

# The Future of DTC Genomics and the Law

*Henry T. Greely*

The LawSeq project's mission was both to lay out the law of genomics as it exists today and to suggest the shapes it may take.<sup>1</sup> Today, with only a few exceptions, DTC is effectively, in law, a consumer service, with little regulation beyond the potential for claims based on false advertising, contract, or tort liability. Much good work has been done, inside and outside LawSeq, about the legal issues DTC genomics raises and whether its current treatment is appropriate.<sup>2</sup>

This article asks a different question: What will DTC genomics and its legal issues look like in ten to twenty years? Its speculation about the future starts with a look at the five current uses of DTC genomics: ethnic and family information, traits, medical information, “wellness,” and other. It then identifies three current legal issues — medical uses, privacy of genomic information, and privacy in collection and analysis of human DNA — before concluding the first two will become less important in coming decades, while the third will be increasingly significant.

## Current Uses of DTC Genomics

November 19, 2007 can be called the effective beginning of DTC genomics, although a few firms offered some services earlier. That day the industry flagship — 23andMe — began offering genetic tests to the public without requiring any medical approval.<sup>3</sup> Originally 23andMe focused exclusively on non-medical uses of their customers' genotypes, things that customers would find informative and entertaining. These were largely ethnic or family information but also some traits, like a genetic prediction of ear wax type. Eventually 23andMe moved into the medical end of the market, particularly after its two medical use competitors, Navigenics and deCODEme, left the field in 2012.<sup>4</sup> Meanwhile, other companies entered the market, in various ways, for different uses, and without significant regulatory scrutiny.

### *Ethnic and Family Information*

People most commonly use DTC genomics for ethnic and family information. Of the three biggest DTC genomics companies in the U.S., two of them to date provide only ethnic and family information: Ancestry and Family Tree DNA. The third, 23andMe, provides ethnic and family information, but also medical, wellness, and trait information. Ancestry has about 15 million customers, 23andMe about 9 million, and Fam-

---

**Henry T. Greely, J.D.**, is the Deane F. and Kate Edelman Johnson Professor of Law, Professor by Courtesy of Genetics, and Director of the Center for Law and the Biosciences at Stanford University.

ily Tree about 2 million, while other firms have much smaller markets.<sup>5</sup>

The big firms' offerings in this area provide two services, which I call ethnicity information and family information. Ethnicity information tells people what ethnic groups their ancestors came from, by percentage. Thus, Ancestry DNA thinks my ancestors are 61 percent from England, Wales, and Northwestern Europe (which includes the Low Countries and the western parts of Germany), 28 percent from Ireland or Scotland, 4 percent from Norway, 3 percent from France, 3 percent from Sweden, and 1 percent from "Germanic Europe." The Ancestry assessment does not match exactly with my family history but is fairly close. Sometimes, though, ancestry information does provide family surprises. Some people end up with ethnic backgrounds that shock them — African-Americans with unexpected European ancestry, white nationalists with African ancestry, anti-Semites with Jewish ancestry, and so on.

Family information may be the most popular DTC use. The three big firms allow their customers the choice to have their DNA analysis included in a big database, matching them with other consenting customers to see whose DNA suggests likely genetic relationships. Customers who opt in can see customers they match with, listed by names or handles, and can communicate with them through the firm. Typically, the firms will show relatives by degree of closeness, picking out parents, siblings, aunts and uncles, first cousins, second cousins, and so on. In my case it successfully identified my mother, an aunt, a first cousin, and a variety of second cousins. At third cousins and beyond, false positives are common. I have discovered a few relatives I had not known but all on branches of my family I knew about; thus far, I have not had any real surprises.

This is not the universal experience. Some people discover that the man they thought of as their father was not their genetic father, because of an unknown adoption, an undisclosed infidelity or rape, and sometimes an anonymous sperm donor. Others learn they have half-siblings from undisclosed (to them) children born to one of their known genetic parents or previously unknown cousins as a result of undiscussed and unacknowledged matings by more distant relatives. And some find tens or scores of half-siblings as a result of having a popular sperm donor as their genetic fathers. Discovering that a long dead uncle had an illegitimate child 70 years ago, producing a newly discovered half first cousin, is unlikely to be deeply disturbing. Learning that you have 100 half siblings as a result of a sperm donor or that you have a half-sib

from an unknown liaison may be more upsetting or may also be exciting and positive.<sup>6</sup>

Paternity testing firms provide a third kind of ethnic and family information testing. These firms and their services are common but little discussed.<sup>7</sup> Conventional wisdom says their customers are men, who were told they are a child's genetic father (and may be liable for child support as a result), who want some scientific evidence on the question, and who may surreptitiously take samples that contain DNA. At least one firm advertises that it will analyze DNA from everything from a used band aid, to a facial tissue, chewing gum (sugar free only), a toothbrush, or a pacifier, providing success probabilities for each type — 90% for the used tissue, 75% for the chewing gum, and 40% for the pacifier.<sup>8</sup> Firms willing to test unconventional samples for paternity could well be willing to test surreptitious samples for other ends.

#### *Traits*

23andMe also offers trait testing. It uses this term for genetic conditions that are not (clearly) medically significant. It currently provides reports for 33 such traits, from "ability to match musical pitch" to "cilantro taste aversion" to "earwax type" to "misophonia" (hatred of the sound of chewing) to hair color to "unibrow."<sup>9</sup> It is not clear why people are interested. Presumably, they already know whether they have a unibrow, hate cilantro, or have wet or dry earwax. What value comes from knowing whether your genes do, or do not, predict your actual traits?

Other firms provide more nebulous, and less easily evaluated, trait information, from what kinds of wine you'll like to whom you should date. These have much less scientific evidence behind their predictions.

