulation and that only 73 of approximately 300 tissue banks in America are AATB accredited).

[94] Wolf, *supra* note 68, at 107.

[95] *See, e.g.*, *MUSC Biomedical Research Bank*, S.C. CLINICAL AND TRANSLATIONAL RES. INST., https://sctr.musc.edu/index.php/musc-biomedical-research-bank (last visited Jan. 2, 2012) (soliciting samples from patients and explaining the need for such samples in large scale biomedical research).

[96] *Id.*

heavyweight prizefight.[97] The developers of the technologies, pharmaceuticals and other treatments invest a tremendous amount of overhead into the products, and, in order to offset that development costs, seek patents for those products. The exclusivity afforded by a patent can allow profits to dwarf the original outlay of cash.[98] Consequently, the ownership question is coupled with the financial element: a formidable duo that can lead to extensive litigation.[99]

The seminal case of *Moore v. Regents of the University of California*[100] established the prevailing thought that tissue donors do not retain a property interest in the biological material they voluntarily parted with.[101] John Moore received treatment for hairy-cell leukemia at the University of California Los Angeles (UCLA) Medical Center; treatment included the removal of his spleen.[102] Portions of Moore's spleen—the lymphokines—were later used to develop a cutting edge cell line to treat leukemia.[103] Moore's lymphokines gave researchers a blueprint from which they could synthetically reproduce the cellular secretions for mass production.[104] Expectedly, UCLA patented the cell line and a private company made millions from the cancer treatment.[105]

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[97] For example, *Moore* was appealed all the way to the California Supreme Court; such extensive litigation underlines the huge amounts of money involved. Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990).

[98] *See, e.g.*, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 203 (S.D.N.Y. 2010) (explaining that Myriad enjoyed revenues of $222 million dollars in 2008 after the $32 million it cost to provide the tests requested in that year).

[99] As discussed *supra* note 98, *Moore* was appealed all the way to the California Supreme Court. *Moore*, 793 P.2d 479. This was no doubt costly for both parties and is illustrative of the long, costly fights that ensue when large amounts of patent money enter the picture.

[100] 793 P.2d. 479 (Cal. 1990).

[101] *Id.* Although a very significant consideration, the issue of informed consent and the extent of a knowing and voluntary release of right in biological samples is beyond the scope of this article. For a thorough discussion of those issues, see Wolf, *supra* note 68.

[102] *Moore*, 793 P.2d at 481.

[103] *Id.* at 481-82 (explaining that pieces of Moore's spleen were used to develop the ultimate product and defining lymphokines as substances secreted by cells of the immune system).

[104] *Id.* at 482.

[105] *Id.* While the researchers and UCLA received only an initial payment from a private-sector developer, no one, including Moore's physician, ever informed him that his cells were used to generate profitable medical technology. *Id.* at 481.

Moore then sued for, among other things, a violation of his property rights.[106] The California Supreme Court rejected Moore's claims by determining that Moore's biological material could not be "unique" to him; his lymphokines possessed the same basic molecular structure as any other person's lymphokines.[107]

Moore stood as the foundation for insulating research—and the valuable products—from the pesky donors.[108] *Moore* "makes obvious that individuals have no control over their genetic profile—and no property right or privacy right can create that control."[109] *Moore* does not stand alone, however, and its underpinnings have surfaced in other cases, albeit under different circumstances. In *Washington University v. Catalona*,[110] the debate once again focused on ownership, but the ensuing mêlée pitted the scientist against his prior research university.[111] Dr. Catalona, a noted urologist, pioneered a new prostate-specific antigen (PSA) test used for prostate cancer screening.[112] Dr. Catalona developed this test during the course of his research at both Washington University and Northwestern University.[113] While at Washington University, Dr. Catalona helped to create a Genitourinary (GU) Biorepository that contained biological samples accumulated by Dr. Catalona and his Washington University colleagues.[114]

When Dr. Catalona moved to Northwestern University, he took his research and many of his patients' biological samples with him.[115] Washington University was none too pleased that Dr. Catalona moved both his research and the samples to Northwestern, and the school filed a declaratory judgment action

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[106] *Id.* at 482.

[107] *Id.* at 490.

[108] *See* Gabel, *supra* note 42, at 32 (explaining that *Moore* makes it obvious that individuals have no property rights to their DNA).

[109] *Id.*

[110] 490 F.3d 667 (8th Cir. 2007).

[111] *Id.* at 670.

[112] Wolf, *supra* note 68, at 113.

[113] *Id.* at 113-14.

[114] *Catalona*, 490 F.3d at 670.

[115] *Id.* at 672. Dr. Catalona sent written requests to his patients asking that they consent to the transfer of the materials to the Northwestern tissue bank. *Id.* Some 6000 patients (of the 50,000 to 60,000 who received requests) agreed to and signed the transfer. *Id.*

against the doctor seeking ownership rights to the samples.[116] Tribulation and litigation followed, but ultimately the district court granted Washington University's request, recognizing the school's ownership rights and expressly stating that neither the doctor nor the donors had any ownership interest in the samples.[117] Consequently, the signed transfer agreements were invalid.[118] The Eighth Circuit affirmed this decision, agreeing that public policy demanded an open-access format that prevented any one researcher (or donor) from hoarding samples.[119] At the time, the district court seemed to dramatize an inevitable Biorepository Armageddon had it reached a different result:

> Medical research can only advance if access to these materials to the scientific community is not thwarted by private agendas. If left unregulated and to the whims of a [research participant], these highly-prized biological materials would become nothing more than chattel going to the highest bidder. . . . Selling excised tissue or DNA on E-Bay would become as commonplace as selling your old television on E-Bay. . . . No longer could research protocols rely on aggregate collections since individual samples would come and go. Accountability would no longer exist since institutions would merely be warehouses filling purchase orders.[120]

Whether this characterization marks the beginning of an urban legend (note the *Urban Dictionary*'s definition of "organ harvest")[121] or uncannily predicts the future of biomedical research, those concerns belie a larger incongruity. One scholar astutely observed: "It is ironic that among those who have sought to remove their materials from research have done so not to prevent others from sharing the benefits of research, but rather to broaden access or to avoid exploitation and research viewed to denigrate a person's racial or ethnic background."[122]

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[116] *Id.*

[117] *Id.* at 673.

[118] *Id.*

[119] *Id.* at 676-77.

[120] Wash. Univ. v. Catalona, 437 F. Supp. 2d 985, 1002 (E.D. Mo. 2006).

[121] *See, e.g.*, *Organ Harvest Definition*, URBANDICTIONARY.COM, http://www.urbandictionary.com/products.php?txtid=1925819 (last visited Jan. 2, 2012).

[122] Wolf, *supra* note 68, at 118.

As cases like *Moore* and *Catalona* demonstrate, the issue of individual ownership of biological samples seemed settled; biomedical research could proceed with fewer restrictions in order to advance science, medical treatment, and the continued health of the target patient groups. But what happens when the research implicates not just a set of individual, largely unrelated, and sometimes anonymous samples, but an entire culture, its people, and its origins? And what if that research occurs without the consent of the participants? Does the ownership calculation change at all?

Members of the Havasupai Tribe occupy a small village in the bottom of the Grand Canyon.[123] In 1963, John Martin, an anthropology professor from Arizona State University ("ASU") began studying the Havasupai.[124] Over the course of decades, Martin fostered a strong relationship with the Havasupai, working with its members on a variety of social, community, and environmental programs. In 1989, Martin was asked to study the "perceived 'epidemic' of diabetes among tribal members."[125] Martin hypothesized that the diabetes was connected to genetics and diet.[126] Thus, Martin contacted his colleague, Therese Markow, an ASU genetics professor, who agreed to collaborate with him on a "diabetes-centered project."[127] For her part, Markow sought to expand the research to the incidence of schizophrenia among tribe members.[128] Martin thought the tribe would reject any additional studies, but did not throw the kill switch on the idea.[129]

Ultimately, the ASU researchers proposed a large blood draw from more than 200 Havasupai.[130] As a token of its appreciation for the research cooperation, ASU benevolently bestowed some free summer classes upon fifteen tribal members.[131] The diabetes

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[123] Havasupai Tribe of Havasupai Reservation v. Arizona Bd. of Regents, 204 P.3d 1063, 1066 (Ariz. Ct. App. 2008).

[124] *Id.*

[125] *Id.*

[126] *Id.*

[127] *Id.*

[128] *Id.*

[129] *Id.* at 1066-67.

[130] *Id.* at 1067.

[131] *Id.*

research soon reached an end with the conclusion that the disease ran rampant through the tribe at such a pace that the cause could not be genetic.[132] In 1991, Markow published a paper to that effect.[133] While the diabetes research ended with little more information than where it started, the blood samples (and the data collected from them) still existed, and new research was born.

Researchers at ASU and other institutions continued to use the Havasupai data to research "schizophrenia, inbreeding and theories about ancient human population migrations from Asia to North America."[134] This research precipitated dozens of publications, including doctoral dissertations and academic papers.[135] One such article pinpointed that the Havasupai engaged in a high degree of inbreeding; a condition linked to an increased predisposition to disease.[136] Another article struck the core of Havasupai belief by proposing that the tribe's ancestors came to the Grand Canyon only after crossing the frozen Bering Sea into North America.[137] This theory denigrated the traditional Havasupai legend that its people originated in the Grand Canyon and served as the canyon's guardians.[138] When Martin learned of the additional genetic research that went far beyond the original diabetes-oriented consent of the tribe, he informed the Havasupai that "ASU may have 'mishandled' blood samples taken as part of the diabetes research project."[139] As a result, the Havasupai issued a banishment order in May 2003, barring ASU from the reservation.[140]

The tribe soon sued the Arizona Board of Regents (who oversee ASU) and Dr. Markow, but the trial court dismissed the case for failure to comply with Arizona's notice-of-claims statute.[141] But an appellate decision breathed new life into the

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[132] *Id.*

[133] *Id.*

[134] *Id.*

[135] Amy Harmon, *Indian Tribe Wins Fight to Limit Research of its DNA*, N.Y. TIMES, Apr. 22, 2010, at A1, *available at* http://www.nytimes.com/2010/04/22/us/22dna.html.

[136] *Id.*

[137] *Id.*

[138] *Id.*

[139] *Havasupai Tribe*, 204 P.3d at 1067.

[140] *Id.*

[141] *Id.* at 1071.

case and in April 2010, the Board of Regents agreed to pay $700,000 to forty-one members of the Havasupai Tribe.[142] In addition, the Board also returned the blood samples and promised some much-needed assistance to the struggling tribe.[143] Amid concerns that researchers exploited a vulnerable group of people, the *Havasupai* case is also significant because the settlement suggests (among other things) that "the rights of research subjects can be violated when they are not fully informed about how their DNA might be used."[144] Moreover, it implies that scientists may have an obligation to inform donors when research "creeps" beyond the scope of the study that donors initially agreed to participate in.[145]

Moreover, the *Havasupai* case may also demonstrate the notion of "what you don't know *can* hurt you." Do donors know the extent of the genetic information that can be collected and interpreted from a single sample? It is clear from cases like *Moore* and *Havasupai* that what science would categorize as leftovers is the same material that donors consider to be an extension of who they are.[146] The plaintiffs in those cases "were willing to bring suit, with all the financial, emotional, and time burdens involved in litigation, and despite the long odds of winning," to preserve their right to control the research performed on their biological samples.[147] Similarly, although the research may be divorced from the corporal connection, *Catalona* emphasizes that research institutions that house these samples feel a sense of ownership as well, and that they do not like to share.[148] Beyond the ownership issue, however, an argument can be made that many of these cases (excepting *Havasupai*) also underscore a monetary component. While research is expensive and time consuming, the rewards can be well worth the payout.[149] Donors and developers

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142 Harmon, *supra* note 135.

143 *Id.*

144 *Id.*

145 *See* Gabel, *supra* note 42, at 48 ("Mission creep involves the expansion of a project beyond its original mission.").

146 Wolf, *supra* note 68, at 108, 125.

147 *Id.* at 127.

148 *Id.* at 116.

149 *See, e.g.*, Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 482 (Cal. 1990) (acknowledging from plaintiff's brief that competing firms estimated the value of the lymphokines lines developed from Moore's tissue at 3.01 billion dollars).

alike are interested in a piece of the pie when the research produces money-making treatments and products. For developers, the patent is the primary tool to preserve their interest and offset the research and development costs.[150] For donors, concerns over ownership and control transition into perhaps a more egocentric interest: remunerating the cradle of the crop.[151]

2. Money: Don't Take a Slice of My Gene

Companies have held patents for isolated genes and DNA for decades.[152] A 2005 survey showed that twenty percent of human genes had been patented.[153] There is no recent estimate, but chances are that the number of patented genes now exceeds twenty percent.[154] The practice of patenting genes grew out of the use of the biological material in diagnostic tests and pharmaceutical research.[155] DNA is big business and rather than treating it like a part of the human body (such as a birthmark or eye color), it has been elevated to a product that generates profit.[156]

Consequently, an isolated gene or DNA sequence[157] "can be patented in the same manner that a new medicine, purified from a plant, could be patented if an inventor identifies a [new] application."[158] So, with at least 4000 of the nearly 24,000 genes in our body under patent protection, the patent holders hold property

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[150] *Id.*

[151] Greenberg v. Miami Children's Hosp. Res. Inst., Inc., 264 F. Supp. 2d 1064, 1067 (S.D. Fla. 2003).

[152] *Myriad's Gene-patent Battle, Gene-uinely Unclear*, ECONOMIST.COM (Aug. 4, 2011, 3:47 PM), http://www.economist.com/blogs/schumpeter/2011/08/myriads-gene-patent-battle.

[153] Stefan Lovgren, *One-Fifth of Human Genes Have Been Patented, Study Reveals*, NAT'L GEOGRAPHIC NEWS (Oct. 13, 2005), http://news.nationalgeographic.com/news/pf/22064243.html.

[154] Jason Mick, *Federal Court Rules it is Illegal to Patent Unaltered Human Genes*, DAILY TECH (Apr. 1, 2010, 12:00 PM), http://www.dailytech.com/Federal+Court+Rules+it+is+Illegal+to+Patent+Unaltered+Human+Genes/article18033.htm (explaining that over twenty percent of human genes are now patented).

[155] Lovgren, *supra* note 153.

[156] *Id.*

[157] "Gene isolation" refers to the isolation of a particular gene from the rest for use in genetic engineering. *See Gene Isolation Definition*, BIOLOGY ONLINE, http://www.biology-online.org/dictionary/Genetic_isolation (last visited Jan. 2, 2012).

[158] Lovgren, *supra* note 153 (internal quotation marks omitted).

rights over these genes.[159] In that same 2005 survey, it was estimated that about sixty-three percent of patents are held by private firms while twenty-eight percent reside with universities.[160] Setting aside the moral debate as to whether someone *else* owns our genes, the legal implications alone can be mind-numbing. One recent case underscores that.

In 2006, Genae Girard was diagnosed with breast cancer.[161] Girard later took a genetic test to determine if her genes also indicated an increased risk for ovarian cancer.[162] When the results for ovarian cancer were positive, Girard sought a second opinion.[163] But Girard could not take a different genetic test because none existed; only one company, Myriad Genetics (Myriad), occupied that genetic testing territory due to its patent on two genes that are closely associated with increased risk for breast cancer and ovarian cancer.[164] Myriad also held the exclusive patent on the corresponding test that measures a patient's risk of developing either disease.[165] Girard decided to battle the legal monopoly in court, and led a lawsuit against the patent holders—Myriad and the University of Utah Research Foundation—and against the entity in charge of reviewing and determining whether to grant a patent—the United States Patent and Trademark Office (PTO).[166]

The American Civil Liberties Union and the Public Patent Foundation filed the groundbreaking suit on behalf of Girard, other cancer patients, researchers, genetic counselors, women's health groups, and "scientific associations representing 150,000 geneticists, pathologists, and laboratory professionals."[167] More than just a question about the sanctity of a patent, the plaintiffs

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159 *Id.*

160 *Id.*

161 John Schwartz, *Cancer Patients Challenge the Patenting of a Gene*, N.Y. TIMES, May 13, 2009, at A16, *available at* http://www.nytimes.com/2009/05/13/health/13patent.html?pagewanted=print.

