

mind•full: a brainsnack for future leaders with ethical appetites

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genetic testing

The accelerated pace of genetic discoveries and the information generated from them raises social and ethical concerns. With new capabilities in biotechnology, genetic testing to determine one's susceptibility to diseases is becoming more widely available around the world. The increasing ability to acquire sensitive genetic information about individuals, families, and populations has many medical, ethical, legal, and social implications. With the race to sequence the human genome to be finished by the year 2003, these are issues we likely will face within a short time.

Deciding how to deal fairly in the medical and nonmedical uses of genetic information is stirring up new debates among scientists, policy makers, and the public. Genetic discrimination, gene therapy, privacy and confidentiality, reproductive issues, the accuracy of genetic testing, and the integration of genetic information into health care are but a few of these issues.

Safeguarding against potential negative outcomes of these matters is extremely difficult due to the lack of adequate regulations, especially in terms of who will have access to genetic information and how that information will be used. Efforts to set state, federal, and global standards on the accuracy and quality of genetic tests are moving slower than the commercialization of genetics. Also, only a small number of physicians, clinicians, and health care providers are properly educated in genetics and most lack genetic counseling training.

Critics worry that we are heading for a "Brave New World," a society that might include "designer" babies and genetic discrimination. Proponents feel that genetic testing could give people the ability to make informed decisions about their future. Some hope it will provide opportunities for scientists to develop strategies to treat, cure, and prevent genetic diseases, opening new doors for human health.

The mission of Student Pugwash USA is to promote the socially responsible application of science and technology in the 21st century. As a student organization, Student Pugwash USA encourages young people to examine the ethical, social, and global implications of science and technology, and to make these concerns a guiding focus of their academic and professional endeavors.

The **mind•full** series encourages readers to explore crucial ethical dilemmas associated with the application of science and technology.

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go figure!

Scientists have shown that inherited errors in our genes are responsible for an estimated 3,000 to 4,000 diseases. Today, genetic testing ranging in cost from hundreds to thousands of dollars is available for some of these diseases, such as Huntington's disease, cystic fibrosis, and Duchenne muscular dystrophy. However, testing procedures and access to genetic information is not fully monitored and many studies show an increasing amount of misconduct with testing and a growing concern for prohibiting access to genetic information.

Because genetic testing is not diagnostic like conventional medicine, but only indicates a predisposition to disease, contemplating what test results reveal and what to do about results is perplexing, to say the least. Interestingly, a 1998 survey, in which 1,000 US adults were polled on the use of emerging biotechnologies, suggests Americans approve of gene therapy in cases of usually fatal genetic diseases.

what's the score?

testing the tester

Researchers recently evaluated the use of one genetic test for colorectal cancer. They concluded the patients received "inadequate" counseling and would have been given "incorrectly interpreted" results. Here's what they found:

83%	Of those tested had clinical features of the disorder or were at risk for the disease
19%	Received genetic counseling before the test
17%	Gave written informed consent
32%	Of the time, physicians misinterpreted the test results

Source: "The Use and Interpretation of Commercial APC Gene Testing for Familial Adenomatous Polyposis," Francis M. Giardiello, et al, in *The New England Journal of Medicine*, Volume 336, Number 12, March 20, 1997. Found September 22, 1999, at www.nejm.org/content/1997/0336/0012/0823.asp. Based on telephone interviews with physicians & genetic counselors in a nationwide sampling of 177 patients from 125 families who underwent genetic testing for the colorectal-cancer-causing adenomatous polyposis coli (APC) gene during 1995.

americans' attitudes toward genetic testing

85%	Think employers should be prohibited access to genetic information
69%	Think health & life insurers should be prohibited access to genetic information
65%	Think relatives besides spouse/child should be prohibited access to genetic information
36%	Probably would not take test if employer/insurer have access
27%	Definitely would not take test if employer/insurer have access
85%	Approve altering the makeup of human cells to cure a usually fatal genetic disease
86%	Approve altering cells to prevent children from inheriting a usually fatal genetic disease
22%	Think it's morally wrong to change genetic makeup, regardless of the purpose
10%	Religious leaders that believe genetic treatment is morally wrong
48%	Physicians say their formal training in genetic testing, screening, and counseling is inadequate
15%	Physicians say their formal training in these matters is very inadequate

Source: *Attitudes Toward Genetic Testing*. Survey commissioned by the National Center for Genome Resources, in collaboration with the New York Academy of Sciences, and released March 4, 1998. Conducted by Schulman, Ronca, and Bucuvalas, Inc., who polled 1,000 adults across the US and, separately, smaller groups of primary care physicians, leaders of health care organizations, scientists, religious leaders, and the media. Found September 22, 1999 at www.ncgr.org/about/news/1998/0304.html.

in control or out of it ?