#### *Medical Information*

23andMe is the only firm offering what is clearly medical information on what is a clearly DTC basis in the United States, but its offerings have had a troubled course. After a slow start, by October 2013, it was providing 254 health related tests. All had some peer reviewed publications supporting their findings although most of the evidence was very limited. In that month, FDA sent a letter to 23andMe, warning that it appeared to be introducing a "medical device" into interstate commerce without the necessary FDA approval or clearance and telling it to stop.<sup>10</sup> It did. It continued to sell its genealogical, ancestry, and trait services in the U.S. (and its health-related services in some foreign countries), but it stopped offering health information in the U.S. Over the next several years, it worked with FDA to get approval for some

medical tests, with some success. Although genetic testing is a large and fast-growing part of medicine, as of late September 2019, 23andMe remains the only DTC genomics firm that has FDA approval for any DTC medical tests.<sup>11</sup>

Traditionally, laboratories or firms have offered genetic testing for medical purposes only through health care providers — the tests are ordered by physicians (or the fairly uncommon medical geneticists) and the results are delivered to providers.<sup>12</sup> Several other firms, such as MyHeritage,<sup>13</sup> Color,<sup>14</sup> and recently Ancestry, offer an intermediate model, providing medically relevant genetic information but with more physician interaction required than by 23andMe.

#### *Other*

Some DTC genomics companies have other interesting niches, focusing on more sophisticated consumers. A few firms, perhaps worried about the FDA's regulation of medical tests, have provided raw genomic data but no analysis.<sup>20</sup> Their hope may be that without any medical analysis, FDA will not consider them a regulated "medical device." At the same time, other companies do not genotype, sequence, or otherwise analyze any DNA, but provide interpretations for genetic information that is submitted to them.<sup>21</sup> When the information is medical, these firms, too, hope to avoid FDA regulation. So far FDA seems to have ignored both groups.<sup>22</sup>

**With one big, and several small, exceptions, DTC genomic testing is subject to little specific regulation in the United States. Like any other consumer product, the firms are subject to general rules about false advertising, fraud, and so on. They may be subject to potential liability for harm done, although whether based on negligence standard or on a product liability standard is unclear. But DTC genomics does raise three special kinds of legal problems: regulation of its medical uses, disclosure and use of a person's genetic information, and issues around unauthorized collection and analysis of a person's DNA.**

23andMe now offers four kinds of medical tests: for carrier screening, for genetic disease risks, for pharmacogenomic tests (assessing the effects of a person's genomic variations on their reactions to various prescription drugs), and for "polygenic risk factors."<sup>15</sup> (It now lumps the last three into what it calls a "health predisposition report.") Since February 2015, the first three have obtained some FDA approvals; the fourth, recently introduced, has neither sought nor received FDA approval. (FDA has recently strongly discouraged other DTC firms from providing pharmacogenomic information, a position attracting some controversy.<sup>16</sup>)

#### *"Wellness"*

More recently 23andMe has begun offering "wellness reports."<sup>17</sup> Currently, the firm offers tests for alcohol flush reaction, caffeine consumption, deep sleep, genetic weight, lactose intolerance, muscle composition, saturated fat and weight, and sleep movement. FDA has not asserted pre-market approval jurisdiction over these tests, apparently because it views them as low risk.<sup>18</sup> This is consistent with FDA's general hesitancy about the extent to which it wants to try to regulate "wellness" products, genetic or not.<sup>19</sup>

#### **Three Current Legal Issues**

With one big, and several small, exceptions, DTC genomic testing is subject to little specific regulation in the United States. Like any other consumer product, the firms are subject to general rules about false advertising, fraud, and so on. They may be subject to potential liability for harm done, although whether based on a negligence standard or on a product liability standard is unclear.<sup>23</sup> But DTC genomics does raise three special kinds of legal problems: regulation of its medical uses, disclosure and use of a person's genetic information, and issues around unauthorized collection and analysis of a person's DNA. This section identifies the issues; it does not attempt to solve them.

#### *Regulation of Medical Uses*

As a general matter, medical tests are classified as medical "devices," subject to regulation by the FDA under 1939's Federal Food, Drug, and Cosmetic Act and its Medical Device Amendments of 1976.<sup>24</sup> For medical devices, FDA often exercises, implicitly or explicitly, what it calls "enforcement discretion." FDA uses this enforcement discretion to avoid treating most diagnostic tests as devices subject to its approval require-

ments. These have traditionally been tests ordered by a physician and performed by licensed clinical laboratories,<sup>25</sup> with the results sent back to the ordering physician. FDA calls such tests “laboratory developed tests” or “LDTs.”

It takes a different position with respect to DTC tests. It has announced that it will *not* exercise enforcement discretion with them but will require the firms demonstrate to FDA that their tests are not only analytically valid, accurately identifying the genetic variations they claim to find, but also clinically valid, demonstrably related to the condition or the risk they purport to diagnose or identify.<sup>26</sup>

The FDA’s role has sparked bitter disputes about DTC genomic tests. Some have argued that genetic information, even that with medical implications, should be available to all because it is, after all, the customer’s DNA.<sup>27</sup> Others argue, equally vehemently, that genetic information with medical implications should be delivered through a trained medical professional, for fear that customers will misinterpret the information to their own harm.<sup>28</sup>

Within the medical realm this question is about the quality of care. No one should doubt that medical genomic information provided through a trained physician, medical geneticist, or qualified genetic counselor is usually better than information provided by email or the website of a DTC company. But the higher quality comes with a higher cost.