162 *Id.*

163 *Id.*

164 *Id.*

165 *Id.*

166 *ACLU Challenges Patents on Breast Cancer Genes*, ACLU (July 30, 2011), http://www.aclu.org/free-speech-womens-rights/aclu-challenges-patents-breast-cancer-genes-0.

167 *Id.*

alleged that the gene patents and resulting market restrictions hindered the practice of medicine to the point of "mediocrity" and blocked new areas of research and development.[168] For the patent holders, the argument was more simplified and based on the bottom line: the patents served as the reward for the money invested to get there.[169]

The stage was set for a battle, and it was clear from the outset that this was one case that could not be settled. The issue is not lengthy: Can a company patent a gene? As of this writing, that answer is yes, but this case is one that seems destined for a turn in the Supreme Court.[170] The first decision in this case featured a brazen 156-page opinion authored by Judge Sweet in the Southern District of New York,[171] and answered the same question with a resounding no.[172] In *Association for Molecular Pathology v. United States Patent and Trademark Office* (Myriad),[173] the district court agreed that Myriad's patents on the BRCA1 and BRCA2 genes prevented other clinicians from independently looking at and interpreting a person's BRCA1 and BRCA2 genes.[174] It also concluded that the patents precluded easy access to predictive tests and retarded potential innovation in testing technologies used to detect increased cancer risks in patients.[175]

After denying Myriad's motion for summary judgment, Judge Sweet ultimately found the patents invalid. His reasoning showed a shift in perception concerning genes, which had long been thought of as chemical entities, that, when isolated, became unique and patentable.[176] In his opinion, Judge Sweet determined that because genes are information-carrying molecules whose data

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[168] Lovgren, *supra* note 153.

[169] *Id.*

[170] Ellen McDermott, *Myriad Ruling is a Signal to the Supreme Court*, MANAGING INTELLECTUAL PROPERTY (Aug. 11, 2011), http://www.managingip.com/Article/2882082/Myriad-ruling-is-a-signal-to-the-Supreme-Court.html.

[171] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

[172] *Id.* at 232.

[173] 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

[174] *Id.* at 208-09.

[175] Andrew Cohen, *Nature vs. Nurture: The Continuing Saga of the Gene Patenting Case*, ATLANTIC (Apr. 3, 2011, 8:27 AM), http://www.theatlantic.com/national/archive/2011/04/nature-vs-nurture-the-continuing-saga-of-the-gene-patenting-case/73359/.

[176] *Id.*

content does not depend on whether they are in their natural environment, isolation by itself does not make the gene *novel*, a prerequisite for patentability.[177] In an amicus brief filed in the federal appeals court, the Department of Justice agreed, advocating the position that human genes which had only been isolated should not be eligible for patents.[178]

Though the district court decision raised alarm among pharmaceutical companies and research institutions alike, it was initially seen as cabined, both in the type of patent held invalid (seven specific genes) as well as the authority of the decision (it was only binding in the southern district of New York, and even then, only if it was not overturned on appeal).[179] As it turned out, the consolation prize would become the crowning victory for Myriad when the Federal Circuit Court of Appeals overturned Sweet's ruling in a resounding, albeit splintered, opinion.[180]

The majority opinion, authored by Judge Alan Lourie, rejected the "magic microscope test"[181] proffered by the government in its amicus brief and instead held that "when cleaved, an isolated DNA molecule . . . [is] a distinct chemical entity."[182] The court focused on this cleaving, characterizing it as "the act of human invention"[183] and voiced concerns that the magic microscope test was a visualization test which could be focused in on any part of a DNA molecule, rendering it unpatentable, and thereby chilling innovation.[184] In addition to the majority opinion, Judge Kimberly Moore wrote a concurring opinion in which she used slightly different reasoning to reach the

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[177] *Id.*

[178] Ashby Jones, *A Patent Mistake? DOJ's Reversal on Genes Raising Questions*, WALL ST. J. L. BLOG (Nov. 2, 2010, 5:39 PM), http://blogs.wsj.com/law/2010/11/02/a-patent-mistake-dojs-reversal-on-genes-raising-questions/.

[179] Andrew Pollack, *After Patent on Genes is Invalidated, Taking Stock*, N.Y. TIMES, Mar. 30, 2010, at B1, *available at* http://www.nytimes.com/2010/03/31/business/31gene.html?scp=1&sq=gene&st=cse.

[180] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 2011 U.S. App. LEXIS 15649, at *74-75 (Fed. Cir. July 29, 2011).

[181] *Id.* at *50 (explaining the government's position that if a "magic microscope" could focus on the claimed DNA molecule as it exists in nature, then the claim is for unpatentable matter).

[182] *Id.* at *57.

[183] *Id.* at *62.

[184] *Id.* at *61.

majority's conclusion.[185] Meanwhile, Judge William Bryson dissented from the majority opinion concerning the patentability of the isolated genes.

In his dissent, Bryson stated that, contrary to the majority opinion, he did not believe that the mere act of isolating a gene is enough to make the resulting product patent-eligible material. [186] In support of his view, Bryson noted that Myriad is free to patent applications of its discovery, but not the genes themselves.[187] Judge Bryson compared the isolation of genes to snapping a leaf from a tree,[188] and noted that policy considerations (such as the frustration of research and the future treatment of breast and ovarian cancers) militated against granting a gene patent.[189] Moreover, Bryson emphasized broader concerns over the potential hurdles smaller gene patents place in front of firms attempting to sequence many genes or even entire human genomes rapidly.[190] To Bryson, the majority's opinion was one so focused on economics that it ignored the potentially larger consequences.[191]

But the patent reward is meant to offset upfront costs.[192] Without it, companies would be unwilling to invest the time, personnel, and millions of dollars on a venture that would later be shared by others riding on the coattails of their investment.[193] But can this outweigh the concern that those same patents stifle later innovation that might advance the technology?[194] That question will not be answered by this Article, but for now it seems that biotech companies have quite literally bought some time. Given the Federal Circuit's fractured opinion, however, this likely is not

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[185] *Id.* at *92 (Moore, J., concurring) (explaining that the mere fact that the isolated DNA consisted of different molecules than native DNA was not enough to render the isolations patent-eligible, but since the isolated DNA is not naturally occurring in nature without the assistance of man, the DNA, once isolated, became patent-eligible material).

[186] *Id.* at *118 (Bryson, J., dissenting).

[187] *Id.* at *119.

[188] *Id.* at *129.

[189] *Id.* at *120.

[190] *Id.* at *138.

[191] *Id.* at *137-38.

[192] Deborah L. Shelton, *Gene-Patenting Issue Not Settled Despite Ruling*, CHI. TRIBUNE (Apr. 1, 2010, 8:28 PM), http://archive.chicagobreakingnews.com/2010/04/issue-of-patenting-human-genes-not-settled-despite-ruling.html.

[193] *Id.*

[194] *Id.*

Myriad's last dance in court.[195] The Supreme Court's hand may finally be forced to give a bright line rule on the parameters of patent-eligibility for genes (and maybe other biological samples).[196]

Beyond the context of property rights and patent claims lies a more fundamental concern about the information our DNA contains and what we understand about those contents. Just as forensic DNA testing has expanded in criminal cases to identify offenders, so too has the warehousing of the DNA collected. All fifty states and the federal government[197] have laws on the books pertaining to the collection and retention of DNA samples and test results. In some states, these DNA data banking laws require the collection of samples from both convicted offenders and arrestees.[198]

The argument for storing all of this genetic information has long been that forensic DNA testing specifically uses non-coding

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[195] Michelle Spektor, *Genes are Still Patentable, Federal Appeals Court Rules*, SCIENCE PROGRESS (Aug. 17, 2011), http://scienceprogress.org/2011/08/genes-are-still-patentable/ (explaining that Myriad plaintiffs are expected to either ask for an en banc rehearing or appeal to the Supreme Court).

[196] The Supreme Court's recent ruling in *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), offers some guidance on novel patents. *Bilski* was highly anticipated because it gave the justices an opportunity to close the door on business method patents by requiring an invention to be associated with a particular machine or transform something into a different state or thing in order to be patentable. Such a ruling could have had a devastating impact on gene patenting, which doesn't quite fit into either definitional confine. *Bilski*, however, failed to measure up to the landmark decision hoped for by its followers and the justices, while holding the specific patent in question was invalid, did not limit patents to only those inventions which passed the machine or transformation tests, leaving the door open for future business method patents. *See* John Schwartz, *Justices Take Broad View of Business Method Patents*, N.Y. TIMES, June 29, 2010, at B1, *available at* http://www.nytimes.com/2010/06/29/business/29patent.html; John Schwartz, *Justices Hear Patent Case on Protecting the Abstract*, N.Y. TIMES, Nov. 10, 2009, at B1, *available at* http://www.nytimes.com/2009/11/10/business/10patent.html?sq=bilski&st=cse&adxnnl=1&scp=2&adxnnlx=1310954447-jPAj2p9y+Z2quK4zGVp2Qw.

[197] *See* 42 U.S.C. §§ 14131-14134 (2006); *see also* Robin Cheryl Miller, Annotation, *Validity, Construction, and Operation of State DNA Database Statutes*, 76 A.L.R. 5TH 239, 252 (2000).

[198] *See, e.g.*, VA. CODE ANN. § 19.2-310.2:1 (2008) ("Every person arrested for the commission or attempted commission of a violent felony . . . shall have a sample of his saliva or tissue taken for DNA . . . analysis to determine identification characteristics specific to the person.").

regions on DNA.[199] In other words, those segments of DNA—called short tandem repeats—have no bearing on gene expression and the genotypes and phenotypes associated with those genes.[200] Termed "junk DNA," law enforcement officials contend that genetic information retrieved in forensic DNA testing has no more significance than numbers on a license plate. The CODIS loci function as identifiers, and nothing more.[201] Critics of this convenient explanation—including myself—argue that the breakneck pace of genetic technology demonstrates that what we once referred to as "junk DNA" may later be found to contain valuable genetic information.[202]

In *People v. Buza*,[203] a California appeals court held the collection of DNA samples from arrestees unconstitutional as a violation of the Fourth Amendment's protection against unreasonable searches and seizures. Buza was arrested on suspicion of lighting a police car on fire. Under the California DNA Act, as amended by California voters in 2004,[204] a DNA specimen is to be taken from individuals arrested and charged with a felony "immediately following arrest, or during the booking"[205] of that individual. Buza repeatedly refused to consent to a buccal[206] swab after his arrest and was charged with a misdemeanor for failure to provide a DNA sample.[207] After initially pleading not guilty to all charges, Buza admitted at trial to setting fire to the police car and was found guilty of all counts, including the misdemeanor for failure to provide a DNA sample. Shortly after his conviction, the court ordered Buza to provide a

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[199] *See Saved By Junk DNA: Vital Role in the Evolution of Human Genome*, SCI. DAILY (May 28, 2009), http://www.sciencedaily.com/releases/2009/05/090528203730.htm ("Scientists used to believe that . . . non-coding DNA is useless trash that has sneaked into our genome and refuses to leave.").

[200] JOHN M. BUTLER, FORENSIC DNA TYPING: BIOLOGY, TECHNOLOGY, AND GENETICS OF STR MARKERS 17-22 (2d ed. 2005).

[201] *Id.*

[202] *Id.*

[203] 129 Cal. Rptr. 3d 753 (Cal. Ct. App. 2011).

[204] *Id.* at 757 (explaining that voters amended the California DNA Act by "enacting Proposition 69, the DNA Fingerprint, Unsolved Crime and Innocence Protection Act").

[205] *Id.* (internal quotation marks omitted).

[206] *See* IDA G. DOX ET AL., ATTORNEY'S ILLUSTRATED MEDICAL DICTIONARY B35 (1997) (defining buccal as "relating to the cheek"). Thus, a buccal swab is a cheek swab.

[207] *Buza*, 129 Cal. Rptr. 3d at 755.

DNA sample. He again refused, and this time the court authorized the use of reasonable force to bring him within compliance.[208]

After eventually providing the sample, Buza was sentenced to sixteen months in jail and informed that his conviction would cause his sample to be included in the state's forensic DNA database.[209] Buza appealed the misdemeanor conviction on the collateral issue that the mandatory DNA sample violated his Fourth and Fourteenth Amendment rights in addition to his privacy rights under the California Constitution.[210] The court honed in on the Fourth Amendment claim and reversed the misdemeanor conviction.[211]

Within its reasoning, the court faulted the language of the California DNA Act for authorizing warrantless, suspicionless searches (vis-à-vis the collection of DNA evidence) without a judicial determination of probable cause.[212] In doing so, the court distinguished the case at bar with *United States v. Pool*[213] where the court held that certain arrestees could be required to give a DNA sample as a condition for pretrial release.[214] The *Buza* court emphasized that the arrestee in *Pool* was required to give a sample "after a judicial . . . determination of probable cause [had] been made for felony criminal charges against [the] defendant."[215] This judicial determination was the lynchpin for the *Buza* court; without it, an arrestee cannot be forced to give a DNA sample. In so holding, the court seemed a bit skittish about relying solely on the arresting officer's determination of probable cause, voicing concern that officers seeking a DNA sample from an individual may arrest them simply to obtain it.[216]

Next, the court addressed the prosecution's argument that DNA samples—as vehicles of identification—were no different from fingerprints.[217] The court pointed to two other cases that had

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[208] *Id.* at 755-56.
[209] *Id.* at 756.
[210] *Id.* at 755.
[211] *Id.*
[212] *Id.* at 777.
[213] 645 F. Supp. 2d 903 (E.D. Cal. 2009).
[214] *Id.* at 913.
[215] *Buza*, 129 Cal. Rptr. 3d at 763 (alteration from original).
[216] *Id.* at 780-81.
[217] *Id.* at 768-770.

accepted this analogy: *United States v. Mitchell*[218] and *Haskell v. Brown*.[219] Both courts focused on the difference between DNA samples, containing the entire human genome, and DNA profiles in CODIS, which were derived from "junk DNA."[220] They reasoned that because the profiles only contained limited information, federal statutes protect the misuse of sample information, and the technology behind DNA testing was limited, the DNA profiles could only be used for identification purposes and misuse of the samples was speculative.[221]

Ultimately, the *Buza* court rejected the reasoning in these cases.[222] First, it pointed out that DNA evidence is primarily an investigative tool that is impractical for identification purposes since it can take up to thirty-one days for a sample to be processed and other methods of identification, such as fingerprinting, render it unnecessary to determine identity at booking.[223] Second, it questioned the soundness of the assertion that "junk DNA" does not contain genetic programming material, pointing out that recent studies have questioned this theory.[224] The court also cautioned that even if "junk DNA" does not contain useful information, the profiles themselves are derived from blood and buccal swab samples, which have to be collected and stored.[225] Because of this storage procedure, "the advance of science promises to make stored DNA only more revealing."[226] Finally, the court reasoned that fingerprinting had long been routine before the Fourth Amendment began to be applied to the arrest and booking process, yet this grandfathered-in status could not be used to circumscribe Fourth Amendment protections. The court effectively refused to bootstrap DNA fingerprinting in with traditional fingerprints. [227]

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[218] 681 F. Supp. 2d 597 (W.D. Pa. 2009), *rev'd*, 652 F.3d 387 (3d Cir. 2011).
[219] 677 F. Supp. 2d 1187 (N.D. Cal. 2009).
[220] *Buza*, 129 Cal. Rptr. 3d at 768.
[221] *Id.*
[222] *Id.* at 767.
[223] *Id.* at 772.
[224] *Id.* at 768-69.
[225] *Id.* at 769.
[226] *Id.* (internal quotation marks omitted).
[227] *Id.* at 770.

