

Direct-to-Consumer DNA Testing and the Myth of Personalized Medicine: *Spit Kits, SNP Chips and Human Genomics*

The topic of this report is the burgeoning Direct-to-Consumer (DTC) genetic testing industry, which is promising consumers a guidebook for maintaining health as well as a gene-based horoscope predicting future illness.

Issue & Impact: “Personalized medicine” is based on the belief that we can – or, one day soon will be able to – detect, prevent and treat disease according to an individual’s genetic profile. “Gene-informed,”¹ individualized medicine is being touted as a boon to health and longevity around the world, though its efficacy and usefulness have yet to be demonstrated. Nevertheless, the DNA testing field is advancing rapidly. The global market for personal gene testing is estimated at \$730 million and growing 20% every year, according to market research analysts.² An explosion of unregulated direct-to-consumer (DTC) genetic testing is feeding that growth. Today there are more than one thousand different genetic tests available. Marketers of personal gene testing want us to believe that our genes define us and hold the key to our health and wellbeing. In fact, the information gleaned from most genetic tests has very limited use for patients, but it is extremely valuable to companies and researchers trying to establish links between medical conditions and genetic variations, enabling – they hope – the development of drugs targeted to people with specific genetic profiles. In the shorter term, drugs that have been taken off the market due to unexpected adverse reactions in a small percentage of the population could be re-marketed as personalized drugs, intended only for those with the appropriate genetic profile. Through clever (and often misleading) marketing, some companies are persuading consumers to pay for storage of genetic data and health information, which the companies intend to use (e.g., sell to the pharmaceutical industry) for research and drug development. While DNA testing is currently expensive, risky (e.g., it can result in privacy violations and discrimination) and provides information with extremely limited usefulness, it is being marketed as the next cutting-edge, must-have accessory – the iPod of the medical world.

¹ The phrase is used by Dr. Russ Altman, Department of Bioengineering, Stanford University, in a *Google TechTalk* entitled “Opportunities for Pharmacogenomics and Personalized Medicine,” 22 February 2006, on the Internet: http://thepersonalgenome.com/2006/02/russ_altman_tal/

² Estimate comes from Piper Jaffray & Co., cited in Matthew Herper and Robert Langreth, “Will You Get Cancer?” *Forbes.com*, 18 June 2007, on the Internet: http://www.forbes.com/free_forbes/2007/0618/052_2.html

Variation Celebration: In its year-end issue, the journal *Science* honored “Human Genetic Variation” as the breakthrough of 2007.³ That doesn’t mean scientists spent the year concocting human genetic variation in the lab, but in 2007, according to the magazine, “researchers came to appreciate the extent to which our genomes differ from person to person and the implications of this variation for deciphering the genetics of complex diseases and personal traits.” SNPs (single-nucleotide polymorphisms) – the estimated 10-15 million places along the human genome where variations can occur – are the main focus of this research.

Only about 20% of the SNP spots have been mapped so far⁴ but scientists are already publishing “genome-wide association studies” comparing DNA samples taken from hundreds or, in some cases, thousands of people. These studies chart genetic variations, such as the distribution of SNPs (known as genotype), which are then linked, if possible, to the presence or absence of disease or other quantifiable traits such as blood pressure or adverse drug response (known as phenotype). The goal is to measure the risk or benefit that may be associated with having a particular SNP. To take a very simplified and hypothetical example: if 80% of people with a variation in their genetic code called (hypothetically) SNP called “Rs33333” experience breathing problems after they drink chocolate milk, an association between the two could be made – even with no understanding of the biological processes behind the adverse reaction: Is something in the milk responsible for the reaction? The chocolate? Does something happen to the milk or the chocolate when the two are combined? Nonetheless, a practitioner of “genome-informed medicine” would advise those with SNP Rs33333 to avoid chocolate milk because they, too, would likely experience breathing problems.

Currently, the results of most genome-wide association studies aren’t especially meaningful

³ Elizabeth Pennisi, “Breakthrough of the Year: Human Genetic Variation,” *Science*, Vol. 318, 21 December 2007, pp. 1842-3.

⁴ According to *Science* (see footnote 3), 3 million of a total (estimated) 15 million SNPs have been identified and located. SNPs are being charted by both public and private initiatives, often in combination. One of them is the International HapMap Project, a collaboration between governmental institutions, universities, public research institutions and private biotech and pharmaceutical companies from the US, Canada, UK, Japan, China and Nigeria.

because they provide only a snippet of a much bigger picture: The presence of a particular SNP is just one possible factor among many – including socioeconomic and environmental conditions, other genetic factors and behavior – that may be associated with increased risk of a specific disease or condition. The vision of personal genomics, though, is that more research data – gleaned from analyses of genotypes and phenotypes of even greater numbers of people – will eventually reveal an “actionable” relationship between genes and health and usher in an era of truly personalized medicine.