This issue is *not* new, but is a deep issue about American medicine generally. Licensed physicians, graduates of accredited medical schools who have met, and maintained, all the requirements for medical licensure, are expected to be better at medicine than less trained “practitioners” — but are also known to be more expensive. Some libertarian thinkers, dating back at least to Milton Friedman, have argued that medical practice should not be limited to licensed physicians but that people should be able to hold themselves out as “healers” of one kind or another, as long as they are honest about their training, skills, and certifications.<sup>29</sup>

Today, the issue of medical information is not “DTC or nothing.” People who want sound genomic medical information can get it through medical practitioners, sometimes with, or sometimes without, insurance. The question is whether they should be required to pay two to five times as much for professional help as for DTC analysis. Still, there is a deep question about paternalism versus liberty. People who think they can usefully absorb the medical implications of their genetic information with no harm and some benefit to themselves ask why they cannot learn, without physician intermediation, this information about their own

bodies. And if told it is because other people would not be able to interpret the information as well, they can ask, “why should we be held up by the limitations of others?”

Different countries and different people have different positions about DTC medical testing. The U.S. is unusually open to such tests; many other countries forbid them.<sup>30</sup> At the personal level, far more people have taken genetic genealogy tests than are taking medical DTC tests.

#### *Protection and Use of Genomic Data*

The second issue revolves around the protection and use of the data DTC consumers give the firms as well as the results of the firms’ analysis. This breaks down into three questions: the measures the firms will take to protect the information from unauthorized parties, the uses the firms will make of the information themselves, and with whom the firms will “share” the customers’ information.

For the most part, the protection and confidentiality of the materials consumers submit to DTC firms, and the data gleaned from them, are governed by the agreements between the parties. This is similar to how the law treats information you give — or unknowingly “give” — Facebook, Google, or your cell phone or credit card company. It presumes an entirely unrealistic degree of knowledge and intended “consent” on the part of the consumer. Many DTC companies do not have express privacy policies, and the policies of those that do vary somewhat from one to another.<sup>31</sup> Few of the policies go into any detail about how they will keep a customer’s information secure from unauthorized users. And none, of course, can honestly promise that they will prevent hacking. At most, they can promise to try.

The firms generally state that they have the right to use the customers’ data for their own purposes. These may be quality assurance or may be further ethnicity or even medical research. More controversial is whether the firm may “share” those data, directly or indirectly, with others. This has recently attracted great attention in the forensic context. Some firms, or organizations, have allowed law enforcement officials to use their customer databases in an effort to solve crimes. In widely discussed cases, law enforcement was allowed to submit a DNA profile from a crime scene in order to look for the suspects’ relatives in the organization’s database. The so-called Golden State Killer was identified by matching his crime scene DNA to a third cousin in a service called GEDmatch, which allows people to upload their data from one of the ancestry firms to a database where it can be compared with data from people who used a different service. Since then, sus-

pects in more than fifty cases have been identified by this kind of genealogical forensic testing.<sup>32</sup>

Another conflict concerns the “sharing” of analyzed data for research purposes by that firm, usually for compensation, with pharmaceutical, biotechnology, or university researchers.<sup>33</sup> Presumably such sharing will improve public health in general. Some customers are eager to have their information used to advance medicine; some may object to the firms being paid for “selling” their customers’ DNA data; and others may just not want their data shared, period, whether from fear of privacy leakage or other reasons.<sup>34</sup>

Note that the discussion is, thus far, purely a matter of either contract law or of the firms’ discretion. Five states do have specific genetic privacy statutes that give the sources a property right in their genetic information: Alaska, Colorado, Florida, Georgia, and Louisiana.<sup>35</sup> The meaning and limits of these statutes are not clear, although ongoing litigation is testing the limits of Alaska’s genetic privacy statute.<sup>36</sup> One might argue for stronger state or federal laws to require the DTC firms to protect consumer information and to require “better” authorization — specific, affirmative agreement by the consumer for specific kinds of uses, or even for uses by specific recipients. Or one might argue, as some did with the Genetic Information Non-Discrimination Act, that special treatment is needed to reassure people that getting genetic testing is a good thing,<sup>37</sup> but that argument works better when individuals are being asked to participate in either genetics research or their own health care — the social value of the DTC uses are much lower. There is Congressional interest in privacy legislation around DTC genomics with at least two bills in the works that address genetic information specifically, as well as a coalition of genomics firms — including Ancestry, 23andMe, and Helix — lobbying for legislation on the topic.<sup>38</sup>

The underlying deep privacy issue may be as stark as whether we should, or can, try to preserve privacy. Scott McNealy said twenty years ago: “You have zero privacy anyway. Get over it.”<sup>39</sup> How much do we care about genetic privacy — and how much do we care about protecting people who do not care enough to protect that privacy themselves? In DTC genomics, this question is further exacerbated by the likelihood that, for most of us, our genomic information is less revealing than much of our other data that are fairly widely available, such as credit card expenditures, Google searches, or cell phone locations. This likelihood, however, is not widely appreciated by the public and, in any event, will not be true for the minority of people with a clear and strong genetic disease risk (or, perhaps, embarrassing ethnic or family connections).

### *Surreptitious Collection and Analysis of DNA*

The third legal question concerns surreptitious collection and analysis of DNA. Should someone be able to collect and then analyze your DNA without your consent — or even knowledge? There are few cases about surreptitious DNA collection and analysis and almost all of those involve law enforcement. In all but a handful of states, existing doctrines about discarded or abandoned property make the most likely answer “yes.” If the DNA is collected from discarded materials — cigarette butts, drink containers, facial tissue, diapers — the law has largely treated it as “abandoned property,” available to any claimant.<sup>40</sup> In the criminal context where law enforcement surreptitiously collected and analyzed DNA samples, those actions have been universally upheld.