An increasing amount of documented cases, where erroneous test results encouraged individuals to make drastic life changes, has heightened awareness over test accuracy. Genetic tests are not subject to formal oversight required of standard medical tests, leaving monitoring to test providers. The Food and Drug Administration has opted not to regulate them, in part, due to its lack of resources. Many experts believe we are not prepared enough in this area to continue providing testing. Almost every major cancer and genetics organization, such as the American Cancer Society, has at some point called for a moratorium on non-research-related testing until the efficacy of the tests can be established. A new advisory committee to the US Health and Human Services is to decide by the end of this year how to ensure the quality of genetic testing in the US.

In parallel, gene therapy is becoming more available to correct certain genetic disorders. However, evaluations of genetic counselors have found a lack of training. Approximately only 1,200 genetic counselors at around 350 counseling services exist in the US. Establishing a strong foundation of counseling will require funding long-term and expensive studies on the psychological stress of genetic tests and appropriate advising skills. There are societies in the US that assist consumers in locating genetic counseling services, such as the National Society of Genetic Counselors (NSGC). Physicians also lack training. According to Glenn McGee, associate director of the Center for Bioethics Health System of the University of Pennsylvania, the average practicing internist has had less than one semester of molecular genetics and colleges and universities have emphasized genetics training only in the past ten years.

Furthermore, documented cases of genetic discrimination in the workplace and by health care providers have amplified the need for genetic-specific legislation. Some employers and insurance companies feel they have the right to require genetic testing from employees for the purpose of determining future job performance and potential health care costs. There is a lack of consensus on this among policy makers and, as of yet, employers in most US states are not prevented from requiring testing. According to the ACLU, at least 24 states have enacted laws that either provide protection against genetic discrimination or which prohibit genetic testing in either the insurance or employment setting. And, many other states are considering legislation that would provide protection against genetic discrimination in either setting. They also state there are several bills under active consideration in the 106th Congress that directly address genetic discrimination.

learn the lingo

acquired mutations—gene changes that arise within individual cells and accumulate throughout a person's lifetime; also called somatic mutations.

gene—a unit of inheritance; a working subunit of DNA. Each of the body's 50,000 to 100,000 genes contains the code for a specific product, typically, a protein such as an enzyme.

gene testing—examining a sample of blood or other body fluid or tissue for biochemical, chromosomal, or genetic markers that indicate the presence or absence of genetic disease.

gene therapy—treating disease by replacing, manipulating, or supplementing nonfunctional genes.

hereditary mutation—a gene change in the body's reproductive cells (egg or sperm) that becomes incorporated in the DNA of every cell in the body; also called germline mutation.

Source: "Understanding Gene Testing, Glossary," found September 27, 1999 at rex.nci.nih.gov/PATIENTS/INFO_TEACHER/bookshelf/NIH_gene-testing/gene27.html.

At the federal level, the Equal Employment Opportunity Commission (EEOC) has interpreted the Americans with Disabilities Act (ADA) to cover on-the-job discrimination based on genetic information relating to illness, disease, or other disorders. However, the amount of protection the ADA provides has yet to be tested in an actual court case. The National Labor Relations Act (NLRA) offers some protection under its review of "health and safety matters" to employees who belong to unions. Title VII of the Civil Rights Act of 1964 helps shield genetic discrimination in the few cases where it would have a disparate impact along the lines of race, gender, religion, or national origin. And the Health Insurance Portability and Accountability Act of 1996 provides against discrimination by limiting what can be considered preexisting health conditions when an employer provides medical insurance. Additionally, The National Action Plan on Breast Cancer (NAPBC) and the NIH/DOE Working Group on Ethical, Legal and Social Implications (ELSI) of Human Genome Research have drafted recommendations for state and federal policy makers to protect against genetic discrimination in the workplace.

There are also efforts for promoting international understanding of bioethics issues. For instance, UNESCO's International Bioethics Committee sixth session in October 1999 examined "Confidentiality and Genetic Information" and followed up on their Universal Declaration on the Human Genome and Human Rights.

unregulated . . .

Parents are able to learn the possible fate of their newborn in the first few days after birth through genetic testing. In some states this type of testing is required. For instance, Pennsylvania has a policy that every newborn child must be screened for Duchenne muscular dystrophy. At the Institute of Medicine, a panel of experts consisting of geneticists, genetic counselors, pediatricians, ethicists, and lawyers generated a 1993 report recommending, among other guidelines for genetic testing, that widespread testing for incurable diseases should be avoided because it will not benefit those being screened.

unfortunate . . .