Where will the genotype/phenotype data come from?

Getting the Goods: While there is still a focus on the old-fashioned – and controversial – way of DNA sampling (e.g., research teams get funding from public institutions and/or private corporations to sample indigenous groups or communities that have been identified as interesting to genetics researchers), consumers are now doing their part to fill the DNA coffers. In some cases, they are also volunteering information about their health status, environment and behavior that could make genome-wide association studies more useful. “Personal genomics” companies are cropping up all over the Internet, marketing products directly to a public that is willing to exchange some buccal cells (from saliva) and hundreds or thousands of dollars for the promise of self-knowledge. The global market for personal gene testing is estimated at \$730 million, increasing 20% annually.⁵

Some types of genetic tests have been around for decades that have “clinical validity” – they produce results that have meaning – such as tests to establish paternity or screen for an increased risk of giving birth to a child with cystic fibrosis. More than one thousand different genetic tests are available today, with a wide range of clinical validity, and they are bolstering the new wave of direct-to-consumer (DTC) genetic testing that often promises much more – and often delivers much less – than a screen for increased risk of one congenital disease. For \$1000, **Genelex** will test your DNA for eight genetic variations in order to estimate how slowly

⁵ Estimate comes from Piper Jaffray & Co., cited in Matthew Herper and Robert Langreth, “Will You Get Cancer?” *Forbes.com*, 18 June 2007, on the Internet: http://www.forbes.com/free_forbes/2007/0618/052_2.html

or quickly your body metabolizes certain chemical compounds, with the idea that the information will help your doctor determine which drugs to prescribe and in what dosage, and which drugs to avoid. Other companies offer services that may be less consequential, but – the companies are hoping – no less compelling. **ScientificMatch.com** is a dating service that promises “chemistry” between couples to increase chances of a satisfying sex life. By scanning certain genes associated with immunity, the company says it will select potential partners with whom you are more likely to produce healthy children with robust immune systems. (A lifetime membership costs \$1,995, begging the question: If the service really brings soulmates together, why would anyone need a lifetime membership?) **Cygene Direct** will scour your DNA to predict your athletic performance potential and risk of sports injuries. **Consumer Genetics** will tell you how quickly your body metabolizes caffeine (in case the answer hasn’t already come to you, sleepless at 2 o’clock in the morning). **NicoTest** will search your genes to discover how addicted you are to cigarettes or how addicted you could become. One company, **GeneLink**, searches your DNA looking for “variations in key genes related to skin aging, wrinkling and overall skin health” (in case your mirror lies). The point of the test, though, is to determine which ingredients (“SNPactives”) should be infused into your individual skincare or cosmetic product – sold by the company – “to help compensate for genetic deficiencies.” Similarly, Market America claims the Gene SNP Screening Analysis it sells will reveal which areas in your body “need special support” and then the company will formulate “genetically-based,” nutritional supplements to meet “potential health challenges,” based on your SNP profile. **Salugen, Inc.** will sell you its GenoTrim weight-loss product once you’ve taken the GenoScore genetic test, which measures “a series of genes that indicate specific mutations that may cause nutritional imbalances.” Based on your GenoScore, Salugen will formulate your GenoTrim nutritional supplements so that they “address your body’s specific roadblocks to optimal weight.” The message is clear: It is our genes that are making us fat, sick, wrinkled, lonely and addicted – it has nothing to do with our consumption patterns, socioeconomic conditions or our nature as mortal beings. We need help fighting back.

Recreational Genomics: On a lighter note, there is “recreational genomics,” another branch of the new DTC testing industry of which the IBM/National Geographic “Genographic Project” is the most well-heeled and prominent example. These kinds of personal genomics tests don’t aim to make you healthier or more attractive, but they could provide answers to questions that it may not have occurred to you to ask. If you’ve ever wondered about your “deep” ancestry – where your forebears might have lived over 40,000 years ago – several companies, including the Genographic Project, will try to tell you. Genetrack Biolabs has a DNA Ancestry Project that is similar to the Genographic Project but allows you to trace the roots of your surname as well. Using the company’s “Genebase BioNet Builder,” customers register on a social networking web site similar to Facebook or MySpace, where they can create profiles and form groups, upload photos, post comments and blog entries and keep a journal documenting their ‘genetic journey.’

Not All Fun and Games: In addition to the DTC component of the IBM/Genographic Project, there is a 5-year field research component that involves collecting 100,000 DNA samples from indigenous and traditional peoples around the world, creating “the world’s largest survey of DNA samples to map how humankind populated the planet.”⁶ Indigenous peoples have widely opposed the project citing the potential for genetic discrimination, the threat to the rights of indigenous peoples – including land rights – and uncertainties surrounding informed consent. Their opposition led the United Nations Permanent Forum on Indigenous Issues to recommend, in May 2006, that the Genographic Project be suspended.⁷ (This and other large-scale sampling projects will be discussed fully in Part II of ETC Group’s series on human genomics.)