The collection and analysis by people other than law enforcement officials has yet to be fully tested in court in the private context, although one truly bizarre set of lawsuits is proceeding between two South Florida billionaire neighbors, Ike Perlmutter and Harold Peerenboom.<sup>41</sup> Four of the state statutes — in Alabama, Colorado, Florida, and Georgia — proclaim that a person’s “DNA analysis” or “genetic information” is his or her “exclusive,” or “unique” property.<sup>42</sup> These statutes may make that kind of unconsented and surreptitious DNA collection and analysis illegal. But we have no cases yet and the scope of these bans are not clear.

### **The Future**

Within a few years, two of the three legal issues around DTC genomics — medical uses and the protection and sharing of customer data, should fade as an issue, as should those parts of the industry themselves. Surreptitious collection of DNA and its unconsented analysis will remain a potential and likely growing problem.

### *Future Regulation of Medical Uses*

In the near term, it remains unclear what FDA will end up doing about DTC genomic testing, or even clinical laboratory genomic testing. Although some of the 23andMe approvals seemed to indicate significant FDA acceptance of such testing, in late August FDA pushed back against the use of DTC genomic testing for pharmacogenomics.<sup>43</sup> The future course, especially across presidential administrations, seems highly unpredictable.

But, looking 10 to 20 years away, whether it comes quickly or slowly, genomic information *will* become a part of normal health care. When people with health coverage routinely have their whole genomes sequenced and their doctors provided with assessments of their DNAs’ significance, what will be the market for medical DTC genomics? It will be hard to sell when doctors

are using whole genome sequence information and are providing at least some medically useful information, especially if that is covered by health insurance. A market may still exist for “wellness” information and other more scientifically questionable health-related findings, but, even then, the companies will not be reading, collecting, and analyzing DNA, but just interpreting DNA results from their customers’ health providers.

intended to sequence DNA samples from customers and then let them choose what kinds of analysis they wanted through various “apps,” shifted its strategy away from DTC genomics to working with health care institutions; Color has similarly moved away from the DTC approach.<sup>46</sup> Gencove, another firm that provided DTC services, stopped offering them in May 2018.<sup>47</sup>

It is also possible that sales have declined because

### Twenty years ago, DTC genomics did not exist.

Twenty years from now, it may once again not exist, or, at the least, be less common. How much effort should we put into regulating today’s problems when we think they will not be tomorrow’s? This is, to me, an example of the need for regulation that includes monitoring of the actual, changing realities and that modifies itself as those realities change. But it is always easier to find capital — either monetary or political — to start something than to monitor, maintain, and modify it over time. We should work hard to avoid that in the regulation of DTC genomic testing.

And while some Americans might still lack decent health coverage and health care in 10 to 20 years, they will not be people who can afford to support a robust medical DTC genomics industry.

#### *Future Protection and Use of Genomic Data*

Data protection and use issues are most strongly associated with the ethnicity and family information uses of DTC genomics, if only because they have been the most popular. They also are likely to fade away.

For one thing, even though genealogy is a huge interest, it is not an unlimited one. About 30 million Americans have gotten an ancestry/genealogy assessment today. That’s about 9 percent of the population and about 12 percent of the adult population. Many of the others will have no interest in these services; some others will have some interest but will learn enough from relatives who have been tested. After all, if my genetic sister knows her ancestral information and all her genetic second-cousins, I can learn all that from her. There may be a few small differences in our ethnic percentages, but will they be worth spending money to find out?

There already may be some evidence for this.<sup>44</sup> Illumina, the world’s largest provider of genomic analysis, announced in August 2019 that its revenues were going to be sharply lower, mainly because of greatly decreased sales of the SNP chips that feed the DTC market.<sup>45</sup> In May 2019, Helix, a company that

of the publicity about the forensic genealogy searches. Even here, current market driven movements may make these issues less important.

Although the protection of company data is a significant issue, the most important of these issues come not from the *existence* of genomic data on people but the broad availability of that data. GEDmatch has been the prime source for forensic use of genetic genealogy, but after initially embracing police uses, at least in certain serious crimes, in June 2019, GEDmatch announced that it would allow family forensic genealogy searches only of data from participants who affirmatively opted in.<sup>48</sup> Data from those who did nothing — perhaps because they had forgotten they were GEDmatch members, they didn’t care, or they were dead — would be excluded. So far, only 163,000 of the more than 1.2 million GEDmatch members have opted to be available for such searches.<sup>49</sup> (On September 19, 2019, I received an email from GEDmatch encouraging me, as a member, to opt-in for forensic uses.)<sup>50</sup>

Meanwhile, of the three main ethnicity and family information companies, Ancestry and 23andMe have said they will not voluntarily cooperate with law enforcement and will resist, in court, any subpoena or search warrant. Family Tree, on the other hand, has said that it will allow law enforcement to submit genetic profiles to its database (at least in serious cases).<sup>51</sup> And in September 2019 a newly started DTC company, Nebula Genomics, announced that it would

provide whole genome sequencing anonymously, without requiring customers to provide even their names, addresses, or credit card information.<sup>52</sup> That same month the U.S. Department of Justice offered interim guidelines on when it would use these methods.<sup>53</sup>

The availability of non-public databases for forensic searches or for other privacy invasions, either as a result of search warrants and subpoenas or from hacking, will remain possible but the large, and growing, majority of genomic databases will not be in DTC firms but growing medical and forensic databases. Issues of judicially enforced disclosure, or of leaked or hacked “disclosure” will require legal clarity, but they will not primarily issues of DTC genomics.

*Future Surreptitious Collection and Analysis of DNA* Surreptitious collection, on the other hand, not only seems unlikely to go away but may accelerate. New methods are being developed to collect and rapidly analyze DNA samples for forensic purposes.<sup>54</sup> It is not clear how often someone will care, apart from paternity disputes and law enforcement uses, but as DNA analysis becomes cheaper and better, it will be done more often. Early adoption of rules requiring permission would be especially useful.