Additionally, the court balanced the arrestee's interest in privacy against the government's interest in obtaining his DNA. Because an arrestee enjoyed the presumption of innocence, this balance had to be struck in favor of the individual's privacy.[228] This marked a departure from prior court rulings on the subject.[229] Finally, the court emphasized that while DNA databases can be helpful in resolving unsolved cases and pursuing leads in open cases, "the effectiveness of a crime fighting technology does not render it constitutional."[230]

Buza marks perhaps the first time that a court has acknowledged the gravity of collecting, processing, and retaining an individual's DNA in the criminal context.[231] Forensic DNA testing is a significant tool in criminal investigations. It is subject to rigorous testing and protocols, and time and again it has proven to be a reliable method of identifying individuals. Those safeguards cannot, however, insure that a person's biological sample (and thus genetic information) is not vulnerable to misuse.[232] These same concerns also apply to direct-to-consumer genetic testing. If we are still addressing concerns over privacy and security in the context of forensic DNA testing, a science that has been routinely validated in laboratories and courts for almost twenty-five years, then our expectations of genetic testing should be cautious and measured.

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[228] *Id.* at 782-83.

[229] *See* United States v. Mitchell, 652 F.3d 387, 412-13 (3d Cir. 2011) (holding that DNA collection from arrestees is permissible because it occurs only after probable cause for arrest has been determined by the arresting officer); Haskell v. Brown, 677 F. Supp. 2d 1187, 1198-99 (N.D. Cal. 2009) (emphasizing the government's interest in identifying suspects); United States v. Pool, 645 F. Supp. 2d 903, 910 (E.D. Cal. 2009) ("[T]he decision to impose the DNA testing requirement on pre-trial detainees or releasees seems clearly warranted, if not compelling. An arrestee's identity obviously becomes a matter of legitimate state interest.").

[230] *Buza*, 129 Cal. Rptr. 3d at 783.

[231] *See* Paul M. Monteleoni, *DNA Databases, Universality, and the Fourth Amendment*, 82 N.Y.U. L. REV. 247, 247-49 (2007) (explaining that the courts have upheld DNA databank statutes in the face of Fourth Amendment challenges, and arguing that states lack the proper safeguards to avoid the potential for misuse of collected DNA).

[232] *Buza*, 129 Cal. Rptr. 3d at 780-81 (voicing concern that officers would be tempted to make an arrest merely to obtain a DNA sample from a suspect).

II. A NEW MACHINE: DO-IT-YOURSELF DNA

Clearly, the field of genetics can be a cash cow, and it seems everyone from pharmaceutical companies to universities is jumping on the bandwagon to research, develop, patent, and of course, profit.[233] The common thread among those researching and developing this category of *medical-diagnostic* genetic testing is that the end-product generally reaches the patient only through a medical provider after lengthy trials and the Federal Drug Administration approval process.[234] Consequently, medical-diagnostic genetic testing has critical points of regulation—some legal (the FDA) and others informational (individual doctors and other health care providers).[235] But the regulations associated with this sector of genetic testing are not the focus of this Article.

The technology that spurred genetic breakthroughs, however, is not limited to pharmaceutical and educational entities. The profit potential attracted entrepreneurs, who could create other genetic tools for use outside of the medical provider context.[236] The Human Genome Project and its progeny embraced a model of licensing and sharing genetic technology with private companies.[237] Moreover, gene sequencing has become cheaper. In 2009, a Stanford engineer spent a mere $50,000 (pennies in genetic research dollars) to decode his own genome with

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[233] For example, in *Myriad*, The University of Utah Research Foundation held the genetic patents in conjunction with Myriad Pharmaceuticals. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010).

[234] *See Who Regulates Genetic Tests?*, GENETICS & PUB. POL'Y CTR., http://www.dnapolicy.org/policy.issue.php?action=detail&issuebrief_id=10 (last updated May 30, 2008) (explaining that all clinical laboratories are subject to CLIA regulations, and their testing kits are subject to FDA regulation). This is in marked contrast to laboratory developed tests (LDTs)—or "homebrews"—which are medical tests developed and performed in the same laboratory. LDTs fall outside the FDA approval and oversight powers, and many direct-to-consumer genetic testing companies characterize their tests as LDTs. *See, e.g.*, *Diagnostic Kits/ Glossary: Abbreviations*, BERKMAN, *available at* http://cyber.law.harvard.edu/commonsbasedresearch/Diagnostic_Kits/Glossary (last visited Jan. 2, 2012).

[235] *Id.*

[236] Misha Angrist & Robert M. Cook-Deegan, *Who Owns the Genome?*, NEW ATLANTIS, Winter 2006, at 87-96, *available at* http://www.thenewatlantis.com/publications/who-owns-the-genome.

[237] *Id.*

sequencing technology that he invented.[238] The engineer—aptly named Dr. Quake—believed that the lower costs would shake-up the industry and "democratize access to the fruits of the genome revolution."[239] Currently, research groups are in a race to sequence the human genome for $1000.[240] Scientists estimate that this low-dollar figure could be achieved as soon as 2013.[241]

Lower costs breed "new entr[ies] in that horse race,"[242] and this business model has now spawned (and perhaps unknowingly coddled) new genetic tests that are sold directly to consumers.[243] Predictably, there was a market to welcome these new genetic testing applications.[244] Indeed, cases like Myriad demonstrate that consumers want options with genetic testing and will actively seek out the alternatives.[245] Unfortunately, as this Article will illustrate, if gene patenting becomes a routine practice (blessed by the Supreme Court), the result may push patients to the Genetic Groupons, a shadowy industry that has only recently come under some superficial scrutiny from the FDA and other regulatory bodies.[246]

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[238] Nicholas Wade, *Cost of Decoding a Genome Is Lowered*, N.Y. TIMES, Aug. 11, 2009, at D3 [hereinafter Wade, *Cost of Decoding*], *available at* http://www.nytimes.com/2009/08/11/science/11gene.html.

[239] *Id.* Previously, unlocking an entire genome required massive resources, and few companies and universities possessed the technology, staff, and cash to decode a human genome's three billion genetic units. *Id.*

[240] Nicholas Wade, *Decoding DNA with Semiconductors*, N.Y. TIMES, July 21, 2011, at A13, *available at* http://www.nytimes.com/2011/07/21/science/21genome.html.

[241] *Id.*

[242] Wade, *Cost of Decoding*, *supra* note 238.

[243] MARY FRAKER ET AL., DIRECT-TO-CONSUMER GENETIC TESTING: SUMMARY OF A WORKSHOP 1-6 (2010).

[244] *Id.*

[245] Part of the reason cited by plaintiffs for bringing the lawsuit against Myriad was the inability to obtain BRCA1 and BRCA2 analysis from companies other than Myriad. Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Office, No. 2010-1406, 2011 U.S. App. LEXIS 15649, at *24 (Fed. Cir. July 29, 2011), *aff'g in part, rev'g in part* 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

[246] *See, e.g.*, Dan Vorhaus, *DTC Genetic Testing and the FDA: Is There an End in Sight to the Regulatory Uncertainty?*, GENOMICS L. REP. (June 16, 2011), http://www.genomicslawreport.com/index.php/tag/pathway-genomics/.

A. Rise of the Genetic Groupons

Genetic tests have come to hold a more prominent role in health care.[247] While not yet a routine feature of clinical medicine practice, that milestone is probably not far off.[248] There are more than 1000 clinical tests to detect genetic variations and possible disease risks for more than 200 separate medical infirmities.[249] Most of these are available only through a medical provider—such as the BRAC Analysis test for breast cancer—but some two dozen genetic test kits are available directly to consumers, and their use is gaining ground.[250]

The term *genetic testing* covers an "array of techniques" that includes, among other things, analysis of human DNA.[251] Generally speaking, genetic tests are used as a medical tool to detect gene variants connected to a specific disease or condition. In the clinical setting (clinical genetic testing), the tests can be performed to "confirm a suspected diagnosis, to predict the possibility of future illness, to detect the presence of a carrier state in unaffected individuals (whose children may be at risk), and to predict response to therapy."[252] Non-clinical uses for genetic testing include forensic DNA analysis to identify criminal offenders as well as tests to determine paternity, identify health risks, and predict vulnerability.[253] This latter group of tests—paternity, health risks, and disease predictions—has been

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[247] *See Medicine and the New Genetics*, HUM. GENOME PROJECT INFO., http://www.ornl.gov/sci/techresources/Human_Genome/medicine/medicine.shtml (last modified Jan. 2, 2011).

[248] *Id.*

[249] Jennifer A. Gniady, *Regulating Direct-to-Consumer Genetic Testing: Protecting the Consumer Without Quashing a Medical Revolution*, 76 FORDHAM L. REV. 2429, 2436 (2008); *see also Gene Testing*, HUM. GENOME PROJECT INFO., http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetest.shtml (last modified Jan. 2, 2010).

[250] For a comprehensive list of the companies offering DTC genetic testing services, including what they test for and whether the company offers genetic counseling services, see GENETICS & PUB. POL'Y CTR., http://www.dnapolicy.org/resources/DTCTableAug2011Alphabydisease.pdf (last modified Jan. 2, 2011).

[251] *Genetic Testing: Overview of Genetic Testing*, NAT'L HUM. GENOME RES. INST., http://www.genome.gov/10002335 (last visited Jan. 2, 2011).

[252] *Id.*

[253] *Id.*

aggressively marketed to consumers on the internet and elsewhere.[254]

Referred to as "Direct-to-Consumer" (DTC) genetic tests, the kits vary widely in the information provided. Some are diagnostic,[255] others focus on ancestral lineage,[256] some promise to use your DNA to match you with a genetically compatible date,[257] and still others may offer a broad spectrum of information in a combination of categories.[258] In addition, some companies bring the consumer into a genetic social networking community where people with common genes can find each other. Clearly, genetic testing has come a long way.

1. From Doctored DNA to DIY Genetics

Early genetic research took its time to move from Mendel's peas to Watson and Crick's double helix. By comparison, DTC genetic testing, which took its cues from research laboratory and clinical testing, zoomed onto the scene at a speed reminiscent of venture capitalists swarming the dot-com companies in the late 1990s.[259] In the years surrounding the Human Genome Project, the National Human Genome Task Force on Genetic Testing was established by the NIH to propose policies and guidance for the "delivery of safe and effective genetic tests."[260] The Task Force issued a comprehensive report on genetic testing and defined the tests as follows:

> The analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-

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[254] *Id.*

[255] *See, e.g.*, *DNA Predisposition Testing*, THE GENETIC TESTING LAB., INC., https://www.gtldna.net/predisposition.html?source=google_predisposition&gclid=CKPRzuK0h6sCFdgb2godJ2Bz5G (last visited Jan. 2, 2011).

[256] *See, e.g.*, GENETIC GENEALOGY, http://www.dnaancestryproject.com/index.php (last visited Jan. 2, 2011).

[257] *See, e.g.*, SCIENTIFICMATCH, *supra* note 6.

[258] *See, e.g.*, 23ANDME, *supra* note 1.

[259] *See* Ciara Curtin, *The Science Behind DTC Genetic Testing*, GENOME TECH. (March 2009), http://www.genomeweb.com/dxpgx/science-behind-dtc-genetic-testing (describing how DTC testing "exploded onto the scene" in 2008).

[260] *Task Force on Genetic Testing: Joint NIH-DOE Ethical, Legal and Social Implications Working Group of the Human Genome Project*, NAT'L HUM. GENOME RES. INST., http://www.genome.gov/10001808 (last visited Jan. 2, 2012).

> related genotypes, mutations, phenotypes or karyotypes for clinical purposes. Such purposes include predicting risk of disease, identifying carriers and establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn and carrier screening, as well as testing in high-risk families, are included. Tests for metabolites are covered only when they are undertaken with high probability that an excess or deficiency of the metabolite indicates the presence of heritable mutations in single genes. Tests conducted purely for research are excluded from the definition, as are tests for somatic (as opposed to heritable) mutations, and testing for forensic purposes.[261]

The Task Force released its report in 1997. By 2006, "nutrigenetic" tests entered the market, and were sold online by a handful of companies.[262] These tests promised personal genetic testing accompanied by genetic profiles. Nutrigenetics purported to examine genetic variations associated with a body's response to, among other things, diet, nutrition, and metabolism.[263] The companies promised to deliver "[r]ecommendations . . . based on your own DNA" so that by "adjusting your diet and lifestyle to your genetic profile, you can make sure that your body functions at an optimum level."[264] In effect, these tests were the early predecessors to the "Bring Your Genes to Cal" program discussed earlier.[265] In 2006, the federal government's General Accounting Office (GAO) conducted a sting operation of sorts to determine whether the nutrigenetics tests provided the promised individual genetic profiles coupled with personalized nutritional spectrums.[266]

The GAO bought test kits from the companies and submitted saliva samples for testing.[267] The GAO created a group of

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[261] *Guidelines and Policies: Genetic Testing*, HIBM RES. GRP., http://www.hibm.org/hrg/hrgwww/forpatients:guidelines_and_policies (last visited Jan. 2, 2012).

[262] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-997T, NUTRIGENETIC TESTING: TESTS PURCHASED FROM FOUR WEB SITES MISLEAD CONSUMERS 2 (2006), *available at* http://www.gao.gov/new.items/d06977t.pdf.

[263] *Id.*

[264] *Id.* at 18.

[265] *See supra* notes 23-40 and accompanying text.

[266] U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 262, at 2.

[267] *Id.*

"fictitious consumers" by submitting twelve DNA samples all sourced from one nine-month-old female (with consent from her parents).[268] The GAO also submitted two DNA samples taken from an unrelated forty-eight-year-old male in addition to samples taken from a dog, a cat, and "blank" samples containing no DNA information.[269] Perhaps this set of samples was simply for entertainment, but the submissions were in fact returned by the laboratories because they could not be processed.[270] Based on its investigation, the GAO issued a report entitled *Nutrigenetic Testing: Tests Purchased from Four Web Sites Mislead Consumers*.[271]

At bottom, the GAO report determined that the nutrigenetic tests deceived consumers by promising impossible results they could not deliver.[272] Specifically, the GAO concluded that the tests were "medically unproven and . . . ambiguous"[273] with "contradictory and . . . inaccurate lab results."[274] One test showed the presence of a variation in one gene while another test found no such variation.[275] Moreover, the companies seemed to base their predictions on questionnaires filled out by the consumers as opposed to the actual genetic tests.[276] One company even hocked its own expensive line of vitamins and supplements tailored to a consumer's nutrigenetic profile.[277] Ultimately, the GAO cautioned that the "unproven medical predictions" offered by those companies might "alarm consumers into thinking that they have an illness or that they need to buy a costly supplement in order to prevent an illness."[278] Worse yet, the GAO worried that inaccurate

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[268] *Id.* at 2-3. Although not reported, one might guess that this nine-month-old was the child of a parent employed by the GAO. Perhaps "training pants" come very early in that family.

[269] *Id.* at 3.

[270] *Id.*

[271] *Id.*

[272] *Id.* at 22.

[273] *Id.* at 5.