What are the risks to paying customers? First, “the emerging industry of direct-to-consumer genetic tests is developing without oversight.” That’s the conclusion of a December 2007 report, *More Genes Direct*, written by the UK’s Human

⁶ See

https://www3.nationalgeographic.com/genographic/faqs_about.html#Q1

⁷ See press release from Indigenous Peoples Council on Biocolonialism, “United Nations Recommends Halt to Genographic Project,” 26 May 26 2006, on the Internet: http://www.ipcb.org/issues/human_genetics/htmls/unpfii_rec.html

Genetics Commission.⁸ A year earlier, the U. S. Government Accountability Office (GAO) acknowledged, “The current regulatory environment provides only limited oversight to those developing and marketing new types of genetic tests.”⁹ The absence of practice standards and regulation means that consumers don’t know if their DNA samples have been handled properly, if their results are valid, or even if the genetic test was actually performed. Some U.S. states, France and Switzerland have banned DTC genetic testing due to the likelihood of fraud or error in the absence of proper oversight.

But regulation is just one consideration. Another is the fact that the relationship between genes and medical health is currently so little understood that results of genetic testing mean next to nothing, with the exception of a small number of tests that uncover variations that lead to so-called monogenic diseases (i.e., the presence of a particular variation *necessarily* leads to a particular health condition). More than one critic has evoked “snake oil” when discussing current DTC genetic testing. Though most companies acknowledge the limitations of the technology (often in fine print), the marketing pitch is consistent: Your genes define you – who and what you are – and they hold the key to your health and wellbeing. Navigenics, a personal genomics company in California selling a product called Health Compass, articulates the typical formulation on its web site: “My Genes. My Health. My Life. My Guide.”

Many of the most vocal and influential critics of DTC genetic testing don’t really question equating genes and health, but they fear disreputable companies will endanger the future of personal genomics by giving it a bad name. Kathy Hudson, founder and director of the Genetics and Public Policy Center at Johns Hopkins University [Maryland, USA], for example, articulated the concern in a *Science* editorial: “...should the public begin to question the accuracy of genetic tests or insurers begin to question their validity,

⁸ *More Genes Direct* is a follow-up report to a 2003 report, *Genes Direct* and is available on the Internet: <http://www.hgc.gov.uk/Client/document.asp?DocId=139&CategoryId=10>

⁹ Statement to US Congress of Gregory Kutz, Managing Director Forensic Audits and Special Investigations, Government Accountability Office, “Nutrigenetic Testing: Tests Purchased from Four Web Sites Mislead Consumers,” July 27, 2006.

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‘personalized medicine’ will be nothing more than a postscript on the pages of medical history.”¹⁰

How genetic tests work (and don’t): DTC genetic testing kits are sold on the Internet and bought with a credit card. The kit arrives in the mail (the customer pays for shipping) with instructions and supplies for DNA collection¹¹ and for sending the DNA sample back to the company. Almost all companies send a cheek swab kit or a “spit kit” because they want cells from inside the mouth. (NicoTest is an exception – they want blood so they send a finger-prick kit). The customer sends her DNA sample to the company and waits for the results. The company receives the sample, isolates the DNA and prepares it for genotyping to determine if particular genetic variations (SNPs, in most cases) are present. Genotyping requires some kind of “DNA chip” where bits of synthetic DNA, corresponding to particular sequence variations being tested for, are attached to a surface. If complementary sequences are present in the customer’s DNA sample, then it will bind with the synthetic DNA, indicating a positive test result. If there are no complementary sequences in the sample, then binding won’t occur and the test result is negative. DNA chips can hold thousands of bits of synthetic DNA and test for several variations at once.

Let’s Get Personal: Many of the names of DTC genetic testing companies, and the names of products they’re selling, emphasize the “personal” nature of the testing: deCODEme, mycellf, 23andMe, Knome, Made for Me, etc. Ironically, getting personal means forgoing face-to-face contact with doctors, nurses or even cashiers. The go-it-alone feature of DTC genetic testing is marketed as empowerment, enabling the consumer to maintain privacy and anonymity – “we believe that your genetic information should be controlled by you” and “your genetic information is yours to have and explore,” says 23andMe, a personal genomics start-up backed by venture capital, Google and Genentech, the biotech company

¹⁰ Kathy L. Hudson, “Genetic Testing Oversight,” *Science*, Vol. 313, 29 September 2006, p. 1853.

¹¹ One personal genomics company, Salugen, has partnered with DNA Services of America, a chain of local DNA collection centers established throughout the United States, so that consumers have the option of sampling themselves at home or having the sample taken at a local service center.

behind human growth hormone.¹² The reality is something different.