Beyond a few plausible exceptions — such as law enforcement uses, the collection of unidentified human DNA from the environment for research, or parents having the DNA of their minor children tested for medical purposes — there seems no good justification for unconsented, surreptitious DNA collection and analysis.

The circumstances under which this privacy right can be waived, in advance and in general, should also be clarified. Today, an employment contract cannot justify this conduct. Employers are already largely forbidden from collecting, analyzing, or using employees’ DNA even with their consent, as shown in the “Case of the Devious Defecator.”<sup>55</sup> There, a warehouse firm was plagued with human excrement; it suspected two employees, got them to consent to cheek swabs, and tested their DNA against DNA in the excrement. The DNA did not match — and then the employees successfully sued under the Genetic Information Nondiscrimination Act.

Current state genetic privacy laws might be useful models, although muddying a prohibition on unconsented or inappropriate collection and analysis of DNA with the language of “property” or “ownership” will likely cause confusion. Instead, one might just require that whoever analyzes a DNA sample must have good evidence that it was either collected consensually or under an applicable exception.

## Conclusion

Twenty years ago, DTC genomics did not exist. Twenty years from now, it may once again not exist, or, at the least, be less common. How much effort should we put into regulating today’s problems when we think they will not be tomorrow’s? This is, to me, an example of the need for regulation that includes monitoring of the actual, changing realities and that modifies itself as those realities change. But it is always easier to find capital — either monetary or political — to start something than to monitor, maintain, and modify it over time. We should work hard to avoid that in the regulation of DTC genomic testing.

## Note

Preparation of this article was supported by National Human Genome Research Institute and National Cancer Institute of the National Institutes of Health (NIH) under award number R01HG008605 for “LawSeq: Building a Sound Legal Foundation for Translating Genomics into Clinical Application.”

## References

1. S. M. Wolf et al., “Integrating Rules for Genomic Research, Clinical Care, Public Health Screening & DTC Testing: Creating Translational Law for Translational Genomics,” *Journal of Law, Medicine & Ethics* 48, no. 1 (2020): 69-86.
2. See also I.G. Cohen, N.A. Farahany, and H.T. Greely, eds., *Consuming Genomics: Ethical and Legal Considerations of New Technologies* (Cambridge, England: Cambridge University Press, forthcoming 2020) (an edited volume with about 15 chapters, drawn from the May 2019 conference of the same name).
3. 23andMe, About Us, 23andMe.com, available at <<https://mediacenter.23andme.com/company/about-us/>> (last visited September 28, 2019).
4. “Life Technologies Acquires Consume Genetics Testing Firm Navigenics,” GenomeWeb, July 17, 2012, available at <<https://www.genomeweb.com/diagnostics/life-technologies-acquires-consumer-genetics-testing-firm-navigenics#.XY03FZNKjJOY>> (last visited September 28, 2019). D. Vorhaus, “Implications of Amgen/deCODE Deal for Genetic Testing Consumers,” The Privacy Report, December 10, 2012, available at <<https://the-privacyreport.com/2012/12/10/implications-of-amgendecode-deal-for-genetic-testing-consumers/>> (last visited Sept. 28, 2019). For more details about the history of development of medical DTC testing, see H.T. Greely, “Ethical Issues in Clinical Genetics and Genomic,” edited by G.J. Netto and K.L. Kaul, 2d ed. (New York: Springer, 2019).
5. A. Regalado, “More Than 26 Million People Have Taken An At-Home Ancestry Test,” *MIT Technology Review*, February 11, 2019, available at <<https://www.technologyreview.com/s/612880/more-than-26-million-people-have-taken-an-at-home-ancestry-test/>> (last visited September 26, 2019). (These are not just U.S. customers; those numbers do not seem to be available.) Ironically this article states that the number could be 100 million within 24 months if the growth seen in 2018 continues. As discussed below, it did not. In October 2019, Ancestry announced that it would begin offering some DNA-related health information to users, supervised by a physician although not the customer’s primary care physician.
6. R. Imbeault, “A DNA Test Revealed A Sister I Never Knew Existed. Now What?” *The Globe and Mail*, September 17, 2019 (the author expresses a “miscellany of emotions,” including confusion, anger, excitement, joy, and skepticism upon learning he had a sister); D. Shapiro, *Inheritance: A Memoir of*

