Toward a Unified Approach to Protection of Genetic Information

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Human genetic information is proving to be extremely valuable in various forms of research and, as a result, is being used with increasing frequency in a wide variety of applications. However, the resolution of significant questions regarding conditions under which researchers and other entities may properly access and use genetic information has not progressed as rapidly. Because genetic information may hold the key to many important medical breakthroughs, such information has great value to society at large.

At the same time, however, the actual and potential use of genetic information has raised concerns among individuals whose genetic information may be used by researchers and other third parties. Such individual concerns have led to a flurry of legislation designed to place limitations on the ability of various entities to use individual genetic information. Generally, such legislation has taken one of two approaches: it has either focused on categorizing genetic information as something that is private to the individual and therefore cannot be disclosed without the individuals’ consent, or it has focused on labeling genetic information as something that is proprietary to the individual and thus not capable of being taken or used in the absence of the permission of, and perhaps payment to, the individual owner. This article proposes to examine these two approaches and how they are being implemented through legislation. In so doing, we highlight the need for a more unified approach to addressing concerns about the use of genetic information.

WHY ARE THERE SPECIAL CONCERNS ABOUT GENETIC INFORMATION?

While many individuals are concerned about protecting the privacy and controlling the use of their personal information, some people are of the view that genetic information warrants special protection. The perception that genetic information can serve as an important predictor of the health, not only of a particular individual, but also of his or her family members has led to concerns that employers and insurers may use this information as a means for limiting such individuals’ employment opportunities or insurance coverage.1 While the perception of the possibility of this kind of discrimination appears to be rather widespread, there continues to be debate about whether the current data regarding employers’ and insurers’ use of such information actually reveals the existence of policies of genetic discrimination.

Regardless of what the current data actually reveal, it is clear that information garnered through the use of genetic tests may be of potential interest not only to the particular individual who has been tested but also to other entities, including employers, schools, insurers, personal physicians, and medical researchers. The growing number and use of genetic tests has many worried about discrimination resulting from inappropriate access to, and use of, private genetic information. Without adequate safeguards, genetic information could be misused, and, if the practice carried out systematically, such misused genetic information could lead to the creation a new underclass of genetically less-fortunate individuals.

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APPROACHES THAT EMPHASIZE PRIVACY

Special protection for genetic information?

It is generally accepted in the United States that medical information is confidential. Laws in all states restrict access to medical records, and new federal regulations enacted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) provide comprehensive protection to individually identifiable health information. However, there continues to be debate over whether genetic information should be protected generally, as another component of health data, or by special privacy laws. Those who are against special protections for genetic information tend to assert that such information is fundamentally no different from other health data. Accordingly, special protections are not warranted. Others, who are against genetic exceptionalism, have contended that instead of focusing on enhanced protection for genetic information, efforts should be undertaken to strengthen the protection that is afforded to all health-related information. On the other hand, those who advocate special privacy protections for genetic information usually point to its stability, as well as its unique predictive qualities, as evidence that such information deserves special consideration.

U.S. federal legislation

The HIPAA provides comprehensive protection to individually identifiable health information. The law does not focus on genetic information, but it does provide some protection against genetic discrimination, such as requiring that genetic information not be used to deny or limit health insurance coverage for members of a group plan. However, some shortcomings have been identified. For example, HIPAA fails to provide protection in all cases for individuals who seek insurance in the individual or self-employment market. The law does not prohibit rating based on genetic information, nor does it prevent health insurers from disclosing or demanding access to genetic information.

U.S. state legislation

While there is a lack of federal legislation specifically addressing the issue of how genetic information can be used, there is an abundance of often-conflicting legislation at the state level. Currently, a number of state laws require informed consent for a third party either to perform or to require a genetic test or to obtain genetic information. In Arizona, for example, the law provides that “a person shall not require the performance of or perform a genetic test without first receiving the specific informed consent of the subject of the test.” A number of other states require informed consent to disclose genetic information. In addition, several states require written authorization to disclose genetic information. For instance, in South Carolina, the law provides that “[a]ll genetic information . . . must be confidential and must not be disclosed to a third party in a manner that allows identification of the individual tested without first obtaining the written informed consent of the individual.” Furthermore, a small number of states mandate individual access to personal genetic information. The fact that states that have chosen to focus on protecting the privacy of genetic information and have done so in such disparate ways offers further evidence that a more unified approach is necessary.

Advantages and disadvantages of the privacy approach

On first inspection, it would appear useful to address individuals’ concerns about protecting themselves from potential genetic discrimination by focusing on protecting the privacy of individuals’ genetic information. After all, if employers, insurers, school administrators, and other entities about which individuals may have concern do not have access to individuals’ genetic information, it would not be possible for these entities to use the information to engage in genetic discrimination.