First, the information generated by the genetic test (assuming the company has performed the test correctly and provides you with accurate data) is of very limited use, especially on its own.

Even companies that include interpretation, “context” or a consultation with a genetic counsellor as part of their service acknowledge the limitations of testing. Almost all DTC genetic testing companies post legal disclaimers similar to this one from 23andMe:

“23andMe’s service is not a test or kit designed to diagnose disease or medical conditions, and it is not intended to be medical advice. If you have concerns or questions about what you learn through 23andMe, you should contact your physician or other appropriate professional.”

<https://www.23andme.com/about/consent/>

One of the concerns raised by DTC genetic testing and an impetus for the UK Human Genetics Commission’s study, *More Genes Direct*, is “the impact on NHS [National Health Service] resources if patients were to seek advice from their doctors before or after tests, or if patients were to require confirmatory testing within the NHS.”¹³ In countries with national health coverage, DTC genetic testing will likely mean an increase in the number of doctor visits. In countries without national health coverage (e.g., USA), less affluent patients may forego or delay a doctor visit if a genetic test returns (what they understand to be) a favorable result, even if signs of illness appear. There is a danger that the importance of preventative care will be diminished since the emphasis is always on genes, not on the multiple behavioral and/or social changes that can make substantial differences in health. Helen Wallace of GeneWatch UK warns that “Widespread genetic

¹² All in the family: In May 2007, 23andMe announced Google’s \$3.9 million investment. Google co-founder Sergey Brin is the husband of 23andMe co-founder Anne Wojcicki. The amount of Genentech’s investment was not disclosed. Genentech’s CEO, Art Levinson, is on the board of directors at Google (and Apple, Inc.).

¹³ *More Genes Direct*, p. 5, on the Internet: <http://www.hgc.gov.uk/Client/document.asp?DocId=139&CategoryId=10>

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testing may... foster the misleading implication that only a minority of people with so-called ‘bad genes’ need to eat a healthy diet or quit smoking.”¹⁴ In short, DTC genetic testing may mean more trips to the doctor (e.g., in the UK) or fewer (e.g., in the USA), but neither scenario translates into improved patient health since the relationship between genes and illness in most all cases is not exclusive or straightforward. It’s possible to test positive for increased risk of a condition that never materializes just as it’s possible to test negative for increased risk of a condition that does – with social, economic and environmental conditions playing important roles.

“The risk is that 20 years from now everyone gets tested and learns they have a 5% risk for developing 10 diseases and a 2% risk for 20 other diseases – and what we do is increase neurosis instead of improving health.”¹⁵ – Richard Lifton, Chairman, Department of Genetics, Yale University

Second, the “genetic privacy” offered by DTC gene testing is illusory. Many testing companies tout their privacy policies, assuring customers that payment information (i.e., name, address, credit card number) is kept apart from genetic information (i.e., results of tests) so that customers can remain anonymous and genetic information can be kept secure. On the other hand, customers are encouraged to share their genetic information over the Internet with friends, family and members of the public interested in comparing genetic markers: gene-based social networking. In 2006, a 15-year old boy was able to identify his biological father – who had been promised anonymity by the sperm bank to which he had donated – by combining information from a gene-based social networking web site (www.familytreedna.com) and information from another web site (www.omnitrace.com).¹⁶

Companies – like Genetrack Biolabs, deCODEme and 23andMe – that offer information sharing on their web sites consider the storage of customers’ genetic data on company servers a part of their

¹⁴ Helen Wallace, “Misleading Marketing of Genetic Tests,” *GeneWatch*, Vol. 18, Number 2, April 2005; available on the Internet: <http://www.gene-watch.org/genewatch/articles/18-2Wallace.html>

¹⁵ Quoted in Matthew Herper and Robert Langreth, “Will You Get Cancer?” *Forbes.com*, 18 June 2007, on the Internet: http://www.forbes.com/free_forbes/2007/0618/052_2.html

¹⁶ Sam Lister, “How a donor sperm boy traced his father using the internet,” *Times Online* (UK), 3 November 2005.

service. For example, deCODEme's initial fee for account set-up and testing (\$985) includes one year of data storage. If the customer wants continued access to her information, she must pay an annual fee. These companies are aware there may be risks, and their legal consent forms ensure the risks are borne by the customer and not the company.

23andMe warns customers in the United States that "if an employer or insurance company obtained

your genetic information through your sharing or by *legally binding*

requirements, they could use your genetic data to deny you employment or coverage." Law

enforcement agencies could also require genetic testing companies to turn over private customer information. DeCODEme says they won't release any customer's stored genetic data to a third party "unless required to do so by law or by an order of a court having jurisdiction." Even if you cancel your account, deCODEme may continue storing your data in the company's "archival and backup media and systems for an indefinite time, and deCODE will not be obligated to delete this data." (In other words,

deCODEme charges a fee to store your data; the company may continue storing and using your data even if you stop paying the storage fee, but you lose access to the data.)