- Genealogy, Paternity, and Love* (New York: Alfred A. Knopf, 2019), (mixed reaction to misattributed paternity revelation); R. Hertz and M. K. Nelson, *Random Families: Genetic Strangers, Sperm Donor Siblings, and the Creation of New Kin* (New York: Oxford University Press, 2018); E. Baden-Lasar, "A Family Portrait: Brothers, Sisters, Strangers," *New York Times Magazine*, available at <<https://www.nytimes.com/interactive/2019/06/26/magazine/sperm-donor-siblings.html>> (last visited October 7, 2019).
7. N. Moray et al., "Paternity Testing Under the Cloak of Recreational Genetics," *European Journal of Human Genetics* 25, no. 6 (2017): 768-770. For a larger discussion on the ethics of paternity testing generally, see R.J. Trent, "Ethical, Legal, and Social Issues," in *Molecular Medicine, Genomics to Personalized Healthcare* (Elsevier, 2019): 301-328, 322.
  8. DNA Solutions, "Secret Paternity Test," available at <<https://www.dnanow.com/secret-dna-test.htm>> (last visited October 7, 2019).
  9. "23andMe, Our Services," 23andMe.com, available at <<https://www.23andme.com/dna-reports-list/>> (last visited September 27, 2019).
  10. Alberto Gutierrez to Ann Wojcicki, Warning Letter, November 22, 2013, available at <<https://wayback.archive-it.org/7993/20170722040905/https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm>> (last visited September 28, 2019); A. Pollack, "F.D.A. Orders Genetic Testing Firm to Stop Selling DNA Analysis Service," *The New York Times*, November 25, 2013, available at <<https://www.nytimes.com/2013/11/26/business/fda-demands-a-halt-to-a-dna-test-kits-marketing.html>> (last visited October 8, 2019).
  11. U.S. Food and Drug Administration, Lists of Direct-to-Consumer Tests with Marketing Authorization, available at <<https://www.fda.gov/medical-devices/vitro-diagnostics/direct-consumer-tests>> (last visited September 26, 2019).
  12. This is not quite technically accurate. Clinical human geneticists can also order genetic tests and receive results from traditional laboratories, but they can be people with Ph.D.s in genetics and not M.D.s, and hence not "physicians." But they are few in number — about 1,600 in the United States (some of whom will also have M.D. degrees and be licensed physicians). Compare D. S. Regier et al., "Medical Genetics and Genomic Medicine in the United States. Part 2: Reproductive Genetics, Newborn Screening, Genetic Counseling, Training, and Registries," *Molecular Genetics & Genomic Medicine* 5, no. 6 (2017): 621-630, 625 (noting, as of 2015, there are about 1600 clinical geneticists) with A. Young et al., "A Census of Actively Licensed Physicians in the United States," *Journal of Medical Regulation* 103, no. 2 (2017): 7-21, 7 (noting there are nearly 1 million active physicians).
  13. MyHeritage, "Health," MyHeritage.com, available at <<https://www.myheritage.com/health>> (last visited September 28, 2019); See also J. Petrone, "MyHeritage Moves Into Health with New Genetic Testing Offering, Underscoring Industry Trend," *GenomeWeb*, May 28, 2019, available at <<https://www.genomeweb.com/applied-markets/myheritage-moves-health-new-genetic-testing-offering-underscoring-industry-trend>> (last visited September 28, 2019).
  14. "Color, How it Works," Color.com, available at <<https://www.color.com/providers/how-it-works>> (last visited September 27, 2019). Consumers cannot directly order genetic tests through Color. Instead, genetic testing must be ordered by a healthcare provider. Results are provided to both patient and healthcare provider, and genetic counselling is offered with each test. Healthcare providers can order testing on hereditary risk for high cholesterol, certain cancers, and responses to medication.
  15. 23andMe, *supra* note 9.
  16. R. Robbins, "FDA Warns Testing Companies: Don't Tell Patients How Their DNA Influences Responses to Specific Drugs," *Stat+*, August 28, 2019, available at <<https://www.statnews.com/2019/08/28/fda-warns-pharmacogenetic-testing-companies/>> (last visited September 26, 2019); R. Robbins, "Industry Groups Push Back Against 'Troubling' FDA Crackdown on Genetic Tests Used to Predict Response to Drugs," *Stat+*, September 18, 2019, available at <<https://www.statnews.com/2019/09/18/industry-groups-push-back-against-troubling-fda-crackdown-on-genetic-tests-used-to-predict-response-to-drugs/>> (last visited September 26, 2019); "Mental Health Advocacy Groups Appeal to FDA to Reconsider PGx Enforcement Activity," *GenomeWeb*, September 26, 2019, available at <<https://www.genomeweb.com/molecular-diagnostics/mental-health-advocacy-groups-appeal-fda-reconsider-pgx-enforcement-activity?>> (last visited September 26, 2019).
  17. "23andMe," 23andMe.com, available at <<https://www.23andme.com/dna-health-ancestry/#all-reports-list>> (last visited September 27, 2019).
  18. U.S. Food & Drug Administration, Direct to Consumer Tests, *supra* note 11; U.S. Food & Drug Administration, General Wellness: Policy for Low Risk Devices, General Guidance for Industry and Food and Drug Administration Staff (2019), available at <<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>> (last visited September 28, 2019).
  19. U.S. Food & Drug Administration, "General Wellness," *id.*
  20. D. Vorhaus, "DNA DTC: The Return of Direct to Consumer Whole Genome Sequencing," *The Privacy Report*, November 29, 2012, available at <<https://theprivacyreport.com/2012/11/29/dna-dtc-the-return-of-direct-to-consumer-whole-genome-sequencing/>> (last visited September 28, 2019) (interesting discussion by of one such company and its likely reasons); A. Regalado, "How a Wiki Is Keeping Direct-to-Consumer Genetics Alive," *MIT Technology Review*, October 19, 2014, available at <<https://www.technologyreview.com/s/531461/how-a-wiki-is-keeping-direct-to-consumer-genetics-alive/>> (last visited September 26, 2019).
  21. S.C. Nelson, "Consumer Genetic Testing Consumers Stretch Their DNA Data Further with Third-Party Interpretation Websites," *The Conversation*, June 13, 2019, available at <<https://theconversation.com/consumer-genetic-testing-customers-stretch-their-dna-data-further-with-third-party-interpretation-websites-118248>> (last visited September 28, 2019); T. Moscarello et al., "Direct-to-Consumer Raw Data and DNA Interpretation Services: More Burden Than Bargain?" *Genetics in Medicine* 21, no. 3 (2019): 539-541, 539; Promethease, available at <<https://promethease.com/>> (last visited September 28, 2019).
  22. Interestingly, in September 2019, two of these services, Promethease and SNPedia.com, were acquired by the relatively new "quasi-DTC" firm, MyHeritage (which does require professional medical intermediation, at least in the United States, for its health products). Esther, "MyHeritage Acquires Promethease and SNPedia," MyHeritage Blog, available at <<https://blog.myheritage.com/2019/09/myheritage-acquires-promethease-and-snpedia/>> (last visited September 26, 2019).
  23. G. Marchant, "Liability Implications of Direct-to-Consumer Genetic Testing," presentation at 2019 Petrie-Flom Center Annual Conference on Consumer Genetics: Ethical and Legal Considerations of New Technologies, Cambridge, MA, May 17, 2019, available at <<https://vimeo.com/338077232>> (last visited October 8, 2019).
  24. Federal Food Drug and Cosmetic Act, 21 U.S.C. §§ 321, 360 et seq.; Medical Device Amendments of 1976, Pub. L. No. 94-295 (1976); Greely *supra* note 4; B.J. Evans et al., "How Can Law and Policy Advance Quality in Genomic Analysis and Interpretation for Clinical Care?" *Journal of Law, Medicine & Ethics* 48, no. 1 (2020): 44-68.
  25. Clinical laboratories are licensed by the states, accredited by the College of American Pathologists, and further regulated by a federal law, the Clinical Laboratory Improvement Amendments Act, implemented jointly by FDA, the Centers for Disease Prevention and Control, and the Centers for and Medicaid Services.