[274] *Id.* at 21.

[275] *Id.*

[276] *Id.* at 18.

[277] *Id.* at 14.

[278] *Id.* at 22.

test results might provide a false sense of confidence in one's health when that is anything but the case.[279]

The GAO's investigation, coupled with a Senate committee directive, prompted the Federal Trade Commission (FTC), the Food and Drug Administration (FDA), and the Centers for Disease Control (CDC) to publish a statement warning consumers to approach such tests with a "healthy dose of skepticism."[280] According to the FDA, none of the nutrigenetic companies involved in the 2006 report remain on the market today.[281]

In 2007, a new set of genetic tests emerged. Several new companies entered the scene selling DTC genetic testing services, smartly avoiding the lambasted nutrigenetic claims.[282] These companies predominantly leveraged recent technological advances that featured a single test, required only a small biological sample, and promised a broad array of genetic information.[283] In its infancy, DTC genetic testing was largely recreational, revealing ancestry, physical characteristics, and other non-medical information.[284] The testing companies quickly adopted the same tag line: the tests were not—in any form—diagnostic in nature and instead provided a form of consumer education in the context of their own genetics.[285] Some of the companies farmed out the actual genetic testing and analysis to different laboratories rather than performing the tests in house.[286] In 2007 and 2008,

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[279] *Id*.

[280] FED. TRADE COMM'N, AT-HOME GENETIC TESTS: A HEALTHY DOSE OF SKEPTICISM MAY BE THE BEST PRESCRIPTION (2006), *available at* http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea02.pdf.

[281] FOOD & DRUG ADMIN., MOLECULAR & CLINICAL GENETICS PANEL 16 (2011), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MolecularandClinicalGeneticsPanel/UCM249857.pdf.

[282] Andrew Pollack, *Consumers Slow to Embrace the Age of Genomics*, N.Y. TIMES, Mar. 20, 2010, at B1, *available at* http://www.nytimes.com/2010/03/20/business/20consumergene.html.

[283] *Id*.

[284] *Id*.

[285] *Id*.

[286] Dan Vorhaus, *Personal Genomics Follows Pathway to Corner Drugstore; Is Regulation Next?*, GENOMICS L. REP. (May 11, 2010), http://www.genomicslawreport.com/index.php/2010/05/11/pathway-walgreens-and-dtc-regulation/ (explaining that 23andMe, for example, outsources its genetic testing to an outside lab).

the FDA noted that most of the reporting of test results appeared to come from facilities that were not certified CLIA laboratories and, moreover, were not certified by the state in which they were located.[287]

While federal concern was rising, some states also started to scrutinize DTC genetic testing. California took matters into its own hands in 2007 when it issued thirteen "cease and desist" letters to DTC testing companies that offered the genetic tests despite a state law that required a doctor's prescription for testing.[288] Moreover, California took aim at the companies' use of non-CLIA certified labs.[289] On the heels of California, New York also demanded that DTC genetic testing not be offered for specimens originating in the state of New York.[290] By 2009, the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS),[291] which operates under the Department of Health

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[287] *See* 42 U.S.C. § 263a (2006). The Clinical Laboratory Improvement Amendments (CLIA) of 1988 are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States. *See Clinical Laboratory Improvement Amendments* (*CLIA*), FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm (last visited Jan. 2, 2012). Clinical trials and basic research are exempt from CLIA. *Id*. In connection with the CLIA, the CLIA Program sets standards and issues certificates for clinical laboratory testing. *Id.* CLIA defines a laboratory as "any facility that does laboratory testing on specimens derived from humans to give information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health." *Id.* The CLIA Program is a safeguard of the accuracy, reliability, and timeliness of test results. *Id*. The program model is that regardless of where a test is performed, the standards should produce accurate and precise results across CLIA certified laboratories. *Id.*

[288] Alex Soojung-Kim Pang, *Cease-and-Desist Letter Sent to California-Based Personalized Genetics Startups*, FUTURE NOW BLOG (June 19, 2008), http://www.iftf.org/node/2048.

[289] Emily Singer, *Genetic Testing for Consumers Scrutinized*, TECH. REVIEW (June 23, 2008), http://www.technologyreview.com/printer_friendly_article.aspx?id=20995.

[290] N.Y. COMP. CODES R. & REGS. tit. 10, § 58-1.7 (2011) ("No establishment other than a clinical laboratory under permit shall accept specimens for the purpose of obtaining information for the diagnosis, prevention, or treatment of a disease or the assessment of a health condition.").

[291] The SACGSU charter provides:

> Scientific advances in genetics and genomics help provide a better understanding of health and disease and lead to new technologies and tools that are used in research, clinical care, public health, and nonmedical areas such as forensics. To maximize the contributions of genetic and genomic knowledge and technologies to personal and public health requires consideration of their appropriate integration into health promotion and

and Human Services, opened discussions on DTC genetic testing.[292] Soon after, the FDA sent letters to and met with representatives of several DTC genetic testing companies. Through those letters and in those meetings, the FDA signaled that it had regulatory authority over DTC testing, but the companies unanimously claimed that they had "laboratory developed test" (LDT) status and, therefore, were beyond the reach of the FDA.[293]

These early inquiries into DTC genetic testing represent only a small subset of a much larger discussion that involves issues such as the high price of health care, personalized medicine, and overregulation by "nanny-states." As discussed in more detail *infra*, the "to regulate or not to regulate" debate has reached a tipping point. As of February 2010, more than thirty companies sell DTC genetic services, mostly through online marketing and

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> disease prevention and management. In addition, ethical, legal, and social issues raised by genetic and genomic technologies must be considered to avoid the misapplication of emerging technologies or the creation of inequitable access to technologies with known clinical utility.
>
> To consider these issues and concerns, the Secretary's Advisory Committee on Genetics, Health, and Society was established. This committee will: (1) provide a forum for expert discussion and deliberation and the formulation of advice and recommendations on the range of complex and sensitive issues raised by new scientific and technological developments in human genetics and genomics; (2) assist the Department of Health and Human Services (HHS) and other Federal agencies, at their request, in exploring issues raised by the development and application of genetic and genomic technologies; and (3) make recommendations to the HHS Secretary on how to address such issues.

NAT'L INSTS. OF HEALTH, DEP'T OF HEALTH & HUM. SERVS., CHARTER (2010), *available at* http://oba.od.nih.gov/oba/SACGHS/2010_SACGHS_Charter_Renewal001.pdf. The charter expired on February 28, 2011. *Id.*

[292] Dan Vorhaus, *HHS Pulls the Plug on Genetics Advisory Committee*, GENETICS L. REP. (Sept. 23, 2010), http://www.genomicslawreport.com/index.php/2010/09/23/hhs-pulls-the-plug-on-genetics-advisory-committee/.

[293] LDTs are defined as "medical tests performed by the laboratory in which the test was developed, and the test is neither FDA-cleared nor FDA-approved." *Laboratory Developed Test Oversight Should Be Strengthened*, C. AM. PATHOLOGISTS (Sept. 24, 2009), http://www.cap.org/apps/cap.portal?_nfpb=true&cntvwrPtlt_actionOverride=%2Fportlets%2FcontentViewer%2Fshow&_windowLabel=cntvwrPtlt&cntvwrPtlt{actionForm.contentReference}=statements%2Fldt_oversight_statement.html&_state=maximized&_pageLabel=cntvwr. The regulation is superficial at best. The Center for Medicare and Medicaid Services (CMS) currently manages quality assurances through the authority of the CLIA, but the oversight is little to none, thus making it safe territory for DTC genetic tests. *Id.*

sales.[294] These tests run the gamut and include: single-disorder tests such as Alzheimer's,[295] asthma,[296] breast cancer,[297] and celiac disease;[298] ethnic and hereditary diseases;[299] metabolic health assessments;[300] multi-level disease predisposition and drug interaction tests;[301] to an entire genome spectrum.[302] The tests range from bargain basement deals ($99)[303] to the pricey ($1100)[304] to the outrageous ($4998 per genome for an entire genome map when you order a *minimum* of ten genomes).[305] Concerns about the use of DTC genetic testing fluctuate as much as the price. From the purpose of the test to the quality of the laboratory facility to the business model employed by DTC genetic testing companies, regulators, scientists, entrepreneurs, and consumers have much to consider.

2. Test Prep Course

Despite the variation among the price points and products offered, the tests all share two things in common. First, the tests are sold directly to, and the sample collection is performed by, the

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[294] SEC'Y ADVISORY COMM. ON GENETICS, HEALTH, & SOC'Y, DEP'T OF HEALTH & HUM. SERVS., DIRECT-TO-CONSUMER GENETIC TESTING 5 (2010), *available at* http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_DTC_Report_2010.pdf.

[295] GRACEFUL EARTH, http://www.gracefulearth.com (last visited Jan. 2, 2012).

[296] *Asthma Drug Response Test: β16AsthmaGEN*, CONSUMER GENETICS, http://www.consumergenetics.com/DNA-Tests/Asthma-Drug-Response.php (last visited Jan. 2, 2012).

[297] *Inherited Risk for Breast Cancer ('BRCA Gene-Gene Panel')*, MATRIX GENOMICS, http://www.matrixgenomics.com/resources-breastcancer.php (last visited Jan. 2, 2012).

[298] ENTEROLAB, http://www.enterolab.com (last visited Jan. 2, 2012); HEALTHCHECKUSA, http://www.healthcheckusa.com (last visited Jan. 2, 2012).

[299] FAMILY TREE DNA, http://www.familytreedna.com (last visited Jan. 2, 2012).

[300] *Metabolic Health Assessment DNA Analysis*, CYGENE DIRECT, http://cygene.infinityarts.com/browse-10868/Metabolic-Health-Assessment.html (last visited Jan. 2, 2012).

[301] *GTL DNA Tests*, GENETIC TESTING LABS., http://www.gtldna.com/dnatests.html (last visited Jan. 2, 2012); EASYDNA, http://www.easy-dna.com (last visited Jan. 2, 2012); BIOMARKER PHARM., http://www.biomarkerinc.com (last visited Jan. 2, 2012); 23ANDME, *supra* note 1.

[302] SEQWRIGHT DNA TECH. SERV., http://www.seqwright.com (last visited Jan. 2, 2012).

[303] 23ANDME, *supra* note 1.

[304] *Store, Our Products: deCODEme Complete Scan*, DECODE GENETICS, https://www.decodeme.com/store (last visited Jan. 2, 2012).

[305] KNOME, http://www.knome.com/ (last visited July 20, 2011).

consumer. In many cases a medical provider plays absolutely no role in the process.[306] Second, the tests do not purport to make an actual diagnosis. Rather, the results report the presence of genetic variations and attempt to predict (usually in the form of a percentage) the likelihood of developing a disorder related to that variation.[307] Where a company calculates the genetic risk for upwards of fifty conditions and traits, the results can lead to both relief and distress, much like a tarot card reading.

Predictive genetic testing that is administered by a physician is no different in this respect. It too delivers a likelihood calculus to express the risk of developing a disease or disorder.[308] The differences between tests overseen by a medical provider and DTC genetic tests come in the form of the mechanism of collection, the laboratory process and analysis, and the confidence in the final report.[309] Many DTC genetic tests come in the form of a prepackaged kit that contains a tube for saliva collection.[310] The consumer effectively spits a sizeable amount of saliva (if you can quantify a little vs. a lot of saliva) into the tube, pops the cap on it, seals it into the pre-addressed box, and mails is off to a laboratory which may or may not be the same location as the company offering the DTC genetic testing.[311]

Genetic testing in the clinical setting encompasses more than just predictive genetics, however. Clinical genetics tests generally fall into three categories: "predictive, diagnostic, and prenatal."[312] At-home genetic tests generally steer clear of the prenatal tests, and instead put their eggs in the predictive basket.[313] The

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[306] *See, e.g.*, websites listed *supra* notes 295-302.

[307] *Id.*

[308] NUTRITION AND GENOMICS: ISSUES OF ETHICS, LAW, REGULATION, AND COMMUNICATION 91 (David Castle & Nora M. Ries eds., 2009).

[309] *Id.*

[310] *See, e.g.*, *A Peak Inside the 23andMe Package*, AMAR'S BLOG (April 9, 2011), http://blog.zumkhawala.com/2011/04/peak-inside-23andme-package.html.

[311] *Id.*

[312] Gniady, *supra* note 249, at 2441.

[313] But see SEQureDx™ technology, a DTC genetic test that relies upon a maternal blood supply and is marketed as a "revolutionary approach to prenatal genetic screening. Rather than harvesting placental tissue cells (as is required for chorionic villus sampling), or entering the uterus to sample the amniotic fluid surrounding the baby (as is done with genetic amniocentesis), this proprietary technology extracts and analyzes DNA material directly from a maternal blood sample. SEQureDx technology utilizes circulating cell-free fetal nucleic acids in maternal plasma to examine

predictive testing model answers a basic question: whether a person has a particular genetic variation known to be related to the development of a particular disorder.[314] That answer is then translated into a likelihood ratio of actually developing the disorder and then generally compared to the average incidence of that disorder in a larger population.[315] One person's individual disease risk calculus may or may not factor in family history. Some DTC testing companies have lengthy questionnaires that a consumer is invited to fill out.[316] Whether that data is used in either the sequencing or the analysis portion of the tests is difficult to ascertain since much of the process is protected as a trade secret.[317]

3. Grading the DTC Genetic Tests

Without a doubt, gene sequencing and genetic analysis are critical components to future scientific discoveries and medical breakthroughs.[318] Many medical and pharmaceutical research projects require some amount of genetic testing. New drugs and treatment rely on genetics.[319] Preventative medicine has become more prevalent because of genetic testing.[320] Scientists isolate, probe, and manipulate genes in multiple ways to further our understanding of how our bodies work.[321] The difficult part is that using genes to treat health concerns is not as simple as using aspirin to alleviate a fever. Genetics is a complex field. After all,

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variances in the genetic material of the fetus, such as aneuploidies." *Fetal Nucleic Acid Technology*, SEQUENOM, http://www.sequenom.com/home/products---services/diagnostics/prenatal-diagnostics/fetal-nucleic-acid-technology/ (last visited Jan. 2, 2012).

[314] Gniady, *supra* note 249, at 2441.

[315] *Id.*

[316] 23ANDME, *supra* note 1.

[317] *See, e.g.*, *Terms of Service*, 23ANDME, https://www.23andme.com/about/tos/?version=1.1 (last visited Jan. 2, 2012).

[318] Dhavendra Kumar, *Clinical Medicine in the Genome Era: An Introduction*, *in* GENOMICS AND CLINICAL MEDICINE 145, 145 (Dhavendra Kumar & Sir David Weatherall eds., 2008).

[319] *Id.* at 149 (discussing the emergence of pharmacogenetics—the "study of the role of inherited genetics in individual variation in drug response and toxicity").

[320] *Id.* (discussing "personalized medicine").

[321] Kumar, *supra* note 318, at 595 (discussing the process of gene isolation and manipulation).

with nearly 25,000 genes making up the lattice work of our genomes, it is easy to get lost amid the twists and turns.