The full legal, medical, privacy and social implications of volunteering your genetic and health information cannot be known today. The same is true for DNA samples stored in state-sponsored "biobanks," which also link genetic data with personal, non DNA-derived data for research, administrative or forensic purposes, a topic to be discussed in Part II of ETC's human genomics series.

The Bottom Line: It's clear that there are some companies in the DTC genetic testing industry that

aim to turn a quick profit by capitalizing on science and technology news hyping personalized medicine. An investigation by the U.S. GAO, for example, uncovered one (un-named) DTC genetic testing company selling personalized nutritional supplements for more than \$1200 per year when the same supplements could be bought in a store for \$35.¹⁷ Other companies, however, are more seriously invested in the long-term profit prospects of personal genomics.

These companies market their DTC genetic testing as a service but acknowledge its current limited usefulness.

23andMe's consent form, for example, explains that though the company tests for more than a half-million SNPs, only a small percentage of them are known to be significant. But, they say, advances in the field "could translate into meaningful information about your genetics." Nonetheless, there is a concerted effort to market genetic testing as a helpful aid to maintaining current health and as crucial in the near future when the rapidly advancing personal genomics field matures.



Art by Stig

There's also an effort to market personal genomics as a "lifestyle choice"¹⁸ and genetic testing as fun and fashionable. DeCODEme offers family discounts and whoever succeeds in recruiting a

¹⁷ Statement to US Congress of Gregory Kutz, Managing Director Forensic Audits and Special Investigations, Government Accountability Office, "Nutrigenetic Testing: Tests Purchased from Four Web Sites Mislead Consumers," 27 July 27 2006.

¹⁸ "Genomics as a medical tool and lifestyle choice" is the tagline of a blog written by Jason Bobe, "director of genetics community" for the Personal Genome Project, an effort by genetics professor George Church (Harvard Medical School) to sequence genomes of volunteers who will also provide copious personal health information. The aim is to sequence genomes from 100,000 people. There are ten participants so far.

friend will get \$50 off the price of his or her genetic scan. 23andMe held a “spit party” in Silicon Valley, California in November 2007, complete with movie stars, promotional t-shirts (reading “Great Expectations”) and a “spit room.”¹⁹ In January 2008, the company distributed one thousand saliva kits free-of-charge to the movers and shakers – and spitters – attending the World Economic Forum in Davos, Switzerland. There’s even SNPedia – a wikipedia with a chat room where genotyped users can share information.²⁰ Despite the risks involved in relinquishing your DNA to a corporation – “Your saliva, once submitted to and analyzed by us, becomes our property,” warns 23andMe – on-line information-sharing and genetics-based social networking make it seem like no big deal, not so different from sharing thoughts about your favorite rock band or film.

For now, at least, it’s all about them. While companies like Knome, 23andMe and deCODEme sure sound like they’re all about “me,” in reality, they are about furthering the

field of personalized medicine (and its profit potential). What’s really happening is that consumers are being recruited to be research subjects in the next phase of an on-going and global scientific study. They are paying out of their own pockets for the privilege, armed with little knowledge and even less control over the final use of their samples.

Identifying and mapping possible variations along the entire human genome was the first phase of this research, and for that, phenotypic information wasn’t necessary. All that was needed was DNA from people living in every corner of the world – the more genetically distant, the better, so as to capture as many variations in the genome as possible. It didn’t matter how little was known about their health status, if they had ever been to a doctor, how affluent they were, even if they were alive or dead – what mattered was the secret SNPs they might be holding in their cells.

Now that mapping genetic variations is well underway, the next phase of research has begun:

¹⁹ For photos and a report from 23andMe’s spit party, see <http://blog.guykawasaki.com/2007/11/23andme-party.html>

²⁰ Michael Cariaso, “SNPedia: A Wiki for Personal Genomics,” *Bio-IT World*, Dec./Jan. 2008, pp. 14-15.

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associating specific genotypes with specific clinical phenotypes in genome-wide association studies, with little attention paid to environment and behavior, and even less to socio-economic conditions. Still, most researchers, the genomics and pharma industries and governments view these studies as “laying the groundwork” for personalized medicine.²¹ What’s needed to do them are data – genotyped DNA samples from as many people as possible, along with enough detailed information about their physical differences and health status to establish associations that are considered “statistically significant.” This is where affluent consumers come in – they’re paying for the opportunity to provide companies with genotypic, phenotypic information, sometimes including information about behavior and environment.

What’s really happening is that consumers are being recruited to be research subjects in the next phase of an on-going and global scientific study. They are paying out of their own pockets for the privilege, armed with little knowledge and even less control over the final use of their samples.