While legislation that focuses on protecting the privacy of individual genetic information may be useful in preventing some forms of genetic discrimination, this approach is not without its drawbacks. One of the main disadvantages of the privacy approach is that it does not provide individuals with continuing control over the use of their information.

2 Public Law 104–191.
3 See, e.g., Lawrence O. Gostin and James G. Hodge, Jr., Genetic privacy and the law: an end to genetics exceptionalism, 40 Jurimetrics J. 21, 24 (1999).
For example, legislation that emphasizes privacy rights may require that an individual provide consent before her genetic information can be disclosed to certain third parties. However, once the individual provides her consent, in most cases, she will no longer be able to control how her information is used by any entities that come in contact with it. Additionally, placing too much emphasis on the privacy of genetic information may create obstacles to the use of genetic information for positive purposes, such as the prevention and early detection of disease.

**APPROACHES THAT EMPHASIZE PROPERTY RIGHTS**

As an alternative approach to protecting an individual’s genetic information, some jurisdictions, in lieu of privacy legislation, recognize a protectable property interest in an individual’s own genetic material. By receiving a property interest, an individual may be given a more robust bundle of rights and protections than is available through privacy legislation alone. It has been observed that a privacy right merely affords an individual a “right of non-interference,” while a property right is a “right of positive entitlement.” Conceivably, through property rights, an individual could be provided with a series of rights regarding the control, possession, and transferability of his genetic information that are unavailable through privacy legislation. For example, the creation of property rights could help give individuals continuing control over what is done with their genetic information and allow them to share in its commercialization.

**Is genetic information properly characterized as property?**

Property is defined as “[t]hat which is peculiar or proper to any person; that which belongs exclusively to one. In the strict legal sense, an aggregate of rights which are guaranteed and protected by the government.” Using this definition, it is clear that genetic information has many characteristics of property:

- The DNA in an individual’s body is unique to that individual.
- DNA resides in an individual’s body and as such, belongs exclusively to that individual.
- The use of the DNA in an individual’s body is controlled exclusively by the individual.
- The individual alone possesses the ability to transfer his DNA through either donation or reproduction.

Nevertheless, even though genetic information possesses certain property-like traits, without legislation recognizing genetic material as personal property, the decision about whether genetic information is afforded the same rights and protections as personal property under the common law will be left to the courts. When confronted with this very issue, the Supreme Court of California held that an individual does not retain a protectable property interest in his excised cells. In *Moore*, plaintiff’s spleen was removed and, without plaintiff’s permission, used, along with other of his biologic samples, for medical research that led to the development of certain pharmaceutical products. Plaintiff brought suit against his doctors for *inter alia* conversion of his genetic material. After balancing the relevant public policy considerations, including the impact on the research community, the Court was unwilling to expand conversion law to cover genetic material. If such an expansion were to occur, the Court believed that “the Legislature should make that decision.”

**U.S. state legislation**

As suggested in *Moore*, some states have chosen to recognize an individual’s property right in his genetic information. The first state to adopt legislation to that effect was Oregon. In 1995, Oregon enacted a law that gave a person ownership rights in his genetic information, including DNA intended for use in anonymous research. This law, however, was short lived. Amid concerns that pharmaceutical and

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6 Intellectual property rights in genes are outside the scope of this article.
7 Dr. Graham Laurie, Privacy, Property or Permission? Need Our Models for Regulating Personal Genetic Material be Mutually Exclusive? Proceedings of the Third International Conference Law and Technology at 16 (Nov. 6–7, 2002).
9 See *Moore v. The Regents of the Univ. of California*, 51 Cal. 3d 120 (1990).
10 Although rejecting plaintiff’s conversion claim, the Court did not leave the plaintiff without remedy. The Court also held that plaintiff’s complaint stated a cause of action for “breach of fiduciary duty or lack of informed consent.” *Id.* at 147.
11 *Id.*
12 ORS 659.700–720.
biotechnology research was being negatively im-
pacted, a bill was passed in 2001 that took away
this property right and replaced it with broad pri-
vacy protection. Under the present law, genetic
information is no longer considered private property
once it is removed from a person’s body. However,
researchers are not entitled to use a person’s genetic
information without first obtaining the subject’s in-
formed consent.