Genetics should be the farthest medicine can get from a "one size fits all" model of care. It has the potential to be the most individualized form of personalized medicine. But as a predictive tool, genetic testing offers what is effectively an educated guess.[322] Although we seek certainty, science cannot yet offer that based on a predictive genetic test.[323] The disparity between a predictive genetic assessment and an actual diagnosis is often referred to as a "therapeutic gap." Despite the information that genetic testing provides, in most cases the information does not change the course of treatment until the disorder manifests.[324] Moreover, for DTC testing, few companies offer any sort of genetic counseling once a consumer receives results.[325] Other companies outsource their genetic counseling and charge users a fee.[326] For example, 23andMe's genetic counseling provision states:

> A genetic counselor can help you understand more about your 23andMe reports and respond to your genetic health questions. 23andMe is collaborating with Informed Medical Decisions, Inc., to give you direct access to board-certified counselors that have been specifically trained to guide you through your 23andMe results.[327]

Clicking on the link to learn more about 23andMe's genetic counseling options reveals that it costs at a minimum $99 to speak with a genetic counselor, and up to $250 to have *comprehensive* clinical genetic counseling.[328] Query whether such an approach to

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[322] *See, e.g.*, Andrew Pollack, *A Blood Test Offers Clues to Longevity*, N.Y. TIMES, May 19, 2011, at B1, *available at* http://www.nytimes.com/2011/05/19/business/19life.html?_r=2&ref=dnadeoxyribonucleicacid&pagewanted=all (explaining that new genetic tests purporting to give insight into a person's lifespan cannot specify how many years or months one can expect to live).

[323] *Id.*

[324] Gniady, *supra* note 249, at 2431.

[325] *Id.* at 2451.

[326] For example, 23andMe outsources its genetic counseling services to Informed Medical Decisions, Inc. *23andMe*, INFORMED MED. DECISIONS, http://informeddna.com/index.php/23andme/schedule-appointment-23.html (last visited Jan. 2, 2012).

[327] *Pseudicholinesterase Deficiency - Sample Report*, 23ANDME, https://www.23andme.com/health/Pseudocholinesterase-Deficiency/ (last visited Jan. 2, 2012).

[328] INFORMED MED. DECISIONS, *supra* note 326.

genetic counseling can be successful given that it is telephonic and there is no preexisting medical relationship between the parties.[329] A counselor is limited to the genetic results and whatever information is reported by the consumer. It seems to be more of a profit tool rather than a patient service.

Beyond the emotional and psychological impact, there are even fewer resources available to gauge the reliability of the DTC genetic tests.[330] Accuracy and reliability of genetic testing depends on the related *analytic* and *clinical validity* of the test.[331] *Analytic validity* pertains to the test arriving at the "'right answer' as to whether a specific gene mutation is present or absent" in that individual.[332] *Clinical validity* builds upon the "right answer" and asks whether that specific "test result correlates with the presence or absence of a specific disease, or heightened risk of disease," in the individual.[333] Accuracy and reliability work in tandem in the same manner as analytic and clinical validity. *Accuracy* concerns whether genetic variations are in fact present in that person.[334] *Reliability* is another way of examining precision. In other words, if the genetic test is performed one hundred times, the same genetic variations would be found each time.[335] Measuring accuracy, reliability, and validity (both clinical and analytic) largely depends on the specific mechanics of that test and on the capabilities of the laboratories performing the test.[336] Last, *clinical utility* must also be considered. Does the test have a "positive impact on a patient's health and wellbeing?"[337] According to the Genetics and Public Policy Center, "Evidence demonstrating utility can take years to establish. The current oversight system does not ensure the analytic or clinical validity or the clinical utility of genetic tests."[338]

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[329] Gniady, *supra* note 249, at 2449–51.

[330] *Id.* at 2442.

[331] Audrey Huang, *Who Regulates Genetic Tests?*, GENETICS & PUB. POL'Y CTR., http://www.dnapolicy.org/policy.issue.php?action=detail&issuebrief_id=10 (last modified May 30, 2008).

[332] *Id.*

[333] *Id.*

[334] *Id.*

[335] *Id.*

[336] *Id.*

[337] *Id.*

[338] *Id.*

Whether there is independent review of a specific DTC genetic test to assess its performance depends on whether the company developed its test as an LDT.[339] As noted earlier, LDT kits are not required to undergo an independent evaluation of their clinical validity.[340] It falls to the individual laboratory director to determine whether to offer a test for review.[341] That means few, if any, DTC genetic tests have undergone an independent review to assess accuracy, reliability, and validity.[342] Furthermore, the laboratories that perform the analysis may fall below the radar and go unchecked for safety, contamination, and methodology issues.[343] The foregoing does not even touch upon the mathematical algorithms and population genetics the various DTC companies use to arrive at their results.[344] Consequently, these tests contain a massive amount of information. How useful and accurate that information is remains to be seen.[345]

4. Mean Genes: What Your Genes Say About You When You're Not Around

Popular culture portrays genetics as an omniscient and omnipotent force of nature.[346] Indeed, television programming is saturated with crime and medical dramas where the lynchpin to cracking a case or determining a diagnosis is housed in DNA.[347] The movie *Gattaca*—named for the first letters of the nucleobases that form the basic building blocks of DNA—depicted a society beholden to a future predetermined by one's DNA. The test of a single drop of blood forever set a person's destiny; the course could not be altered.[348] Genetics even made its way into song and dance. The 2008 comedy-horror-musical movie titled *Repo! The Genetic*

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339 *Id.*

340 *See* discussion *supra* note 293.

341 Huang, *supra* note 331.

342 *Id.*

343 *Id.*

344 Gregory M. Lamb, *How Reliable is Personal DNA Testing?*, CTR. FOR GENETICS & SOC'Y (Sept. 15, 2010), http://www.geneticsandsociety.org/article.php?id=5372.

345 *Id.*

346 Jessica D. Gabel, *Forensiphilia: Is Public Fascination With Forensic Science a Love Affair or Fatal Attraction?*, 36 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 233, 243 (2010).

347 *Id.* at 240.

348 *Id.*

Opera featured an organ-financing program structured in the same manner one would find a standard car loan.[349] The repossession clause (i.e., reclaim the organ for nonpayment) proved fatal.[350]

The point here is that genetics has become an almost ubiquitous feature of modern life. Despite the advanced and technical aspects of the science, more and more people feel comfortable with the concept that genes and DNA play a role in many different facets of our lives.[351] Skepticism has been replaced with complacency, and the lay public—future consumers and patients—generally have a positive view of genetics.[352] A 2005 survey revealed that seventy-two percent of women aged eighteen to seventy-four consider genetics to be one of the key causes of cancer.[353] The study's authors suggested that this uniform endorsement of the significance of genetics in causing disease (to the exclusion of environmental and lifestyle choices) may demonstrate that people might give undeserved credence to the role that genes play in disease causation.[354]

Unfortunately, genetic perception and genetic literacy are not mutually inclusive concepts. Although various public interest organizations attempt to raise the level of genetic education, the efforts often lose out to the constant stream and sensationalism of the twenty-four-hour news cycle, hand-wringing blog postings, and entertainment offerings. One could imagine a reality game show where contestants must use genetic information to piece together who else in the confined but posh living quarters they are related to. Another program might take its cue from shows like *Intervention* and *Hoarders* and depict someone who learns that she has the gene that causes an inevitably fatal disease and

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[349] *See Repo! The Genetic Opera*, INTERNET MOVIE DATABASE, http://www.imdb.com/title/tt0963194/ (last visited Jan. 2, 2012).

[350] *Id.*

[351] Kiley Ariail, Carolyn Cindy Watts & Deborah J Bowen, *Retention in a Breast Cancer Risk Information Trial: Motivations of a Population-Based Sample of Women*, 33 HEALTH EDUC. & BEHAV. 591-603 (2006).

[352] Tania M. Bubela & Timothy A. Caulfield, *Do the Print Media "Hype" Genetic Research? A Comparison of Newspaper Stories and Peer-Reviewed Research Papers*, 170 CAN. MED. ASS'N. J. 1399 (2004).

[353] *Id.*

[354] *Id.* at 1403-04.

proceeds to document her personal "Bucket List"[355] and preparations for death.

Thus, the "war" between information and entertainment can increase the potential for misunderstanding the possibilities and limitations of genetics. To fill the gaps, people now turn to the internet to do research. A Google search for "genetic testing" immediately results in three advertisements at the top of the screen.[356] Each one is a DTC genetic test.[357] What also pops up is a 2008 *Time Magazine* article heralding DTC genetic testing as the "best invention" of the year.[358] What consumer would distrust the esteemed editors of *Time*? In fact, flipping through the pages of most popular magazines, consumers will find the pages littered with various advertisements for pharmaceutical products. The fine print is accurate (indications and side effects), but the photos and bold words are intended to convey positive and promising messages to consumers.

The "get better" mentality is what brings consumers to pharmaceutical products, and demand drives profit. Similarly, tag lines from DTC companies send the same messages to their consumers: "Gene-ius. A smart way to look at your health;"[359] "Start filling in the gaps with your DNA;"[360] "From DNA to Discovery;"[361] "deCODE your health, Calculate genetic risk—Empower prevention: your genes are a road-map to better health."[362] Of course, the purpose of advertising is to bring

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[355] A bucket list is a "list of things you want to do before you die." *Bucket List Definition*, URBANDICTIONARY.COM, http://www.urbandictionary.com/define.php?term=bucket%20list (last visited Jan. 2, 2012).

[356] *Genetic Testing – Google Search*, GOOGLE, http://www.google.com/search?q=genetic+testing&ie=utf-8&oe=utf-8&aq=t&rls=org.mozilla:en-US:official&client=firefox-a (last visited Jan. 2, 2012).

[357] GENETIC TESTING LABS., http://www.gtldna.net (last visited Jan. 2, 2012); THE PATERNITY DOCTOR, http://www.thepaternitydoctor.com (last visited Jan. 2, 2012); 23ANDME, *supra* note 1.

[358] Anita Hamilton, *Best Inventions of 2008: The Retail DNA Test*, TIME SPECIALS (Oct. 29, 2008), http://www.time.com/time/specials/packages/article/0,28804,1852747_1854493_1854113,00.html.

[359] NAVIGENICS, http://www.navigenics.com/ (last visited Jan. 2, 2012).

[360] 23ANDME, *supra* note 1.

[361] *Knome Awards Human Exome Sequencing and Analysis to Biomedical Researchers*, KNOME (Oct. 5, 2010), http://knome.com/2010/10/knome-awards-human-exome-sequencing-and-analysis-to-biomedical-researchers/.

[362] DECODE GENETICS, http://www.decodeme.com/ (last visited Jan. 2, 2012).

consumers to a product, and thus companies focus on their strengths and not their limitations. No DTC genetic company in its right mind would use a slogan like: "Scare Yourself Silly with Our Semi-Reliable Genome Scoping." Nonetheless, because our genetic composition will almost always have both positive and negative aspects, the promises of the testing should incorporate a dose of objectivity and education.[363]

B. Benefits of DTC Genetic Tests

Knowledge itself is power.[364] Genetic testing can dramatically affect the way we lead our lives. Genetic testing for certain diseases can predict or even diagnose disease and correspondingly alter treatment and therapy options.[365] Certain clinical genetic tests have already demonstrated this. For example, if a woman elects to take the Comprehensive BRACAnalysis test (which identifies mutations in the BRCA1 and BRCA2 genes associated with hereditary breast and ovarian cancer) and receives positive results, she has several treatment alternatives.[366] These options range from the less invasive (a wait and see approach or increased surveillance) to the more involved (chemoprevention) to the preemptive strike (preventative mastectomy or oophorectomy).[367] In those cases, some patients feel that it is better to act sooner rather than later.

The potential advantages of DTC genetic testing seem less concrete. There are intangible benefits: "convenience, increased

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[363] The U.S. Federal Trade Commission has the authority to investigate any advertising claims and take action should it find the claims to be false or misleading. Depending on the company, DTC advertising may or may not include all relevant information regarding capabilities and limitations of the tests, and contain a statement referring patients to qualified health providers or genetic counselors to obtain further information. As it stands now, the FTC seems to be reluctant or otherwise occupied, and it has not flexed its regulatory authority to reign in DTC advertising. *See Advertising FAQ's: A Guide for Small Business*, BUREAU OF CONSUMER PROT. BUS. CTR., http://business.ftc.gov/documents/bus35-advertising-faqs-guide-small-business (last visited Jan. 2, 2012).

[364] FRANCIS BACON, MEDITATIONS SACRAE AND HUMAN PHILOSOPHY 71 (Kessinger Publ'g 2005) (1597).

[365] *See, e.g.*, *Genetic Testing*, KIDSHEALTH, http://kidshealth.org/parent/system/medical/genetics.html (last visited Jan. 2, 2012).

[366] *Positive: What Should I do Now?*, BRACANALYSIS, http://www.bracnow.com/understanding-my-results/positive-do-now.php (last visited Jan. 2, 2012).

[367] *Id.*

access to testing, consumer autonomy, and individual empowerment."[368] Information from DTC genetic tests may encourage consumers to take responsibility for their health, and prompt them to implement healthy lifestyle choices.[369] In addition, for those consumers who have some fear of seeking medical guidance, a DTC test might be a non-intimidating first step in connecting with the medical community and opening the door sooner rather than later.[370] These benefits represent a more holistic approach to one's health, lifestyle, and wellbeing as opposed to treating specific disorders and illnesses.[371]

As noted earlier, clinical genetic tests that reveal the possibility of developing a specific disorder might cause that person to monitor the appearance of related symptoms.[372] Family members might be prompted to be tested as well, and potential parents might get screened to determine if they are carriers for certain diseases.[373] In addition, negative test results can reassure individuals that they are, at least, not genetically susceptible to a specific illness. These benefits, however, are currently limited to clinical genetic tests. DTC testing may offer a prediction, but the lack of regulation and laboratory standards detracts from the clinical value.[374]

DTC genetic testing might also provide a private health preview for consumers who might be concerned about genetic discrimination.[375] The Genetic Information Nondiscrimination Act of 2008 (GINA) is intended to provide federal protection against genetic discrimination in both the insurance and workplace settings.[376] GINA, however, is limited in scope. Its protections do not cover life insurance or long-term health care, and individuals

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[368] DIRECT-TO-CONSUMER GENETIC TESTING, *supra* note 294, at 6.

[369] *Id.*

[370] *Id.*

[371] Bridget M. Kuehn, *Risks and Benefits of Direct-to-Consumer Genetic Testing Remain Unclear*, 300 JAMA 1503, 1503 (2008).

[372] DIRECT-TO-CONSUMER GENETIC TESTING, *supra* note 294, at 6.

[373] *See* KIDSHEALTH, *supra* note 365 ("[Genetic Tests] determine whether you, your partner, or your baby carry genes for certain inherited disorders.").

[374] Kuehn, *supra* note 371, at 1504.

[375] DIRECT-TO-CONSUMER GENETIC TESTING, *supra* note 294, at 6.

[376] *Breaking News: GINA Becomes Law May 2008*, HUM. GENOME PROJECT INFO., http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml (last visited Jan. 2, 2012).

might want to gauge their relative genetic risk factors before seeking the clinical confirmation.[377]

C. With Benefits Come Burdens . . . and Concern

Information is not knowledge.[378] DTC genetic tests offer a glimpse into your DNA, but they lack the quantifiable value of the clinical genetic tests.[379] Currently, there is little research on consumers' satisfaction with DTC genomic tests.[380] Concerns about DTC genetic testing seem to vary substantially. The purpose of the test, laboratory quality controls, and the business model of the company offering the test all represent chief concerns among scientists and regulators.[381] There is also a certain amount of uneasiness as to whether genetic testing causes social, emotional, or psychological harm either directly or indirectly.[382]

1. Purpose and Manner of the Test

DTC predictive tests may be very large in scope. They might also be narrowed to just one disease.[383] The severity of the disorder and the gravity of the information being relayed are factors that play an important role to regulators. A test to determine if a person may carry the gene believed to influence the development of cystic fibrosis may raise "few red flags" if the test is conducted by a properly certified laboratory and the company utilizes "credentialed genetic professionals" to discuss the results with the customers.[384] On the other hand, if a company tests for everything from sensitivity of smell to IQ to Alzheimer's disease and provides the bare minimum information about the genetic

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[377] *Id.*

[378] *Albert Einstein Quotes*, QUOTE ARCHIVE, http://www.evula.com/quotes/einstein.php (last visited Jan. 2, 2012).