Knome, a for-profit Harvard/MIT spin-off, is in the business of sequencing entire genomes (rather than SNP genotyping) and charges \$350,000 for its service. Sequencing entire genomes generates much more

information than SNP genotyping, but its cost is still prohibitive, though steadily decreasing – the current holy grail is the \$1,000 sequenced genome.²² Knome’s sales pitch is that “by being amongst the first individuals in history to have their whole genome sequenced, these participants will help pioneer the emerging field of personal genomics.” (A science pioneer and you don’t even have to study biology!) Knome hopes to recruit twenty people for its initial phase; it has recruited two as of early 2008.²³ The company says that those first (very rich) people to know the details of their entire genomes will be the first ones to benefit from personalized medicine, a field that they, theoretically, will have helped bring about because Knome grants them “the ability to share [their]

²¹ <http://www.genome.gov/20019523>

²² Several efforts are in the works to speed up and reduce the cost of whole genome sequencing. One team of researchers is using a scanning tunneling microscope to sequence DNA wrapped around carbon nanotubes. See <http://tinyurl.com/3dzawr>. The Archon X Prize in Genomics will award \$10 million to the first team able to sequence 100 genomes in 10 days. See <http://genomics.xprize.org/>

²³ Knome press release, “Knome commences whole-genome sequencing process for first clients,” 22 January 2008. Harvard Genetics professor George Church is an advisor to Knome: See footnote 18.

genome with researchers and other medical professionals.” 23andMe, as well, plans to form partnerships with “commercial and/or non-profit organizations that conduct scientific and/or medical research,” where external researchers will have access to customers’ genetic and submitted personal information (but no contact information) and can publish results. “We may receive compensation from these research partners,” the company says. How people feel about surrendering their own genetic material and personal information in the

service of industry will depend on how they perceive the “individual benefits” in light of the risk to privacy and how much they trust the genomics and pharmaceutical industries to serve the interests of their paying customers, let alone to serve humankind around the world.

The following table shows a sample of DTC genetic testing companies, with information on each company and its business plan for your DNA.

Personal Genomics Companies Selling Genetic Testing to the Public

Company	Product(s) and Cost	The Fate of your DNA Sample
<p>DNA Print Genomics, Inc. http://www.dnaprint.com (Florida, USA)</p> <p>Subsidiaries: Biofrontera AG, a German specialty pharma co. and Trace Genetics, genetic identity DNA analysis</p>	<p>AncestrybyDNA \$210-\$650</p> <p>Also sells Pharmacogenomic, Forensics products (i.e, DNAWitness) but not DTC)</p>	<p>Legal agreement is not available on web site, but is included with DNA sample kit. “The test results will be returned to you by U.S. standard mail. Your information will be kept confidential... however they may be subpoenaed by court order, which DNAPrint® shall be required by law to turn over the results of the tests to the proper authorities.” http://www.ancestrybydna.com/welcome/consentform/ (28 Feb. 2008)</p>
<p>Genetrack Biolabs http://www.dnaancestryproject.com (Vancouver, Canada)</p>	<p>Genebase Bionet Builder (ancestry, surname projects and social networking web site) \$119 – \$318</p>	<p>DNA sample “will be securely destroyed after the DNA testing is complete,” but, “by submitting your information to Genebase...you grant Genebase a worldwide royalty free, irrevocable, non-exclusive and unrestricted license to transmit, distribute, archive and display any such information.” http://www.genebase.com/term.php (28 Feb. 2008)</p>
<p>DNASecure http://dnasecure.com/ Unit of AQ Projects, Inc. (Texas, USA)</p> <p>DNASecure is not a genetic testing company, <i>per se</i>. It has a contract with Sorenson Genomics for extracting and purifying DNA.</p>	<p>DNASecure Cards contain “your verified, preserved DNA” and can be stored in any secure area and used for future DNA analysis.” The cards can be submitted to a medical or forensic laboratory at any future time for the desired DNA testing. \$125</p>	<p>“Once your DNASecure Cards have been shipped to you, we retain none of they [sic] DNA and the swabs are destroyed by the laboratory, assuring you that no other analysis can be done.” http://dnasecure.com/faq.htm (28 Feb. 2008)</p>
<p>IBM/National Geographic Genographic Project http://tinyurl.com/34yqbu (Washington, DC)</p>	<p>Results will reveal your “deep ancestry” – very broadly – along a single line of direct descent (paternal or maternal) and show the migration paths they followed thousands of years ago. Results will also place you on a particular</p>	<p>“National Geographic will not conduct any health-related tests on the DNA sample provided... We will discard your sample when the Genographic Project is finished, unless you have requested otherwise...” You can “agree to have your anonymous data included in the project’s aggregate database... that manages electronic DNA data for the Genographic Project... Data from the system is stored on a second IBM storage system.”</p>