A recent *Washington Post* article illustrated an unfortunate case of inaccurate testing. In early 1998, Nancy Seeger, 54, tested positive for a genetic mutation that would put her at risk for breast and ovarian cancer. As a result, and after much consultation with her doctor, Seeger quickly underwent surgery to remove her ovaries. Eight months later, the genetic-testing company that performed the test, Oncormed, mailed a refund check for \$350 and a letter retracting their original conclusion. She is in negotiations with Oncormed's former insurer about the test error.

and unknowing

Another recent *Washington Post* article reported that in 1998, the 9th Circuit Court of Appeals in California was the first to propose constitutional limits on how employers may use genetic information. They ruled in favor of employees of the Department of Energy's Lawrence Berkeley National Laboratory, who learned years after they were hired that blood and urine obtained during their pre-employment physical examinations had been used unknowingly for medical tests, including sickle cell anemia genetic tests in the case of black applicants. The issue came to light when an employee filed for workers' compensation and was shocked to see the information in medical records.

(anything but a) conclusion

What we choose to do with genetic information will shape the paths of present and future lives. Being socially responsible in the use of this information is complicated by the murky understanding of the significance of test results. The prospect that humans may be able to direct their own evolution by interfering with the very codes for life itself is the underlying debate in the field of genetics today and will likely continue to have a profound impact on our every day lives far into the future.

How do **you** answer the **tough questions**

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What are the pros and cons that can come from genetic testing? Do you think the pros outweigh the cons? Where do we draw the line in determining how many benefits outweigh any one con?

If you have had a blood test at anytime in your life, your genetic information may be out there somewhere, without your control. Does this concern you? How? Is genetic information different than other medical information? Why is informed consent so important with genetic tests?

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How important is it that geneticists have a stronger grounding in bioethics? Should bioethics be required in college and university medical programs? Why or why not? How do we train geneticists in bioethics once they leave school? Who should be responsible for this training?
.....



Is there special responsibility to ensure the accuracy of genetic tests? What is the responsibility of the physician or company supplying the test to regulate accuracy and provide proper counseling? Should licensing of genetic counselors be federally required? Why or why not? Who should set the qualifications for counseling and testing procedures? Why?

If you have a genetic test done, should employers have access to your information? Should insurance companies? Should employers and insurance companies be allowed to require genetic tests? Why or why not? Should genetic information be used in any other way, such as in criminal court or police records?



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 • If it will be possible, do you think genetic
 • tests that search for characteristics such
 • as intelligence and personality traits
 • should be limited? Do you think that
 • gene therapy should be used to “design
 • babies” for those traits, or even for eye
 • color and other features? Should gene
 • therapy be restricted to correcting genetic
 • diseases only? Why or why not? Where
 • do you draw the line?
 •

For some, the genetic makeup of humans defines who we are. Do you agree or disagree and why? How does this affect how one might view individual health versus societal health? Do you think genetic tests should be stopped and that money and research should go into studying the ethical and social implications of genetics?

What is considered "ethical" in one country might be considered less "ethical" in another. Do you think the international science community should set standards for the worldwide use of genetic information? If we limit universal access to genetic information, how might this affect genetic research in the future?



Who should be involved in the decision-making process for genetic testing regulations—the public, scientists, private companies, policy makers, or all? How important is it that the public and policy makers be educated in genetics and bioethics before participating in decisions? Who is responsible for providing such an education—schools, government, the media, or others?

In what ways will other sciences, such as computer and environmental science or neuroscience, be affected by an increase in genetic information and the regulation of it? For instance, how can genetic information benefit or regulation limit neuroscientists' knowledge of how the brain works?



What kind of social implications might a child that has been given a genetic test, early in life without their knowledge, face later in life? If you were told that your genetic information is available to you, would you want to view it? If you found you were susceptible to a certain disease, would you share your information with family members? Would you take precautionary action if it were for an incurable disease? What if it were a curable one? Would you test children of your own? Why or why not?