[379] Karen Norrgard, *DTC Genetic Testing for Diabetes, Breast Cancer, Heart Disease and Paternity*, SCITABLE (2008), http://www.nature.com/scitable/topicpage/dtc-genetic-testing-for-diabetes-breast-cancer-698.

[380] DIRECT-TO-CONSUMER GENETIC TESTING, *supra* note 294, at 10.

[381] *Id.* at 6.

[382] *Id.* at 8-9.

[383] *Id.* at 5.

[384] *Id.* at 6.

variants or DNA regions being analyzed, then it might "provoke outcries from the medical community."[385]

Genetic tests and the interpretation of their results can fluctuate in their quality, and it can be difficult for consumers to discern the differences.[386] There is a potential for predictions to be exaggerated, and results may imply a confidence and level of accuracy that is simply unsubstantiated.[387] While the DTC genetic tests purport to be risk assessments, that label is challenging to characterize given the variety of contextual applications. Some tests fail to report the results in terms of understandable levels of specificity, sensitivity, and confidence.[388] A statistical estimate can be confusing to the average person (consider the DNA statistics offered at the O.J. Simpson trial).[389] Although this type of testing can be informative, without the proper knowledge to interpret and put it into the context, the results can be deceiving.

Receiving a statistical predictor or even a generic statement of risk (such "above average risk") makes the likelihood of disease hard to quantify for a consumer.[390] A risk is simply that—something that may or may not happen. But when delivered in the confines of a medical statement such as "you have a 13% risk of developing Alzheimer's disease," what exactly should a consumer take away from that missive? Does it mean that thirteen out of one hundred times your memory will be wiped away in your old age? Can that number change? To whom is the thirteen percent relative to? Is it along ethnicity or racial lines? Gender? Age? Does thirteen percent make Alzheimer's a remote possibility or a foregone conclusion? When results are dropped on someone by

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[385] *Id.*

[386] JEREMY GRUBER, COMMENTARY, MOLECULAR AND CLINICAL GENETICS PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE ON DIRECT TO CONSUMER GENETIC TESTS 2 (Mar. 8-9, 2011), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MolecularandClinicalGeneticsPanel/UCM248557.pdf.

[387] *Id.* at 3.

[388] *Id.* at 5.

[389] ACLA, COMMENTARY, MOLECULAR AND CLINICAL GENETICS PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE ON DIRECT TO CONSUMER GENETIC TESTS (Mar. 8, 2011), *available at* http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MolecularandClinicalGeneticsPanel/ucm245447.htm [hereinafter ACLA COMMENT].

[390] *Id.*

email or online account, the *personalized* level of medicine suddenly becomes just a medical bar code. As a result, some consumers might find themselves confused and frightened due to a lack of communication from the company (and corresponding misunderstanding) of the meaning or relative significance of the test results. The American Clinical Laboratory Association (ACLA) believes that these "unintended consequences can be minimized when appropriate medical personnel are involved in the test ordering, reporting and consultation, as appropriate."[391]

Some of the more reputable DTC testing companies do a "decent job" of informing the consumer of what and where along a DNA strand they are testing.[392] But as the Council for Responsible Genetics points out, these companies are stuck between a rock and a hard place as "they attempt to market their services while at the same time communicating the current limitations of what we can learn from genetic information."[393] While companies routinely proclaim that these tests do not offer medical advice, what is said can be very different from what is heard. The result "you have a 13% risk of developing Alzheimer's disease," certainly sounds like medical advice. Overstating the significance of genetic results, especially for tests that lack a level of reliability or standardization set by a professional genetics association might be no different than throwing darts at a target to determine the predictive risk of developing a disease.[394]

2. Quality Controls in the Laboratories

Both CLIA and state agencies regulate clinical laboratories.[395] In addition, ACLA has instituted certain safeguards and requirements for its member laboratories, "including the requirement that its members gain accreditation by an independent, CLIA recognized organization."[396] DTC companies are not independently regulated by CLIA—although

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391 *Id.*

392 GRUBER, *supra* note 386, at 3.

393 *Id.*

394 *Id.*

395 Rebecca Antar Novick, *One Step at a Time: Ethical Barriers to Home Genetic Testing and Why the U.S. Health Care System is not Ready*, 11 N.Y.U. J. LEGIS. & PUB. POL'Y 621, 630 (2008).

396 ACLA COMMENT, *supra* note 389.

some critics have called for such regulation.[397] The American Society on Human Genetics has called for the development of "detailed national standards for genetic tests" and that labs that perform genetic tests should be assessed on the basis of these standards.[398] This dovetails into concerns over sample switching and contamination.

In reality, all medical testing is vulnerable to the possibility for laboratory errors, yet we as patients would like to believe that it does not happen (unless we get bad news). Laboratory errors can be the result of one or several factors, such as the misidentification or contamination of the chemicals used for testing.[399] Of course, mistakes happen. Over the past decade, lab errors have occurred at numerous state, federal, and military crime labs and have included the mishandling and contamination of DNA samples.[400] As DNA became a routine part of criminal investigations and prosecutions, the public has been lulled into accepting the notion that forensic DNA testing is infallible.[401] It is only logical that this trust would carry over into genetic testing. But mistakes in genetic testing are just as likely, if not more. Forensic DNA testing has become a very standardized process and most laboratories use the same standards, methods, and equipment to extract, test, and analyze DNA.[402] This standardization has yet to be replicated on the DTC genetic testing side. Just as mistakes in a forensic crime lab can have far reaching implications, so too can errors in DTC labs.

In June 2010, 23andMe reported that "a number of new 23andMe customer samples were incorrectly processed" by its

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[397] Gniady, *supra* note 249, at 2436-37.

[398] AMERICAN SOCIETY FOR HUMAN GENETICS, COMMENTARY, MOLECULAR AND CLINICAL GENETICS PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE ON DIRECT TO CONSUMER GENETIC TESTS (March 7, 2011), *available at* http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MolecularandClinicalGeneticsPanel/ucm245447.htm.

[399] *See* William C. Thompson, *Tarnish on the "Gold Standard": Recent Problems in Forensic DNA Testing*, CHAMPION 10 (Jan.-Feb. 2010), *available at* http://www.nacdl.org/champion.aspx?id=1537.

[400] *Id.*

[401] Gabel, *supra* note 346, at 251.

[402] Thompson, *supra* note 399 (describing forensic DNA as the "gold standard of forensic science").

third-party laboratory that actually performs the tests.[403] In its press release, the company acknowledged that as many as ninety-six people received test results that were not their genetic profiles.[404] One of the distressed consumers posted her concerns on the 23andMe message board. The tests results indicated that her son had hemochromatosis[405] despite the fact that she and her husband were not carriers for the disease.[406] Whether misplaced or not, this woman worried that perhaps her son had been switched at birth with another baby at the hospital.[407]

This mix up does little to allay concerns that DTC companies use unreliable laboratories that operate outside the reach of regulators. In its remedial statement, 23andMe pledged to put "additional procedures in place that will add an extra layer of safeguards."[408] The company also stated that it was considering a fully automated process, which would remove the possibility of human error.[409] Of course, it still takes a human to insert samples into and operate the machine, but clearly, that is beside the point. Perhaps it is not a coincidence that a mere two days after 23andMe publicly acknowledged the lab error, the FDA informed the company that its 23andMe Personal Genome Service qualified as a medical device under the federal Food, Drug, and Cosmetic Act, making it subject to regulation by the FDA.[410] However innocent and "it could happen to anybody" in nature the error may have been, 23andMe's carelessness provides more impetus for stringent regulation and, perhaps, government intervention.[411]

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[403] Amar Toor, *23andMe's DNA Mixup Leaves 96 Customers With Wrong Test Results*, SWITCHED (June 8, 2010, 12:45 PM), http://www.switched.com/2010/06/08/23andmes-dna-mixup-leaves-96-customers-with-wrong-test-results/print.

[404] *Id.*

[405] Hemochromatosis is the abnormal accumulation of iron in certain organs that lead to organ toxicity. It is one of the most common genetic diseases in the United States. *Hemochromatosis*, MEDLINEPLUS, http://www.nlm.nih.gov/medlineplus/hemochromatosis.html (last visited Jan. 2, 2012).

[406] Toor, *supra* note 403.

[407] *Id.*

[408] *Id.*

[409] *Id.*

[410] Letter from the FDA to Ann Wojicki (June 10, 2010), *available at* http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM215240.pdf.

[411] *Id.*

3. The DTC Business Model

A primary concern with the DTC business model is that it purposely lacks the medical advice component. Genetic testing provides a snapshot of information about a person's health.[412] It does not make connections between family medical history, lifestyle choices, and environmental factors that may also affect a person's risk of developing many disorders.[413] A discussion about the whole picture of health is something that ordinarily occurs between doctor, patient, and possible genetic counselor. With many companies, these additional factors are not—and to some extent cannot—be addressed by DTC genetic tests.

Many of the companies that offer DTC genetic tests provide the results via a secured internet account that the consumer sets up upon ordering the test.[414] Thus, all results are delivered in a rather robotic fashion where the consumer clicks from link to link to reveal their genetic information.[415] This online format is perhaps the easiest way to provide the results along with detailed studies and the standard "for more information, click here" link. Otherwise, companies that test for a broad range of information would have to send a consumer a volume of material that is impossibly thick. While these accounts are no doubt secure, they are not impervious to being hacked by some third party. When credit card companies reveal that accounts have been breached by a sinister criminal, we worry about whether someone will charge a tank of gas or a trip to Puerto Rico. Those problems are just a matter of numbers and can be readily repaired. But if your account with a DTC company is compromised, suddenly there is a massive amount of private information in the hands of an unintended recipient.[416] Yet consumers would probably be more concerned about who is taking their money and what it is being used for than having their genetic information on the loose. For

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[412] GREGORY J. WALTERS, HUMAN RIGHTS IN AN INFORMATION AGE: A PHILOSOPHICAL ANALYSIS 155 (2001).

[413] *Id.*

[414] *See, e.g.*, 23ANDME, *supra* note 1.

[415] *Id.*

[416] *See* discussion *infra* Section IV.A. (explaining the extensive surveys one such company asks its customers to participate in as part of the process).

some people, it may not matter much whether genetic information is public or private. But for others, it is a very real concern.

Setting security issues aside as perhaps a minor concern, another problem is the genetic social networking that some DTC companies offer. Consumers who have similar genetic profiles can interact with each other. With some DTC genetic tests, consumers must affirmatively opt-out of being included within that social networking community and the larger research projects carried out by the companies. Not surprisingly, the terms and conditions related to sharing of information are buried in fine print on a crowded webpage.[417] 23andMe offers its "Relative Finder" that allows customers to reach out and touch the branches of his or her family tree.[418] The company proclaims that Relative Finder can find kin "on any branch of your tree," and that, as a 23andMe member, "you will likely find over 100 relatives, depending on your ancestry."[419] The company also contends that those customers with Ashkenazi Jewish ancestry "might find well over a thousand relatives."[420] When 23andMe launched this service, it stated (somewhat with tongue-in-cheek) that Relative Finder allows customers to "discover more about your ancestry than you ever thought possible! . . . After all, you never know who you might find."[421]

The relative stalking feature gives information about your genetic commonalities to other persons who share them. Many of these "relatives" fall into the cousin category and labeled as "3rd to 6th Cousin" or "3rd to Distant Cousin."[422] How related they are seems to be a subjective assessment determined by 23andMe. The perils of Facebook faux pas have been widely chronicled by the

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[417] *Terms of Service*, 23ANDME, https://www.23andme.com/about/tos/ (last visited Jan. 2, 2012).

[418] *Ancestry*, 23ANDME, https://www.23andme.com/ancestry/relfinder/ (last visited Jan. 2, 2012).

[419] *Id.*

[420] *Id.*

[421] Lawrence Hon, *Introducing Relative Finder: The Newest Feature from 23andMe*, SPITTOON (Nov. 19, 2009, 5:13 PM), *available at* http://spittoon.23andme.com/2009/11/19/introducing-relative-finder-the-newest-feature-from-23andme/.

[422] *Id.*

media.[423] Facebook has become a breeding ground for bullying, rumor-mongering, and poor judgment. As more people become members of the genetic social networks offered by some DTC companies, it would not be hard to imagine similar antics taking place.[424]

4. The Harm Factor

In my view, the harm factor involves both direct and indirect effects of genetic testing. The direct effects concern the impact on a person's health and *individual* health-related decisions subsequent to receiving test results. The indirect effects involve ethical issues surrounding genetic testing. Some critics liken DTC genetic testing to arming an untrained consumer with a loaded weapon.[425] This is an exaggeration. For years, the medical community has preached that patients should take the lead in observing and reporting their health concerns to their doctors.[426] The argument can be made that DTC genetic testing is part of that picture (assuming the patient discusses it with his or her doctor).

The indirect effects that function more like ticking time bombs relate to the effects on family members. Some DTC companies report "carrier status" for certain diseases that may be passed on to offspring. A couple may choose not to have children if it is determined that they both carry the genes that depending on how they were inherited would leave a child with a debilitating disease.[427] In addition, individuals who are adopted (and do not know it) or the product of donated eggs and/or sperm may unknowingly discover this through genetic testing. The social networking and "Relative Finder" features may cause this person to stumble upon relatives that do not want to be found or that the

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[423] *See, e.g.*, *25 Common Facebook Faux Pas that College Students Make*, ONLINECOLLEGE.ORG (July 19, 2010), http://www.onlinecollege.org/2010/07/19/25-common-facebook-faux-pas-that-college-students-make/.

[424] DIRECT-TO-CONSUMER GENETIC TESTING, *supra* note 294, at 35-36.

[425] Geoffrey S. Ginsburg, *Controversies in Medicine: Direct-to-Consumer Genetic Testing*, DUKEHEALTH.ORG (June 18, 2010), http://www.dukehealth.org/health_library/health_articles/controversies_in_medicine_direct_to_consumer_genetic_testing/.

[426] *Id.*

[427] *Id.*

person does not want to find. It may also unrealistically raise hopes of someone who is seeking to find biological relatives.

There is also a concern with what I euphemistically term "Ninja DNA." While some DTC companies seek saliva samples that require an involved and deliberate process of producing a substantial amount of spit in a tube, other companies need a much smaller biological sample—saliva or otherwise. For these tests (think paternity), a crafty person could surreptitiously obtain a biological sample, submit it to the company, and receive the results without ever involving the actual source of the DNA.[428] The companies do not require proof of identity nor do they require that the person submitting the sample is in fact the source of that sample.[429] Simply put, there is room for exploitation of vulnerable individuals.

In terms of direct harm, DTC-testing skeptics worry that without the benefit or guidance of a medical professional, consumers could misinterpret the results and take unnecessary and harmful actions (e.g., foregoing more traditional tests such as colonoscopy or mammograms if results are negative).

IV. NO DARK SARCASM IN THE LABORATORY: REGULATING THE GENETIC GROUPON

There are multiple federal agencies, federal laws, state regulators, and state laws that cover DTC genetic testing. As a result, the convoluted swamp of patchwork regulations is a steaming hot mess. Heading up the federal team, the Centers for Medicare and Medicaid Services (CMS) regulate laboratory testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[430] As detailed above, CLIA covers *all* laboratories that conduct testing on human specimens for the purposes of diagnosis

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[428] Eriq Gardner, *Gene Swipe: Few DNA Labs Know Whether Chromosomes are Yours or if You Stole Them*, A.B.A. J., Aug. 2011, at 50, 54, *available at* http://www.abajournal.com/magazine/article/gene_swipe_few_dna_labs_know_whether_chromosomes_are_yours_or_if_you_stole_/.