Company	Product(s) and Cost	The Fate of your DNA Sample
IBM/National Geographic Genographic Project (contd.)	branch of the human family tree. Participation Kit: \$99.95	https://www3.nationalgeographic.com/genographic/faqs_results.html (28 Feb. 2008)
deCODEme http://www.decodeme.com/ Offered by deCODE genetics, a biopharmaceutical company with principal labs in Iceland	Genome scan testing for over one million variants; genetic risk for disease, deep ancestry, gene-based social networking, regular updates on future discoveries and a growing list of diseases and traits \$985 for scan and data storage for one year	“Your sample and all DNA derived from it will be destroyed after it has been analyzed and the results securely stored in your deCODEme account...Information that you provide about yourself under the security of your account and privacy of your chosen username may be used by deCODEme only to gather statistical aggregate information about the users of the deCODEme website. Such analysis may include...associating genetic variants with any of the self-reported user attributes...If you cancel your account...it is possible that all your data may remain stored in deCODE’s archival and backup media and systems for an indefinite time, and deCODE will not be obligated to delete this data.” http://www.decodeme.com/information/faq (28 Feb. 2008)
Navigenics http://www.navigenics.com (California, USA) Navigenics’ lead investors are Kleiner Perkins Caufield and Byers, Sequoia Capital and MDV-Mohr Davidow Ventures.	Navigenics Health Compass, including whole genome scan; web portal with relevant health and wellness information; consultation with a certified genetic counselor; yearlong subscription that continuously checks your DNA against new developments in genetics; updates on new prevention and treatment therapies \$2,500	“Navigenics reserves the right to disclose Your Data and Your Communications as necessary to satisfy any law, regulation, government request, court order, subpoena or other legal process.” “By using the Site or any Services, you authorize and grant to Navigenics...a limited, non-exclusive, royalty-free, world-wide license to use Your Report, and any personally identifiable information that you submit to Navigenics when setting up Your Account or when discussing Your Report with a genetic counselor employed by Navigenics.” http://www.navigenics.com/corp/TermsAndConditions/ (28 Feb. 2008)
23andMe http://www.23andMe.com (California, USA) Google and Genentech are investors. Google co-founder Sergey Brin is the husband of 23andMe co-founder Anne Wojcicki. Genentech’s CEO, Art Levinson, is on the board of directors at Google.	DNA genotyping \$999	You should be aware that “a motivated party with whom you share your data might be able to use our tools to discover things that you had not anticipated. In addition, if an employer or insurance company obtained your genetic information through your sharing or by legally binding requirements, they could use your genetic data to deny you employment or coverage....your genetic and other contributed personal information will be stored in 23andMe research databases and authorized personnel of 23andMe will conduct research using said databases...You acknowledge that 23andMe may enter into partnerships with other non-profit or commercial organizations to conduct scientific research on data collected by 23andMe. You give permission to 23andMe, its assigns, and its

Company	Product(s) and Cost	The Fate of your DNA Sample
23andMe (contd.)		<p>non-profit and commercial partners...to publish results of research as described herein...Your saliva, once submitted to and analyzed by us, becomes our property...DNA and saliva samples are destroyed after the laboratory completes its work, which includes processing, analysis and reporting of data...Genetic Information is then stored securely in our databases and can be accessed by you via our website by using the claim code and creating your personal account.”</p> <p>https://www.23andme.com/our-service/consider/ https://www.23andme.com/about/consent/ https://www.23andme.com/about/privacy/ https://www.23andme.com/about/tos/ (28 Feb. 2008)</p>
SeqWright DNA Technology Services www.seqwright.com (Texas, USA)	Genomic Profiling Service (GPS) that detects “nearly one million” SNPs \$998	<p>“DNA samples will be stored at SeqWright for a period of three (3) months, at which time they will be discarded. A client may ask SeqWright to store his/her DNA sample for a longer period of time for a fee...Please volunteer any diseases from which you currently suffer (this can help us advance medical research by enabling us [sic] discover new SNP/Disease associations)... When your consenting family members also chose [sic] SeqWright GPS, you can learn about how many interesting traits are inherited within your family.”</p> <p>https://gps.seqwright.com/orderform.php http://www.seqwright.com/gps/consent.php http://www.seqwright.com/gps/ (28 Feb. 2008)</p>
African Ancestry http://www.africanancestry.com (Washington, DC)	MatriClan or Patriclan test kit – comparing your genome to the company’s African Lineage Database to determine your present-day African country of origin. \$349	<p>“We destroy all genetic material once a result is determined. We do not share or sell your sequence or markers with any third party...The Company will not disclose or sell a Customer’s name, genetic information, or other personally identifiable information to any third party, other than to its employees, consultants or other agents who must have access to such Customer Confidential Information for such party to perform certain duties in connection with such Customer’s order...the Company may make a disclosure containing Customer Confidential Information without the consent of the Customer, only to the extent such disclosure is required by law, rule, regulation or government or court order or as reasonably advised by the Company’s legal counsel in good faith.”</p> <p>http://www.africanancestry.com/faq.html http://www.africanancestry.com/terms-and-conditions.html (28 Feb. 2008)</p>
Market America http://tinyurl.com/2osthf (North Carolina, USA)	Gene SNP™ DNA Analysis Kit \$250 Also sells nutritional	No posted privacy/consent information beyond the general one related to the use of the web site: http://tinyurl.com/38n6bx