26. See U.S. Food & Drug Administration, Direct-to-Consumer Tests, *supra* note 11.
27. R.C. Green and N.A. Farahany, "Regulation: The FDA Is Over Cautious on Consumer Genomics," *Nature* 505, no. 7483 (2014): 286-287.
28. P.J. Zettler et al., "23andMe, the Food and Drug Administration, and the Future of Genetic Testing," *JAMA Internal Medicine* 174, no. 4 (2014): 493-494.
29. M. Friedman, *Capitalism and Freedom*, Chap. 9 (Chicago, IL: Univ. Chicago Press: Chicago, 1962.) (attacking occupational licensure generally with a particular focus on medicine).
30. In Austria, France, Germany, Hungary, Italy, Lithuania, the Netherlands, Slovenia, Portugal, and Spain; genetic testing for health purposes can only be ordered under the supervision of a medical professional. See L. Kalokairinou et al., "Legislation of Direct-To-Consumer Genetic Testing in Europe: A Fragmented Regulatory Landscape," *Journal of Community Genetics* 9, no. 2 (2018): 117-132.
31. J.W. Hazel, "Privacy Best Practices for Direct-to-Consumer Genetic Testing Services: Are Industry Efforts at Self-Regulation Sufficient?" in *Consuming Genetics*, *supra* note 2; J. Hazel and C. Slobogin, "Who Knows What, And When?: A Survey of The Privacy Policies Proffered By U.S. Direct-To-Consumer Genetic Testing Companies," *Cornell Journal of Law and Public Policy* 28, no. 1 (2018): 35-66.
32. M. Molteni, "What the Golden State Killer Tells Us About Forensic Genetics," *Wired*, April 24, 2019, available at <<https://www.wired.com/story/the-meteoric-rise-of-family-tree-forensics-to-fight-crimes/>> (last visited Sept. 27, 2019). For the first substantial discussion of legal and scientific issues in family forensic DNA testing, see H.T. Greely et al., "Family Ties: The Use of DNA Offender Databases to Catch Offenders' Kin," *Journal of Law, Medicine & Ethics* 34, no. 2 (2006): 248-262.
33. See, e.g., D. Roland, "How Drug Companies Are Using Your DNA To Make New Medicine," *The Wall Street Journal*, July 22, 2019, available at <<https://www.wsj.com/articles/23andme-glaxo-mine-dna-data-in-hunt-for-new-drugs-11563879881>> (last visited September 2, 2019).
34. J. Kim et al., "Patient Perspectives About Decisions to Share Medical Data and Biospecimens for Research," *JAMA Network Open*, August 21, 2019, available at <[doi:10.1001/jamanetworkopen.2019.9550](https://doi.org/10.1001/jamanetworkopen.2019.9550)> (last visited February 9, 2020).
35. J. L. Roberts, "Progressive Genetic Ownership," *Notre Dame Law Review* 93, no. 3 (2018): 1105-1172, 1128.
36. *Cole v. Gene by Gene, Ltd.*, No. 1:14-cv-00004, 2017 U.S. Dist. LEXIS 101761 at 7, \*9 (D. Alaska June 30, 2017) (denying the defendant's motion to dismiss on the ground that Cole was able to demonstrate the requisite injury-in-fact under Alaska's Genetic Privacy Act, which "recognizes an exclusive property interest in one's DNA, and prohibits the unauthorized disclosure of DNA information") See Roberts, *supra* note 35, at 1110 (describing the factual background underlying the Cole case. The Ninth Circuit has affirmed a denial of class certification in the Cole case. *Cole v. Gene by Gene, Ltd.*, No. 17-35837 at 2 (9th Cir. August 21, 2018).
37. H.T. Greely, "Banning Genetic Discrimination," *New England Journal of Medicine* 353: 865 (2005).
38. A. Joseph, "Health Tech Companies Are Swallowing Up Consumers' DNA. Can Congress Safeguard What They Do With It?" *Stat+*, August 9, 2019, available at <<https://www.statnews.com/2019/08/09/health-tech-companies-consumer-dna-congress-safeguards/>> (last viewed September 2, 2019).
39. P. Sprenger, "Sun on Privacy: Get Over It," *Wired*, January 26, 1999, available at <<https://www.wired.com/1999/01/sun-on-privacy-get-over-it/>> (last visited September 26, 2019).
40. While not a case about DNA or genetic testing, the Supreme Court in *California v. Greenwood*, held a defendant has no reasonable expectation of privacy over trash left for pick-up on the curb outside the defendant's home. Law enforcement may, therefore, search or seize this trash without a warrant. 486 U.S. 35, 35 (1988). Subsequent courts have applied similar reasoning to cases of "abandoned DNA." See *People v. Gallego*, 117 Cal. Rptr. 3d 907, 912-914 (Cal. Ct. App. 2012) (finding the DNA testing of a cigarette the defendant threw on sidewalk not a Fourth Amendment search); *Commonwealth v. Cabral*, 866 N.E.2d 429, 435 (Mass. App. Ct. 2007) (finding no reasonable expectation of privacy over saliva, and DNA obtained from it, spit on the ground); *State v. Athan*, 158 P.3d 27, 33-34 (Wash. 2007) (holding that the defendant had no expectation of privacy over DNA obtained from saliva on an envelope he licked and placed in the mail).
41. E. Gardner, "Marvel Chairman Ike Perlmutter Allowed to Pursue Legal Claims over Theft of his DNA," *The Hollywood Reporter*, January 25, 2017, available at <<https://www.hollywoodreporter.com/thr-esq/marvel-chairman-ike-perlmutter-allowed-pursue-legal-claims-theft-his-dna-968493>> (last visited September 20, 2019) (Florida state trial court allows claim to proceed that plaintiff had a property interest in his DNA and its associated information that one neighbor allegedly intentionally stole during a deposition in order to compare it with DNA found on hate mail sent to the plaintiffs). See also K.V. Brown, "How a Legal Brawl Between Two Rich Guys Could Change How We Think About DNA," *Gizmodo*, June 13, 2018, at <<https://gizmodo.com/how-a-legal-brawl-between-two-rich-guys-could-change-ho-1824191082>> (last visited September 2, 2019).
42. J. Roberts, *supra* note 35, at 1128.
43. *Supra* note 16.
44. C. Farr, "Consumer DNA Testing Has Hit a Lull - Here's How It Could Capture the Next Wave of Users," *CNBC*, Aug. 25, 2019, available at <<https://www.cnbc.com/2019/08/25/dna-tests-from-companies-like-23andme-ancestry-see-sales-slowdown.html>> (last visited September 26, 2019). (Quoting sources who suggested as reasons for the lull either saturating markets or privacy concerns.)
45. D. Garde, "Illumina Earnings Point to Worrying Signs for Consumer Genetics Industry," *Stat+*, July 12, 2019, available at <<https://www.statnews.com/2019/07/12/illumina-earnings-points-to-worrying-signs-for-consumer-genetics-industry/>> (last visited September 2, 2019).
46. K.V. Brown, "App Store for DNA Fizzles as Health Startup Shifts Strategy," *Bloomberg*, May 8, 2019, available at <<https://www.bloomberg.com/news/articles/2019-05-08-app-store-for-dna-fizzles-as-health-startup-shifts-strategy>> (last visited September 2, 2019).
47. J. Pickrell, "Sunsetting Glencove for Individuals," *The Glencove Blog*, May 18, 2018, available at <<https://medium.com/the-gencove-blog/sunsetting-gencove-for-individuals-7d24f951193c>> (last visited September 2, 2019). See also S.C. Nelson (2019), *supra* note 21. Another possibly interesting omen comes from 23andMe, which has announced that it is expanding its business into helping to provide clinical trial cohorts for pharmaceutical or biotechnology companies. See R. Robbins, 23andMe, "Moving Beyond Consumer DNA Tests, Is Building a Clinical Trial Recruitment Business," *Stat+*, September 26, 2019, available at <<https://www.statnews.com/2019/09/26/23andme-clinical-trial-recruitment/>> (last visited October 8, 2019). This follows 23andMe's earlier efforts to become a drug discovery and development company, efforts that have not yet borne any fruit.
48. P. Aldhouse, "This Genealogy Database Helped Solve Dozens of Crimes. But Its New Privacy Rules Will Restrict Access Cops," *BuzzFeed News*, May 19, 2019, available at <<https://www.buzzfeednews.com/article/peteraldhouse/this-genealogy-database-helped-solve-dozens-of-crimes-but>> (last visited September 26, 2019).
49. S. Zhang, "The Messy Consequences of the Golden State Killer Case," *The Atlantic*, October 1, 2019, available at <<https://www.theatlantic.com/science/archive/2019/10/genetic-genealogy-dna-database-criminal-investigations/599005/>> (last visited October 8, 2019).