Although Oregon eventually repealed its prop-
erty-based law and shifted to a privacy approach,
four states (Colorado, Florida, Georgia, and Loui-
siana) currently have laws that define a person’s
genetic information as personal property. In Florida,
for example, “the results of DNA analysis, whether
held by a public or private entity, are the exclusive
property of the person tested.” Similarly, Colorado
has taken an approach that emphasizes the propri-
etary nature of genetic information, providing that
“[g]enetic information is the unique property of the
individual to whom the information pertains.” In
each of these states, however, an individual’s own-
ership right in his genetic information is not ab-
solute. Each state recognizes an exception for ge-
etic information needed for the purposes of
criminal investigations or prosecutions, and Col-
orado, Florida, and Louisiana also recognize an ex-
ception for genetic materials needed to determine
paternity. In addition to these four states, legisla-
tion has been proposed recently in at least two other
states that follow the property approach.

Advantages and disadvantages of the property approach

Proponents of the property approach argue that
“[t]he added value of a property model lies in its
ability to empower individuals and communities and
to provide the crucial continuing control over sam-
ple or information through which on-going moral
and legal influence may be exerted.” This added
control, it is contended, will help empower individ-
uals in their dealings with researchers and allow a
research participant to “retain[] a vested interest in
samples and in the goals and outcomes of any re-
search for which those samples are provided.” It
is further argued that greater control over the use of
samples might make individuals who are otherwise
reluctant to participate in research projects more in-
clined to furnish samples.

Apart from the control aspects, others favor the

property model because it could allow research par-
ticipants to share in the profits researchers achieve
through use of genetic material. As one commen-
tator observed, “[t]he profits of these companies are
huge, so why shouldn’t they have to go through the
same process they’d have to go through to access
other kinds of property? If you wanted to mine gold
out of someone’s yard, you’d have to do the same
thing. DNA is our own personal gold.” Thus, sup-
porters of the property approach rely on both auton-
omy and commercial reasons for respecting individ-
uals’ property rights in their genetic information.

Opponents of the property approach see it as a
great impediment to scientific research. They be-
lieve that scientists might be dissuaded from con-
ducting important research if they are required to
trace the chain of title of each sample used or face
potential liability. On this point, the Supreme Court
of California observed that the recognition of per-
nonal property rights would “threaten[] to destroy
the economic incentive to conduct important med-
ical research [because] [i]f the use of cells in re-
search is a conversion, then with every cell sample

13 See Amanda Onion, Should You Own Your Genes? abc-
news.com (May 10, 2001) www.abcnews.go.com/sections/
sctech/DailyNews/geneprivacy010508.html
§760.40(2)(a); Ga. Code Ann. §33-54-1(1)(“genetic informa-
tion is the unique property of the person tested”); La. Rev. Sta.
Ann. §213.7(E)(“an insured’s or enrollee’s genetic informa-
tion is the property of the insured or enrollee.”)
16 See Colo. Rev. Stat. §10-3-1104.7(6)(“section does not limit
the authority of a court or any party to a parentage proceeding
or information obtained from genetic testing for purposes of
determining parentage”); see also Fla. Stat. Ann. §
17 See Colo. Rev. Stat. §10-3-1104.7(4)(“In the course of crimi-
inal investigation or a criminal prosecution . . . any peace officer . . .
may obtain information derived from genetic testing regarding
the identity of any individual who is the subject of the
criminal investigation or prosecution for use exclusively in the
criminal investigation of prosecution without the consent of the individual being tested”); see also Fla. Stat. Ann. § 760.40(2)(a);
18 See New Jersey AB 1379 and SB 542 (state senate and as-
sembly bill introduced January 8, 2002, that recognizes that “an
individual’s genetic information is the property of the individ-
ual”) and New Hampshire HB 1290 (house bill introduced in
2001 session that recognizes that “an individual’s genetic in-
formation and DNA sample are the property of the individual.”
19 Laurie, supra Note 6, at 18.
20 Id.
21 Id.
22 See Note 11 (quoting Steve Chase, founder of Oregonians
for Genetic Integrity).
a researcher purchases a ticket in a litigation lottery. Moreover, others fear that the recognition of personal property rights could lead to the exploitation of donors. They reason that if rights to genetic material can be owned, these rights can also be permanently sold in a genetic black market.

CONCLUSION

In response to individuals’ concerns about the use and disclosure of their genetic information, including, in particular, the potential discrimination that may result from the revelation of their genetic make-up, a number of legislative measures have been proposed and even enacted. As demonstrated herein, such legislation generally either focuses on protecting the privacy or genetic information or upon preserving the individuals’ proprietary interests in his or her own genetic information. While genetic information holds great promise for society at large, the challenge of determining the proper balance between privacy concerns and fair use of genetic information has not yet been resolved. Although the use and value of genetic tests will surely continue to grow, if these issues are not resolved, the absence of a uniform legal approach for balancing individuals’ privacy and proprietary interests in their genetic information may create obstacles to the further development and advancement of genetic research.

23 Moore, supra, 51 Cal. 3d at 146.