[429] *Id.*

[430] The Centers for Disease Control and Prevention (CDC) shares some of CMS's laboratory authority through the Clinical Laboratory Improvement Advisory Committee (CLIAC). CLIAC's charter authorizes the committee to advise the CDC, FDA, HHS, and CMS as to any revisions necessary to carry out the mandate of CLIA. Novick, *supra* note 395, at 629.

and treatment.[431] A laboratory that falls under CLIA's purview must be issued a federal certificate in order to perform clinical laboratory tests.[432] CLIA laboratory tests fall into three broad categories: waived, moderate complexity, or high complexity. [433] As the labels indicate, these tests are scored according to the simplistic (waived) or advanced technical nature (high complexity) of the test.[434] Those that fall in between qualify as tests of "moderate complexity."[435] Facilities that perform moderate to high complexity tests are required to undergo regular inspection, registration, quality assurance checks, and proficiency testing (i.e., clinical validity).[436]

The CDC adds its input through CLIA recommendations and also sponsors the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) program.[437] EGAPP's role is not so much regulatory as it is advisory. The program seeks to establish and assess a "systematic, evidence-based process for evaluating genetic tests that are in transition from research to clinical and public health practice."[438] EGAPP examines the validity and utility of specific genetic tests and makes recommendations thereupon. Laboratories, test manufacturers, and research facilities, however, are not bound by these recommendations and guidelines.[439] Rather, they may simply inform and influence lab practices. Unfortunately, information is not oversight.

In addition to the CMS/CLIA oversight and CDC aspirations, the FDA has a dog in this fight.[440] Under the Food, Drug, and Cosmetic Act (FDCA), the FDA regulates *any* test that qualifies as an "in vitro diagnostic device" (IVD), a term that essentially means a freestanding product used in the diagnosis of a disease or

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431 *Id.* at 624-25.

432 *Id.* at 625.

433 *Id.*

434 *Id.*

435 *Id.* at 626.

436 *Id.*

437 *Fact Sheet*, OFF. OF PUB. HEALTH GENOMICS, *available at* http://www.cdc.gov/ostlts/hop/pdfs/OPHG_Factsheet.pdf.

438 *Id.*

439 *See* EVALUATION OF GENOMIC APPLICATIONS IN PRACTICE AND PREVENTION (EGAPP), http://www.egappreviews.org/ (last visited Jan. 2, 2012).

440 *Id.*

medical condition.[441] DTC genetic testing companies circumvent this definition in two ways: first, by couching their tests as predictive and *non*-diagnostic; and, second, by utilizing so-called "home brew" tests (LDTs) developed internally by their laboratories and commercially sold as a laboratory service rather than as freestanding test kits.[442] If the DTC genetic tests qualified instead as IVDs, then the FDA would have the authority to regulate those devices.[443]

At the risk of inviting acronym fatigue, the party here would not be complete without the Federal Trade Commission (FTC). In short, the FTC operates as the advertising police of the federal government. It also oversees various consumer protection laws, and generally has authority to crack down on unfair or deceptive commercial practices.[444] Despite its clear authority to crack down on any exaggerated claims made by DTC genetic testing companies, the FTC has, for the most part, been hands-off.[445] Whether it is a matter of inter-agency territorial disputes or some other gap in federal oversight, the FTC remains a mostly silent partner in *enforcing* regulations related to DTC genetic testing.

Despite its relative silence on the enforcement end, the FTC has published guidelines for consumers considering an at-home genetic test.[446] Among its recommendations, consumers should first discuss the test with a healthcare practitioner as to whether the test should be taken and should then review the results with a doctor or genetic counselor.[447] The FTC ominously states: "Genetic test results can be complex and serious. You don't want to make any decisions based on incomplete, inaccurate, or misunderstood information."[448] The FTC also advises consumers to "understand

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441 GENETICS & PUB. POL'Y CTR., REPRODUCTIVE GENETIC TESTING: ISSUES AND OPTIONS FOR POLICY MAKERS 31 (2004), *available at* http://www.dnapolicy.org/images/reportpdfs/ReproGenTestIssuesOptions.pdf.

442 *Diagnostic Kits- Glossary: Abbreviations*, BERKMAN, http://cyber.law.harvard.edu/commonsbasedresearch/Diagnostic_Kits/Glossary (last visited Jan. 2, 2012).

443 GENETICS & PUB. POL'Y CTR., *supra* note 441.

444 Gniady, *supra* note 249, at 2452-53.

445 The FTC did, however, join the consumer warning published by the FDA and CDC regarding the nutrigenetic tests in 2006. *See* AT-HOME GENETIC TESTS, *supra* note 280.

446 *Id.*

447 *Id.*

448 *Id.*

the benefits and limits of any test before you buy it—or take it"[449] (Query where that information will come from since the company may not provide it, and, if they do, it may not be delivered in any decipherable manner.). Voicing the aforementioned concerns over security and privacy,[450] the FTC warns consumers that they need to protect their privacy, especially if the company posts patient tests results online.[451] Beyond security breach issues, the FTC is justly concerned over *how* companies use consumer's personal information either for the company's own research agenda or to share with marketers.[452] Finally, if the consumer has not been deterred, the FTC drives the last nail in the coffin by recommending "that consumers avoid home tests unless under a physician's supervision."[453] After all, "most *other* home-use medical tests" have been reviewed by the FDA "to provide a reasonable assurance of their safety and effectiveness."[454] The same cannot be said of at-home genetic tests, and the "FDA has not evaluated the accuracy of their claims."[455]

Rounding out the regulation jumble are state laws that regulate labs and occasionally testing standards. Some state health agencies, particularly state public health entities, regulate the licensing, certification, and accreditation of laboratory personnel and facilities, including some that perform genetic tests.[456] Although most state regulatory bodies employ the CLIA standards with no added flair, a few states go above and beyond the requirement.[457] In addition to laboratory oversight, some state laws specifically apply to direct-to-consumer genetic testing. The laws form a hodgepodge collection of limitations or prohibitions on DTC testing; some expressly include genetic testing, while others

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[449] *Id.*

[450] *See* discussion *supra* Section III.C.3.

[451] AT-HOME GENETIC TESTS, *supra* note 280.

[452] *Id.*

[453] Novick, *supra* note 395, at 630 (emphasis added).

[454] AT-HOME GENETIC TESTS, *supra* note 280.

[455] *Id.*

[456] Novick, *supra* note 395, at 630.

[457] Two states—New York and Washington—are exempt from the CLIA requirements because their regulations and requirements for laboratory certification are more stringent than the CLIA federal standards. *Id.*

do not.[458] Some states authorize laboratories to accept samples from and deliver test results directly to patients without authorization from a health care provider.[459] These exceptions are usually extended to more familiar tests as those for cholesterol or pregnancy.[460] As of 2007, at least twenty-five states limit or prohibit DTC testing.[461]

Due to these limitations, some companies that advertise genetic tests directly to consumers require that a doctor actually order the test.[462] For some, this requirement may have been prompted by the FDA letters in the summer of 2010.[463] Other companies seem to flout at least some state laws by sending the test packages directly to customers to collect and submit their own samples.[464] For the companies that do require a health care provider to be involved in the process, customers have an opportunity to receive counseling and discuss what the results mean. Hopefully, those companies send information to the doctors about the tests—what the statistics are based on, and what the limitations of the results are. If not, the doctor may be in no better position to explain the test results to the patient than if the patient had received them directly from the company.

A. Single Case Study: Innovation and Information vs. Efficacy and Privacy

DTC companies seem to have skirted (intentionally and accidentally) most of the piecemeal regulation that "would have,

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458 *See Survey of Direct-to-Consumer Testing Statutes and Regulations*, GENETICS AND PUB. POL'Y CTR. (June 2007), *available at* http://www.dnapolicy.org/resources/DTCStateLawChart.pdf (outlining testing regulations comprehensively by state).

459 *Id.*

460 *Id.*

461 *See id.*

462 *See, e.g.*, *How Our Services Work*, NAVIGENICS, http://www.navigenics.com/visitor/what_we_offer/how_it_works/ (last viewed Jan. 2, 2012) ("Sign up for Navigenics' services through your physician or corporate wellness program.").

463 Dan Vorhaus, *What Five FDA Letters Mean for the Future of DTC Genetic Testing*, GENOMICS L. REP. (June 11, 2010), http://www.genomicslawreport.com/index.php/2010/06/11/what-five-fda-letters-mean-for-the-future-of-dtc-genetic-testing/ (explaining that the FDA sent letters to five major DTC genetic testing companies, advising them that they were operating without FDA approval).

464 *See, e.g.*, 23ANDME, *supra* note 1.

should have, could have" covered genetic testing. Critics of DTC genetic tests argue that consumers are vulnerable to being misled by big promises and technical wizardry. In the fantasy world of fiction and special effects, genetic knowledge can be liberating, but in the real world, many consumers may be unable to make appropriate decisions about whether to get tested, where to find a test provider, or how to interpret the results. This is not to sell the consumer short. To the contrary, consumers today research their purchases more than ever.[465] But as we have learned from the clash of print journalism and blogs, content matters less than the headlines. So when *Time Magazine* proclaims DTC genetic testing as the invention of the year, it seems legitimate. Of course, if editors announced that "Viagra Sheets"—yes, sheets treated with Viagra that then seeps through the skin and into the bloodstream—were the invention of the year, we might question their selection process.[466]

But I digress. Genetics is not the basic science course we took in the ninth grade. It is a complicated and complex field that involves many moving parts. A consumer considering genetic testing might find it difficult to understand those tests that are accepted by the medical community and those which are offered more for the sake of curiosity. DTC genetic tests results might give you advice on your athletic prowess, your tolerance for spicy food, or your sneeze reflex. They might also reveal that you are at a high risk for diabetes but that, genetically speaking, you might have a low response rate to the most common diabetes medications. What is the scientific validity of either set of data? While this Article speaks of these issues and concerns in the abstract, a case study can illustrate it better.

I, the author, wanted to see what would happen if I participated in genetic testing—twice. First, I used a DTC genetic testing company (DTC Test). Then, with the consult of my primary care physician, I had a clinical genetic test performed (Clinical

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[465] *See* Jack Loechner, *Online Research A Significant Part of Consumer Buying*, MEDIAPOST BLOGS (Feb. 22, 2011, 10:16 AM), http://www.mediapost.com/publications/?fa=Articles.showArticle&art_aid=145226.

[466] Actually, the London newspaper *The Sun* labeled Viagra Sheets as one of the upcoming year's "amazing inventions." Mark Hudson, *Viagra Sheets are Hard to Beat*, THE SUN (Jan. 2, 2010), http://www.thesun.co.uk/sol/homepage/features/2790931/Viagra-sheets-are-hard-to-beat-Best-inventions-for-2010.html.

Test). Both testing providers shall remain anonymous. Since I live in Georgia, a state that seems to prohibit DTC genetic testing,[467] I was curious if the DTC Company would in fact perform the test. It happily accepted my money.

The DTC Test was perhaps most interesting because it tested for so many different diseases, traits, drug interactions, etc. Here is a highlight of the entertaining portions: I have a lower risk of developing near-sightedness among Asian populations (I am not Asian), I am a likely sprinter (not so much), I have more freckles than average (freckle free), and I effectively learn to avoid errors (based on my childhood capers, my parents might disagree). But since the Clinical Test did not examine those genetic traits, there is no basis for comparison.

The real opportunity for comparison comes at the disease prediction level. This is where the tests varied, and sometimes completely disagreed. For example, the DTC Test concluded that I have a 12% chance of developing Alzheimer's disease. According to the DTC Company, the average risk is about 7%. The Clinical Test marked my disease risk at 6%. The DTC Company also reported that I have a 21% chance of developing Atrial Fibrillation (irregular heart rhythm). The Clinical Test showed 14%. The average risk in the female population is 16%. While the discrepancies in the risk statistics for both Alzheimer's and Atrial Fibrillation are not huge spreads, the difference is having an "above average" or "below average" risk. For some of the other

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[467] *See* GA. CODE ANN. § 31-22-4(a) (2011) ("A clinical laboratory shall examine human specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations."). The Georgia Code further defines a clinical laboratory as:

> [A] facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the diagnosis of, recommendation of treatment of, or for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings; the term "clinical laboratory" shall include specimen collection stations and shall include blood banks which provide through their ownership or operation a system for the collection, processing, or storage of human blood and its component parts as well as tissue banks which procure, store, or process human or animal tissues designed to be used for medical purposes in human beings.

GA. CODE. ANN. § 31-22-1(2) (2011).

predictive risks (diabetes, hypertension, migraines) the results were very similar. For others (various forms of cancer, autoimmune diseases, musculoskeletal disorders), the results were at odds with one another, showing either lower or higher than average risks.

The DTC Company also requested my participation in its larger research pool. My results would be used for future studies of that company's genetic "community." I declined that invitation. Apparently, however, this did not un-invite me from the company's genetic social network. My results were delivered through my online account. When I log into the account it tells me that I have new messages from my "genetic kin"—people with whom I share common DNA segments with. I have received what I call "Genetic Friend" requests from a "third-to-distant" cousin in Scotland and "third-to-fifth cousin" in Oregon. To my knowledge, I do not have extended family in either location, and their names do not register anywhere on my family tree. This type of information is not available with the Clinical Genetic Test.

While I was able to review my test results from both companies with my doctor, there are some people who will not or for some reason cannot. While some of the superficial information is entertaining, it should be cause for concern that genetic tests are not standardized, do not report results in the same manner, and do not use the same statistical research pools. If a company informs a customer that they are more resistant to some medications and allergic to others, is that accurate information that the consumer can then put down on his or medical history? One could envision a scenario in the not-too-distant future where a DTC genetic test informs a consumer that she has a reduced risk for breast cancer and she then foregoes a mammogram. Disclaimers and exclusions aside, a lawsuit would still probably be filed. Innovation and information are amazing tools when used correctly. They can also be incredibly destructive. Regulation can and should standardize the DTC genetic tests and filter out the flow of unsupported claims and promises.

B. What the Doctor Ordered: A Dose of Regulation

It would be a misstep, and ultimately a Sisyphean task, to regulate DTC genetic tests without considering the future of the

technology, the broad concerns, and the complete regulatory framework. Consequently, questions arise about how far we should regulate DTC genetic testing, who should be responsible for ordering the test and receiving the results, and how those tests should be marketed. The regulations set forth by the FDA, CMS/CLIA, and the FTC create a confused and jumbled set of impotent laws. Rather than working together, the triad seems to work against each other. And since DTC testing evades the reach of certain regulations, it seems to operate in a vacuum instead of a transparent scheme.

1. Current Events

For more than one year, the FDA has contended that the current crop of DTC genetic tests offered to consumers is subject to regulation under Section 201 of the federal Food, Drug and Cosmetic Act (FDCA).[468] The FDA included that proviso in each of its "it has come to our attention" letters that were sent to DTC companies in June and July 2010. Although the agency made its point, it seems to be dragging its feet on revising how it would regulate these tests and whether it would sweep LDTs within the confines of medical device regulation. If that were in fact the FDA's intent, it would remove LDTs from the loose grips of CMS, which only supervises a tiny fraction of the LDT market.[469]

In an effort to clarify its intentions, the FDA met with DTC industry players in March to discuss the DTC testing and LDT regulatory reform.[470] The meeting also included conversations about how to best integrate the laboratories that lack CLIA certification.[471] The FDA is perhaps in the process of now drafting either new regulations or determining how to revise existing regulations to include LDTs and DTC genetic tests. From the meeting, it appears that the crux of the FDA's regulatory shift is the adoption of a risk-based evaluation system that would develop a standardized regulatory environment for all DTC genetic testing

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[468] Dan Vorhaus, *The FDA and DTC: Setting the Record Straight*, GENOMICS L. REP. (March 11, 2011), http://www.genomicslawreport.com/index.php/2011/03/11/the-fda-and-dtc-genetic-testing-setting-the-record-straight/.