50. Email from GEDMatch Notifications to author (HG, hgreely@stanford.edu), subject line "Important GEDmatch Message," September 12, 2019.
  51. A.D. Marcus, "Customers Handed Over Their DNA. The Company Let the FBI Take a Look," *Wall Street Journal*, August 22, 2019, *available at* <<https://www.wsj.com/articles/customers-handed-over-their-dna-the-company-let-the-fbi-take-a-look-11566491162>> (last visited October 3, 2019).
  52. S. Begley, "Amid Privacy Concerns, Startup Becomes First Consumer DNA Company to Offer Anonymous Sequencing," *Stat+*, September 19, 2019, *available at* <<https://www.statnews.com/2019/09/19/nebula-to-offer-anonymous-dna-sequencing>> (last visited September 26, 2019).
  53. U.S. Dept. of Justice, "Interim Policy: Forensic Genealogical DNA Analysis and Searching (approved September 2, 2019)," *available at* <[justice.gov/olp/page/file/1204386/download](https://justice.gov/olp/page/file/1204386/download)> (last visited October 8, 2019).
  54. GenomeWeb, "FBI Approves ANDE Rapid DNA ID System," *GenomeWeb*, June 4, 2018, *available at* <<https://www.genomeweb.com/applied-markets/fbi-approves-ande-rapid-dna-id-system#.XY74RudKiHo>> (last visited September 27, 2019).
  55. G. Kolata, "'Devious Defecator' Case Tests Genetics Law," *The New York Times*, May 29, 2015, *available at* <<https://www.nytimes.com/2015/06/02/health/devious-defecator-case-tests-genetics-law.html>> (last visited September 26, 2019); *Lowe v. Atlas Logistics Group Retail Services*, 102 F. Supp. 2d 1360, (N.D. Ga. 2015).
-