Disclosing Genetic Test Results:
Duties and Dangers

By Brette McWhorter Sember

In June 2000, the Human Genome Project announced it had completed a rough map of the human genome. The implications of this long-awaited important project are so wide-reaching that we are only beginning to understand them. Geneticists will be able to pinpoint genetic triggers for many diseases, traits, personalities, and behaviors and will be able to find ways to alter and impact those triggers—preventing disease and also perhaps allowing genetic architecture so that parents may pre-select traits and personalities for children. Clearly, genetics are going to play a huge role in everything from reproduction decisions, treatment, and prevention of illness to employment and lifestyle decisions and the like.

As genetic testing becomes more and more common, the role of the physician becomes crucial in protecting privacy and assisting patients in dealing with the new information. Because genetic privacy is likely to be a debated area, it is important to consider when a physician will or should be obligated to disclose the results of genetic testing to third parties and to the patient.

CONFIDENTIALITY

Genetic information is medical information derived from a patient, and it is therefore protected by the confidentiality privilege. However, confidentiality is not absolute, and ethical, legal and statutory obligations exist as exceptions. Key among these are situations where the physician must disclose confidential information when he or she must report an illegal act (such as gunshot wounds or child abuse), in a trial where the privilege is waived, and where there is a clear-cut danger to others, such as the reporting of infectious diseases.

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As we learn more about the human genetic code and genetic testing becomes more common, questions as to the type and extent of confidentiality of this information will become more pressing and will have to be addressed by legislatures.

UNDERSTANDING GENETIC TESTS

The more geneticists learn about human genetics, the more they realize how very complicated the information is. While there are some diseases that have clear, unambiguous genetic triggers, such as Huntington's disease, there are many others we know of, and probably hundreds more yet to be studied, that result from a combination of factors. Some diseases are predisposed by genes but are manifested only with environmental triggers and events. Other diseases cannot be tied to one gene directly and instead are the result of several genes in a complicated interaction.

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It is also important to understand that when a person has genetic testing, what is revealed is not only information about his or her genes, but also about his or her family as well as his or her current or future offspring.

THE RAMIFICATIONS OF DISCLOSING GENETIC INFORMATION

Genetic information is highly personal since it shows many pieces of information about a person's tendencies, abilities, susceptibilities, and physical and mental conditions. When genetic information is given to the patient alone, there can be employment and insurance effects. If a person is tested for Huntington's disease and discovers he or she does carry the gene, he or she may be asked in applying for a job or insurance about any genetic abnormalities he or she is aware of. The patient is then in a position where he or she must disclose this information and risk being denied employment and insurance.

There are social ramifications as well. Discrimination is a very real possibility facing those who discover genetic abnormalities about themselves.

SITUATIONS IN WHICH DUTIES OF DISCLOSURE MAY ARISE

Before considering the standards that should be applied to disclosure, it is important to consider the situations and dilemmas confronting the physician that could require or give rise to disclosure of genetic testing information.

Minors

As more tests become available, more parents will opt to have their

minor children tested for genetic diseases. When the disease is manifested in childhood, there is little doubt the child needs to have access to the information. However, when a child is tested for genetic evidence of adult onset diseases, when should the child have access to this information?

Spouses

The duty of disclosure to spouses becomes an issue when dealing with reproduction. Does a spouse and potential parent have the right to be informed of the other spouse's genetic information that will affect their offspring? Generally it is agreed that most genetic information is not something that needs to be disclosed, but when dealing with serious genetic illnesses such as Huntington's and Sickle Cell Anemia, the issue is disputed.

Family Members

Because genetic information is family-based, the implications for disclosure to family members are one of the most publicized and debated areas. If a woman is tested positive for BRCA1, the breast cancer gene, her siblings and other relatives are also at risk for carrying this gene and experiencing its life-threatening effects. Is a physician under a duty to disclose this information to the woman's relatives against her wishes? And if so, how far along the family tree must this information be spread? At what point does privacy overcome the duty to protect others from a clear-cut genetic health risk?

Research Studies

When a person participates in a genetic research study, he or she usually donates tissue or fluids with the understanding that the information derived from genetic material will not be revealed to him or her personally and will instead be utilized anonymously. While the material is anonymized, records are sometimes preserved that would allow linkage of results with personal data. Also, some studies are not performed anonymously because family histories are important in understanding and interpreting the data.

If a study reveals that a subject has a gene or genetic package that will cause or could cause a serious disease, must or should this information be disclosed to the subject despite informed consent that results will not be disclosed?

Adoption/Genetic Material Donation

When a child is adopted or is created using donated eggs, sperm, or embryo, do the legal parents and the child have the right to access the child's genetic family history even when it is not contained in the original adoption or donation records?

Current Law

There is little law that deals with the issue of the duty to disclose genetic information. In adoption instances, genetic information must be compiled and disclosed by the agency or the biological parents to the adoptive parents. Wisconsin, for example requires that if information of a genetic disease is discovered subsequent to the adoption, the agency must notify the adoptive parents or the child if he or she is over 18. Courts typically hold that adoptees or children conceived through assisted reproduction technology seeking genetic information not provided to them by statute must meet a good cause standard in order for the court to require disclosure. Identifying information is not included in the ordered disclosure unless an even higher standard is met. Most sperm banks and egg donation agencies require genetic disclosure upon donation, but this is not regulated.

There are two cases that deal with the question of whether a patient's genetic disease gives rise to a physician's duty to warn third parties of a danger to them stemming from the information. *Pate v. Threlkel*, 661 So.2d 278 (Fla 1995) involved a daughter suing her mother's physician for failing to inform her that her mother's cancer was hereditary (the daughter had contracted it). The court held that the physician had a duty to warn the mother of the genetic implications to her offspring, but did not have a duty to disclose the information to the daughter herself.