[469] *Id.*

[470] *Id.*

[471] *Id.*

companies and their products.[472] How the FDA plans to parse out risk and harm remains a mystery. But I propose some guiding principles below that might streamline the current regulatory mess and uncertainty.

2. The Mechanics

I submit that we are well past the point of the "will it or won't it" regulate debate. The FDA has taken clear and affirmative steps in circling the wagons around DTC genetic testing, and it's unlikely to just forget and move on to some other regulatory calamity. Any eventual regulation will be the answer to the (literally) million-dollar question: What are "the risks and benefits of making clinical genetic tests available for direct access by a consumer without the involvement of a clinician."[473]

The FDA regulates medical devices by a class hierarchy. Class I devices are the least invasive and least regulated and Class III devices are highly invasive and strictly regulated. DTC genetic tests fall somewhere in between. One could make a strong argument that DTC genetic tests qualify as Class II devices, but a DTC genetic test might also be classified as a Class I Hematology and Pathology device.[474] Strictly construed, 21 C.F.R. § 864.4020(b)(2), dictates that Class I is the correct class for hematology and pathology devices provided that the device is not used in blood banking tests. The FDA added to the confusion by sending letters to the owners of companies that sell DTC genetic tests that reference "section 201(h) of the Federal Food Drug and Cosmetic Act."[475] But the letters were ambiguous letters, and

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[472] *Id.*

[473] *Id.*

[474] 21 C.F.R. § 864.4010 (2011).

[475] This reference should actually be 21 U.S.C. § 321(h) (2006), which defines a device as:

> [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is

provided little, if any, information to companies about how the FDA actually plans to regulate the DTC genetic tests.

As explained above, if DTC genetic tests are regulated as a "device" as provided by 21 U.S.C. § 321(h),[476] they must fit within one of three classes. The baseline is provided by the general controls referenced in the definition of Class I devices in 21 C.F.R § 860.3(c)(1). First, the device must conform to all performance standards of 21 U.S.C. § 360d, which are meant to provide "reasonable assurance of safe and effective performance."[477] Safety and effectiveness must be substantiated with evidence from scientific studies, including clinical tests and controlled experiments, pursuant to 21 C.F.R § 806.7(c), (d) (2011).

Title 21 U.S.C. § 360c(a)(1)(A) discusses the general controls governing "a device for which the controls authorized by or under section 351, 352, 360, 360f, 360h, 360i, or 360j of this title."[478] Title 21 U.S.C. §§ 351(e)(1) and (2) govern the part of the general controls that requires the device to be in conformity with the performance standards of U.S.C. § 360d, or the device will be regarded as adulterated. Oddly, however, the opening words of 21 U.S.C. § 360d(a)(1) state that "the special controls required by section 360c(a)(a)(B) of this title shall include performance standards for a class II device."[479] Thus, it is not clear from the language if the performance standards are actually meant to apply to Class I devices. If, indeed, the performance standards do apply to Class I devices, the device would undergo a litany of pre-market activities. Otherwise, DTC genetic tests should be Class II devices so that performance standards can safeguard efficacy, accuracy, and reliability.

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not dependent upon being metabolized for the achievement of its primary intended purposes.

[476] *Id.*

[477] "Safety and effectiveness," according to 21 U.S.C. § 360c(2) (2006), "are to be determined (A) with respect to the persons for whose use the device is represented or intended, (B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and (C) weighing any probably benefit to health from the use of the device against any probable risk of injury or illness from such use." Title 21, C.F.R. § 860.7(b)(4) (2011), adds that "the reliability of the device" must be considered.

[478] 21 U.S.C. § 360c (a)(1)(A) (2006).

[479] 21 U.S.C. § 360d (a)(1) (2006).

As it pertains to DTC genetic tests, the Secretary of Health and Human Services (Secretary) would publish in the Federal Register a notice of proposed rulemaking for the establishment of a performance standard, which includes justification for the performance standard, as well as proposed findings of the risk that the performance standard is meant to combat.[480] Further, interested persons are invited to submit to the Secretary requests for changes in the classification of the device.[481] Presumably, the DTC companies would submit a request to have the least amount of regulation (Class I) and escape the mandated performance standards. The general controls also include provisions for the construction, testing, measurement of the performance, any necessary restrictions for the sale and distribution of the device, and labeling requirements, pursuant to 21 U.S.C. § 351. They also go on to require annual registration for "every person who owns or operates any establishment" that produces a device, with certain exceptions.[482]

Unfortunately, the regulations lack specific guidance regarding how the FDA measures a device's performance. If a DTC is classified as Class I, 21 U.S.C. § 360i(a)(8) specifically states that the Secretary "may not require a manufacturer or importer of a class I device to maintain for such a device records respecting information not in the possession of the manufacturer of importer, or to submit for such a device to the Secretary any report or information not in the possession of the manufacturer or importer, or on a periodic basis . . . ."[483] Thus, if a study on a specific Class I device is published, the manufacturer need not make the FDA aware of such a report. The FDA does, however, publish information on its website regarding what is required for safety and effectiveness data for Class III devices.[484]

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[480] *See* OFFICE OF DEVICE EVALUATION, FDA SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED): CLINICAL SECTION CHECKLIST (June 10, 2010), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHTransparency/UCM220929.pdf.

[481] *Id.*

[482] 21 U.S.C. § 360 (b) (2006).

[483] 21 U.S.C. § 360i(a)(8) (2006).

[484] *See Medical Devices*, U.S. DEP'T OF HEALTH AND HUM. SERVS. (Feb. 19, 1998), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080195.htm.

Labeling and branding requirements are governed by 21 U.S.C. § 352. The general controls require that a device's label contain, placed "prominently": (1) the name and place of business of the manufacturer, packer, or distributor; and, (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. The label must also contain the established name of the device, adequate directions for use (including warnings for ways in which the device should not be used). This particular section also includes requirements for the contents of "advertisements and other descriptive printed matter."[485]

If the device violates the statutes, the Secretary is authorized to ban it.[486] The Secretary may also require that the manufacturers provide notification of a risk posed by the device to those classes of people the Secretary identifies.[487] Other remedies for statutory violations include repair, replacement, or refund.[488] Placing a device in Class II means that either the general controls for Class I are not sufficient "to provide reasonable assurance of its safety and effectiveness," the device "is purported or represented to be for use in supporting or sustaining human life," or both.[489]

According to 21 U.S.C. § 360c(a)(1)(B), a device is classified as Class II "because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device."[490] This seems to indicate that the special controls are those "appropriate actions as the Secretary deems necessary" in addition to the Class I general controls.[491] Class III indicates that the special controls provided for Class II devices are necessary in combination with pre-market approval, and that "the device is life-supporting or life-sustaining,[492] or for a

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485 21 U.S.C. § 352 (2006).

486 21 U.S.C. § 360f(a) (2006).

487 21 U.S.C. § 360h(a) (2006).

488 21 U.S.C. § 360h(b) (2006).

489 21 C.F.R. § 860.3(c)(2) (2006).

490 21 U.S.C. § 360c(a)(1)(B) (2006).

491 *Id.*

492 Title 21 C.F.R. § 860.3(e) (2011), defines "life supporting or life sustaining" as a "device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life."

use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury. For this reason, it might be difficult to present the DTC genetic tests as devices requiring pre-market approval. One author's argument assumes that Class III is the correct classification, and further posits that the FDA could then deny PMA applications because of the great social harms posed by DTC genetic tests (such as selective abortion).[493] Nonetheless, it is unlikely that the FDA would consider such a hypothetical and unquantified risk.

Premarket Approval (PMA) is often required for types of devices that "involve new concepts and many are not of a type marketed prior to the Medical Device Amendments."[494] This is significant because marketers of DTC genetic tests attempt to frame their tests as more akin to pregnancy tests (or blood glucose level tests) than rapid HIV tests. PMA is governed by 21 U.S.C. § 360e. It requires submission of an application that includes detailed information about the device, some of the contents of which are outlined at 21 U.S.C. § 360e(c). The application should include: (1) All information about investigations that have been made to show whether the device is safe and effective; (2) Full disclosure of the methods for operating the device; (3) Description of the methods and facilities used for manufacture of the device, as well as packaging and installation; (4) Reference to any performance standards relevant to the device if it were a Class II device; (5) Any device samples required by the Secretary; (6) Specimens of the proposed labeling; (7) and, any additional information required by the Secretary.[495]

DTC genetic tests most closely resemble Class II devices because they are usually marketed to consumers as providing information that will allow the consumer to prolong a healthy life or plan for future illness, which fits into the idea of being

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[493] 21 U.S.C. § 860.3(c)(3) (2006); James D. Kerouac, *The Regulation of Home Diagnostic Tests for Genetic Disorders: Can the FDA Deny a Premarket Application on the Basis of the Device's Social Impacts?*, 5 J. BIOLAW BUS. 34 (2002).

[494] *Medical Devices Premarket Approval (PMA)*, U.S. DEP'T OF HEALTH AND HUM. SERVS., http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/default.htm (last visited Jan. 2, 2012).

[495] 21 U.S.C. § 360e(c) (2006).

"represented to be for use in supporting or sustaining human life."[496] By placing DTC genetic tests into Class II, the Secretary must also consider what information about the device must be publicized.[497] Furthermore, this would make the device subject to the general controls of Class I, which might be adequate if enforced systematically.

DTC genetic tests might fall short of meeting the general controls of Class I (therefore placing them into Class II) on assurances of effectiveness. Pursuant to 21 C.F.R. § 860.7(e)(1) (2006), effectiveness requires that the device, when used properly, will provide "clinically significant results." For instance, in *F.T.C. v. Seville Mktg. Ltd.*,[498] the FTC sought an injunction against the marketers of the "Discreet HIV/AIDS test" for deceptive acts in their claims that "the test results are 99.4% accurate. Over the past two years we've had three independent studies done on Discreet and our 99.4% accuracy rate is based upon these studies."[499] The fact that the FTC brought a claim against a company emphasizes that the FTC (which works closely with the FDA in such cases, in as much as the FTC looks at the trade practices of the companies that market devices) recognizes that the claims of marketers are unsubstantiated.

If DTC genetic tests were classified as Class II devices, the Secretary and Commissioner of Food and Drugs (Commissioner) would have the power to require additional studies to ensure the effectiveness of each home use test device. Moreover, classifying DTC genetic tests as Class II devices would ensure that the safety and effectiveness of data submitted to the Commissioner is made available immediately for public disclosure upon request, even if the data has never before been disclosed.[500] In many ways, DTC genetic tests are similar to home use rapid HIV tests, which are Class III devices, only one of which has ever been approved for over-the-counter use.[501] These particular HIV tests require pre-

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496 21 C.F.R. § 860.3(c)(2) (2006).

497 21 U.S.C. § 360c(b) (2006).

498 F.T.C. v. Seville Mktg., Ltd., No. 04CV01181, 2004 WL 4003269 (W.D. Wash. May 14, 2004).

499 *Id.*

500 21 C.F.R. § 860.5(b) (2011).

501 *FDA Discusses Studies to Support OTC HIV Test Kits*, 21 AIDS ALERT 45 (2006).

market approval.[502] This classification is not only based on the fact that the general controls of Class I[503] would be insufficient, but further due to the potential insufficiency of Class II controls, and the fact that the device "is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury."[504] The classification also considers the levels of complexity in using the device, as outlined by CLIA.

Regulation does not come without resistance nor does it come without stumbles. Historically, LDT manufacturers (and therefore DTC genetic tests) have existed outside the restrictions of medical device regulations. A new set of regulatory impediments that apply to either all or some of the LDT market (such as only to DTC genetic tests) could cripple clinical laboratories both financially and on the production and innovation line. If uniformity and standardization across LDTs is the goal, then the FDA would also add a tremendous amount of work to its plate. There will be budget issues on both sides of the fence, but while a transition from lax oversight to full-fledged regulation will not be seamless, it is not impossible. More importantly, if regulation is inevitable, it should happen sooner rather than later.

CONCLUSION

DTC companies post numerous disclaimers telling consumers that the tests do not diagnose disease and that the results are not medical advice. These caveats are crafted with purposeful detail by company lawyers who are trying to insulate the tests from regulatory scrutiny. The FDA has rightly noted that these tests fall within the scope of its regulation. How long it will take the FDA to act upon its intention is a separate matter. Although there are concerns about the repercussions from exposing the public

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[502] Elliot Cowan, FDA Chief of Product Review Branch, Presentation at FDA Workshop on Study Methodology for Diagnostics in the Post-Market Setting: Point-of Care Diagnostics in Post-Approval Settings (May, 12, 2011), *available at* http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM256339.pdf.

[503] 21 U.S.C. § 360c(a)(1)(A) (2006).

[504] 21 U.S.C. § 360c(a)(1)(C) (2006).

genetic information, this concern is abstract and ambiguous. I submit that the proper amount of regulation comes in the form of ensuring the accuracy and reliability of the information in addition to requiring context in reporting the results. The March 2011 meeting between the FDA and DTC companies batted around various suggestions such as requiring DTC company laboratories to have CLIA certification, in-house clinicians, or genetic counselors.[505] Those suggestions are myopic and miss the point. Thrusting specific employees or lab standards on these companies will not necessarily safeguard the validity of the data and manage consumer expectations.

How best to regulate these tests? The CMS/CLIA system is antiquated and limited. DTC genetic tests qualify as medical devices and the FDA should ensure the validity, accuracy, and reliability of these tests and their progeny. That includes applying common scientific standards and principles used for other genetic and DNA-based tests. It also embraces the requirement of analytic and clinical validity and clinical utility. Regulation must, at the very least, include pre-market approval and, hopefully, encompass post-market approval as well. Although the FTC would retain its advertising kingdom, it would actually have to do something affirmative by regulating the accuracy and content of DTC genetic testing advertisements, promotional activities, and online transactions.

The development of DTC genetic tests that purport to provide diagnostic and medically significant information is moving at a pace that has left the law in the dust. With more consumers providing biological samples, reporting health histories, and participating in genetic social networking, the need to regulate the industry is great. As the law struggles to catch up with these technological developments, it must remember to temper its regulatory force in a manner that fosters innovation, protects privacy, and reinforces accuracy and reliability. While it is true that these genetic tests involve a minimally invasive method that simply collects spit, at a minimum, the end result presents real possibilities for intrusion, confusion, and disillusion. Consequently, the most direct approach is to regulate the tests

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[505] *See* Vorhaus, *supra* note 468.

from the bottom-up as opposed to relying on a patchwork of regulations, which only cover their fragmented components. Anything less relegates these tests to the whimsy level of a genetic horoscope—and perhaps that is where they should remain if regulation remains elusive.

As the lines between proactive and reactive medicine begin to blur and converge, direct-to-consumer genetic testing could prove to be a valuable tool in the ongoing health care debate. But in order to attain that status, it must meet set standards. Talk about personalized medicine: "Science itself is incremental, and what we've learned through example after example over decades is that when dealing directly with human health, the integration of science with medicine and other consumer applications must be careful and methodical."[506]

[506] *See* Gruber, *supra* note 386, at 2.