inherent information

- *Access to the Genome: The Challenge of Equality*, Maxwell J. Mehlman and Jeffrey R. Botkin—this book is an exploration of the potential harms of genetic research and technology, focusing on the "genetic haves and have nots." Washington, DC: Georgetown University Press, 1998.
- *The Biotech Century: Harnessing the Gene and Remaking the World*, Jeremy Rifkin—an easy read for those who like predictions. New York: Penguin Putnam Inc., 1998.
- *Brave New World*, Aldous Huxley—(novel) a must-read classic about the not-so-distant future of science and genetics. New York: Harpers and Brother, 1932.
- "Computers & human genetics," Constance Lassiter and Julia Fu, *mind•full: a brainsnack for future leaders with ethical appetites*. Volume 2, Number 7, Student Pugwash USA, October 1998. Available at www.spusa.org/pugwash/.
- *Exploding the Gene Myths: How Genetic Information is Produced and Manipulated by Scientists, Physicians, Employers, Insurance Companies, Educators, and Law Enforcers*, Ruth Hubbard and Elijah Wald—kind of techy but explodes with knowledge of genetics. Boston, MA: Beacon Press, 1997.
- "Exploring human genetics," Constance Lassiter and Susan Higman—a very good introduction to the field of genetics (our personal favorite), *mind•full: a brainsnack for future leaders with ethical appetites*. Volume 2, Number 2, Student Pugwash USA, October 1997. Available at www.spusa.org/pugwash/.
- *Genethics*, David Suzuki and Peter Knudtson—bridges the gap between science and ethics. Cambridge, MA: Harvard University Press, 1990.
- *Genetic Testing and the Use of Information*, Edited by Clarissa Long—six distinguished scholars address some of the major issues confronting society on the brink of a new genetic information age. Washington, DC: The AEI Press, 1999.
- "Genetic Testing's Human Toll"—an account of an extreme case of testing error. *Washington Post*, July 21, 1999.
- *The Gene Wars: Science, Politics, and the Human Genome*, Robert Cook-Deegan—detailed, interesting account of the HGP from an insider's perspective. New York: W.W. Norton Company, 1994.
- *The Lives to Come*, Philip Kitcher—a deep probing of the moral and social issues raised by genetic advances. New York, NY: Touchstone, 1996.
- *Mapping Our Genes: The Genome Project and the Future of Medicine*, Lois Wingerson—a very good read, touches home on the issues of genetic diseases and families. New York: Plume Printing, 1990.
- *Towards the 21st Century: Incorporating Genetics into Primary Health Care*, Nancy Touchette, Neil A. Holtzman, Jessica G. Davis, Suzanne Feetham—exploring the impact of genetics in medicine. New York: Cold Harbor Laboratory Press, 1997.
- Universal Declaration on the Human Genome and Human Rights—proposed safeguards against genetic discrimination and patenting. On the Web at <http://www.unesco.org/opi/29gencon/egenkit.htm>.

check it out!**screening genes**

- *A Question of Genes*—a Public Broadcasting Service special following the lives of several individuals and families as they confront genetic testing. Sponsored by the DOE Human Genome Project and SmithKline Beecham. For information on ordering, go to: www.pbs.org/.
- *The Fly* (I and II)—a scientist (Jeff Goldblum) develops the technique to hybridize human (his own) and insect genes. In the sequel, his son, born of the human-fly hybrid, is employed at the same laboratory and performs research. The entire laboratory waits for his mutant genes to be expressed, 1989.
- *The Island of Dr. Moreau*—Dr. Moreau (Marlon Brando) has successfully combined human and animal DNA to make crossbreeds. As expected, something goes wrong, 1996.

top picks

- Human Genome News (excellent Web site if you have questions concerning any aspect of the HGP, this site links to a number of organizations and institutions where other genome projects are taking place)—www.ornl.gov/hgmis
- National Center for Genome Resources (nonprofit organization focusing on genetic resources)—www.ncgr.org

natural gene selections!**best of the rest**

- Access Excellence About Biotech (a very comprehensive site explaining the expectations of the Human Genome Project)—www.gene.com/ae/AB
- American Civil Liberties Union (lots of info on laws, case studies, and stats of genetic discrimination and other related issues)—www.aclu.org
- American Society of Human Genetics—www.faseb.org/genetics/ashg/ashgmenu.htm
- *Breaking Bioethics* (a weekly commentary on ethical issues in medicine, science, and technology by the University of Pennsylvania)—www.med.upenn.edu/bioethics/index
- Council for Responsible Genetics (provides public with up to date info on genetic technological innovations)—www.essential.org/crg/
- DOE Human Genome Program (info on HGP and protection of human subjects)—www.er.doe.gov/production/ober/HELSDRD_top.html.
- Ethical, Legal, and Social Implications (ELSI) program—www.nhgri.nih.gov/ELSI/
- The Gene Letter (an electronic newsletter on genetics and public policy)—www.geneletter.org
- National Bioethics Advisory Commission (check out their reports on genetics related issues)—www.bioethics.gov
- National Center for Biotechnology Information (links to GenBank and sample DNA data)—www.ncbi.nlm.nih.gov
- National Human Genome Research Institute (formerly the National Center for Human Genome Research)—www.nhgri.nih.gov
- National Institutes of Health (check out the search engine for genetics information)—www.nih.gov
- National Society of Genetic Counselors, Inc. (info on counseling services)—www.nsgc.org/

cyberspace

This **mind•full** was written by Heather L. Stewart, pledge program coordinator and accounts manager at Student Pugwash USA. Special thanks to Stuart Kim, Research Analyst at the National Bioethics Advisory Commission for his comments. Any errors are the responsibility of Student Pugwash USA. ©1999 Student Pugwash USA.

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but wait, there's more!

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- **Science, Technology, and Ethical Priorities: Proceedings of Student Pugwash USA's Ninth International Conference.**
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