In *Safer v. Estate of Pack*, 677 A.2d 1188 (N.J. Super A.D. 1996), a daughter sued her father's physician's estate after contracting colon cancer and multiple polyposis. The father had been treated for the same condition, which is inheritable. The court compared this situation to an infectious disease where a physician has a duty to warn third parties and held that the physician did have a duty to disclose the information to the daughter because the person or group at risk was easily identifiable and any future harm was minimized by a warning that was timely and effective, allowing her to be tested and seek treatment.

GUIDELINES

While the existing law on this topic is sparse, government and professional groups have issued recommendations for these situations.

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The 1983 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research proposed disclosure to family members where:

1. Reasonable efforts to elicit voluntary consent to disclosure have failed;

2. There is a high probability that harm will occur if the information is withheld, and the disclosed information will be actually used to avert harm;

3. The harm that would result to identifiable individuals would be serious; and

4. Appropriate precautions are taken to ensure that only the genetic information needed for diagnosis and/or treatment of the disease in question is disclosed.

The American Society of Human Genetics Social Issues Subcommittee on Familial Disclosure endorsed this guideline, but added that "the health care professional should be obliged to inform the patient of the implications of his/her genetic test results and potential risks to family members. Prior to genetic testing and again upon refusal to communicate the results, this duty to inform the patient of familial implications is paramount." (Professional Disclosure of Familial Genetic Information, Am. J. Hum Genet. 62: 474-483, 1998.)

The American Society of Human Genetics has issued guidelines that genetic history information should be included in an adoptee's record and when medically appropriate, shared with adoptive parents and adoptees.

The American College of Genetics suggests in reference to disclosure to minors, "Although providers generally should respect parent's wishes, the provider must balance the responsibilities to the health and well-being of the child and to the wishes of the parents. . . . Thus, when faced with uncertainty, the provider may be obligated to avoid the possibility of harm rather than provide unclear benefits." (Statement of the American Society for Human Genetics on Genetic Testing for Breast and Ovarian Cancer Predisposition, Am. J. Hum. Genet. 55, i-iv. 1994.)

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become indicated. Notification without consent will be a hotly contested area, as the current case law indicates, and some physicians may use the infectious disease model for familial genetic disclosure. Others will argue the danger to others is not clear-cut as with an infectious disease and thus does not affect confidentiality. Legislation will be necessary to set forth circumstances when disclosure may be made without consent. However, patients should always be informed of genetic implications for family members whenever they are tested for genetic illnesses or abnormalities and encouraged to share that information.

Spouses

The guidelines and current law do not address the issue of disclosure to spouses if the genetic test reveals information that might affect reproduction decisions. It may be argued that spouses should fall under the familial disclosure guidelines; however, the spouse does not appear to have a vested interest in obtaining the information since he or she is not in fact a parent. This may be different if the couple is actively trying to conceive, but still gives the spouse no real vested interest since no child exists. Informed consent with clear disclosure guidelines is the best avenue for handling this matter.

Research

It is important for research to be completed with the screen of anonymity. Because most tests are done without complete understanding and verifiable data to back up the hypotheses being tested, it would be impracticable and unsafe to expect researchers to disclose test results to patients who donated samples when the donations were made under the condition of anonymity—when the researchers themselves may not yet fully understand what the test results mean. Expecting a researcher to give medical advice to a non-patient when the data has not been completely studied is unwise.

Adoption and Donations

While most states will require disclosure of genetic histories to adoptees when there is a need, legislation is lacking for children who are the products of egg, sperm, or embryo donations. These children and their legal parents should also have a legal right to obtain their genetic histories while protecting the identity of the donor. Requiring donors to consent to the release of genetic histories, should the need arise while respecting anonymity, is the safest avenue to protect all of the interests at hand.

While the road ahead is filled with many more exciting discoveries, it becomes clear that the right to genetic information will become more and more contested. It would appear that following the informed consent model is the best avenue, at this time, to control the dissemination of this material and protect all the interests involved.

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STRICT CONSTRUCTIONALISM

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THE PARADOX OF STRICT CONSTRUCTIONALISM

The obvious question which therefore arises is: How can any judge in the 21st century "strictly construe" the intentionally ambiguously designed wording of a document written over 200 years ago by our Founding Fathers, who themselves could not even agree on its meaning at the time? There is little question that the Constitution was intended to be ambiguous in certain critical areas with the intent being that subsequent generations would work out the 'details' later on. Thus, if the near mythical figures who drafted the Constitution could not agree on what it meant at the time, how can mere mortals over two hundred years later make claim to the ability to determine exactly what was intended.

The fallacy of such a belief is further echoed by Benjamin Franklin in his speech entitled "On The Faults of the Constitution":

> I confess that I do not entirely approve of this Constitution at present; but, sir, I am not sure I will never approve of it, for, having lived long, I have experienced many instances of being obliged, by better information or fuller consideration, to change opinions even on important subjects, which I once thought right, but found to be otherwise. It is therefore that, the older I grow, the more apt I am to doubt my own judgment of others. Most men, indeed, as well as most sects in religion, think themselves in possession of all truth, and that whatever else differs from them, it is so far error.[17]

The individual who did more than any other to coin the phrase, "strict constructionalism," was President Richard Nixon:

> Gradually, the term "strict constructionist" entered the Nixon vocabulary, a flabby phrase that drew its meaning primarily from the political views of the speaker. Nixon said he wanted "strict constructionist" judges who would strictly and objectively interpret the meaning of the U.S. Constitution. But what did that mean?
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> Nixon, to be sure, realized the political potency of the "strict constructionist" term. To