Company	Product(s) and Cost	The Fate of your DNA Sample
Market America (contd.) Product brokerage and Internet marketing company	supplements based on results of DNA analysis also available for an additional fee	
ScientificMatch.com www.scientificmatch.com (Florida, USA)	Dating service that makes matches based on personal values and preferences and DNA – specifically, genes associated with the immune system \$1,995 for lifetime membership	“We faithfully guard your DNA. Your genetic information is never made public—not even you can see it...And your DNA sample is destroyed after we’re done with it...In order to protect your security and anonymity, nobody in the laboratory ever knows who you are. The only way they can refer to you is with your customer number. Typically, nobody in our organization ever knows your name and your customer number at the same time. Only our computers ever link the two together...For your security, we ban all felons who’ve been convicted of any sexual offense, a violent crime, a crime involving a weapon, or an Internet crime...Other offenders are allowed, but they’re clearly identified...we also verify everyone’s age, seven-year bankruptcy history, and marital status.” http://www.scientificmatch.com/html/index.php http://www.scientificmatch.com/process.htm http://www.scientificmatch.com/backgroundchecks.htm http://www.scientificmatch.com/html/your_privacy.php (28 Feb. 2008)
Genelex http://www.healthanddna.com (Washington, USA)	\$250-\$1990 Parentage and Forensic DNA Testing, Pharmacogenetic Testing (DNA drug reaction profile), Nutritional Genetic Testing, Ancestry DNA Testing	“All information and materials provided to us by our clients and all test results are held in strict confidence and stored in monitored, secure facilities under the supervision of trained personnel...We are required to provide de-identified information of a statistical nature to our accrediting agencies and reserve the right to use such anonymous information for research purposes.” http://www.healthanddna.com/privacy.html (28 Feb. 2008)
Sciona Mycellf Program www.sciona.com www.mycelf.com (Colorado, USA)	Personalized Diet and lifestyle recommendations based on the analysis of 19 genes – looking for variants that have been associated with 5 areas: bone health, heart health, antioxidant/detoxification, insulin sensitivity, and inflammation.	“Your DNA Sample will be destroyed immediately after the completion and verification of it’s [sic] analyzed for your gene variants...Your Genetic Information will not be directly associated with your personal information collected from the Lifestyle Questionnaire, but will be stored in an anonymized database maintained to facilitate clients’ requests for replacing lost reports. Your anonymized information may be used by Sciona to conduct further analyses for commercial purposes.” http://www.sciona.com/faqs.html (28 Feb. 2008)
G-nostics Ltd. NicoTest http://www.nicotest.com (Oxford, UK)	Personalized Treatment Programme, includes an online lifestyle and smoking history questionnaire, a diagnostic test that	“g-Nostics would like to use the data gathered from your participation in the PTP [Personal Treatment Programme] as part of its research programme...Your express consent is required before we can use your information in this way...We would ask you to provide such consent

Company	Product(s) and Cost	The Fate of your DNA Sample
G-nostics Ltd. (contd.)	identifies likely response to nicotine based products and non-nicotine medications and a Personalised Treatment Report that recommends the most appropriate treatment for each individual £150	by ticking the box marked 'Research Data Programme' on the Participant Consent form." https://secure.nicotest.com/LegalInfo.html
Salugen http://www.salugen.com (USA & The Netherlands)	DNA-based Made for Me Nutritional Supplements \$424.95 set-up + \$99.95/month	"Salugen would like your authorization to store your DNA sample and use your DNA sample and DNA test results to research and develop new products; to conduct clinical and other studies; and to prepare publications discussing the findings...By agreeing to this Policy, you authorize Salugen to use your DNA sample and DNA test results in studies or in research and development of new products according to the terms and conditions of this Policy." http://www.genotrim.nl/index.php?id=70 (28 Feb. 2008)
Knome, Inc. http://www.knome.com (Massachusetts, USA)	Whole genome sequencing, analysis from geneticists, clinicians and bioinformaticians, who will also provide continued support and counseling. Starting at \$350,000	"Clients will retain full ownership of their personal genome and have the ability to anonymously share all or portions of their genome with researchers and other medical professionals." Knome press release, "Human Whole-Genome Sequencing Hits Commercial Market," Nov. 29, 2007, on the Internet: http://tinyurl.com/342fto (28 Feb. 2008)

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