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GENETIC INFORMATION: POTENTIAL USES AND ABUSES

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In 1990 the Federal government, through the coordinated efforts of the National Institutes of Health and the U.S. Department of Energy, initiated funding for an ambitious scientific research project that, in all likelihood, will have a significant impact on the lives of the nation's denizens. The goals of the U.S. Human Genome Project are to identify all of the genes in human deoxyribonucleic acid (DNA), and determine the sequences of the 3 billion chemical bases that comprise DNA. Although the goals are supposed to be achieved by 2005, it is now expected that, because of technological advances, the project will be completed two years ahead of schedule.

According to information published by the project, a genome is all the DNA in an organism, including its genes. The genes carry information for making all the proteins required by an organism, and the proteins determine, among many things, an organism's appearance, behavioral traits, resistance to infection, and metabolic capacities. Obviously, if scientists can identify a gene or sequence of genes that causes or prevents certain maladies, abnormalities, or perceived undesirable traits of the human condition, such knowledge could have a profound impact on individuals and society. Already, the genome project has produced detailed genome maps that have aided researchers seeking genes associated with many genetic conditions, including Alzheimer's disease, certain inherited colon cancers and breast cancers, and dystrophy. Though much remains to be done, increased knowledge about the effects of DNA variations among persons will lead to new ways to diagnose, treat, and perhaps prevent the numerous disorders that affect humans. As Dr. Francis Collins, of the University of Michigan, stated in a lecture last May to the annual meeting of the Massachusetts Medical Society, "In just 12 months, a highly useful working draft of 90% of the genome will be available, and by 2003, the full DNA sequence of the human will give us unprecedented opportunities to observe and understand the literal Book of Life." Further, "The genetic revolution in medicine is under way".1)

While the potential benefits of the genome project show enormous promise, there also are many troubling privacy issues raised by the availability of detailed genetic information. The Human Genome Project has attempted to address these concerns. From 3% to 5% of the annual project budget has been devoted to studying the ethical, legal, and social issues of genetic information. This research has produced numerous reports. Although it is beyond the scope of this article to examine the contents of these reports, the project has explored the following issues:

- Fairness in the use of genetic information by insurers, employers, courts, schools, adoption agencies, the military, etc. Who should have access and how will it be used?
- Privacy and confidentiality of genetic information. Who owns and controls it?
- Psychological impact and potential stigmatization due to an individual's genetic differences.
- Genetic testing of an individual for a specific condition due to a family history, and population screening. Are genetic tests reliable and able to be interpreted by the medical community? Should tests be performed when no treatment is available? Should minors be tested for adult-onset diseases?
- Reproductive issues, including the use of genetic information in reproductive decisions and rights.
- Clinical issues, including implementation of standards and quality control measures in testing.
- Conceptual and philosophical implications, regarding responsibility, free will versus genetic determinism, and concepts of disease and health.

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1) Collins, Francis S., "Shattuck Lecture - Medical and Societal Consequences of the Human Genome Project", *New England Journal of Medicine*, July 1, 1999, p. 28-36.

State Action

Potential genetic privacy issues raised by the Human Genome Project have not escaped the notice of policy-makers in this State. In his 1997 State of the State Address, the Governor announced his plans, later fulfilled by Executive Order 1997-14, to create the Michigan Commission on Genetic Privacy and Progress, "to recommend ways to protect genetic privacy, prevent discrimination and maximize the beneficial uses of new medical knowledge". The Governor again addressed the issue in his 1999 State of the State speech. Mentioning that the Commission's report would soon be published and that its recommendations should be given prompt attention, he said, "Specifically, genetic testing must not be a precondition for obtaining health insurance. And genetic testing must not be allowed as a precondition of employment."

The Commission's report (February 1999) makes several specific recommendations and some general recommendations regarding a wide range of issues surrounding genetic technology. Following is a description of the Commission's findings regarding selected genetic privacy issues.

***Genetic Discrimination*.** The Commission considered the question of whether genetic testing should be part of the application process for health insurance and employment. The Commission pointed out that while there is a lack of conclusive evidence that discrimination based on genetic testing has decreased access to health insurance, there is a perception that the problem exists. Further, while Federal law prohibits discrimination against asymptomatic persons based on genetic testing of applicants or participants in group health plans, the law does not address the availability of insurance for persons who apply for individual health insurance policies. The Commission recommended that health insurers be prohibited from requiring predictive genetic testing or testing for carrier status of asymptomatic individuals.

Regarding employment issues, through the years people have raised concerns about the potential for discrimination in the workplace based on the status of an individual's health. Although both State and Federal laws prohibit discrimination against persons with disabilities, genetic advances raise questions of employers' using information derived from genetic tests to make hiring and work assignment decisions. The Commission recommended that employers be prohibited from using genetic testing as a condition of employment, and that genetic testing not be relied on to assess the qualifications of an individual to perform a job.

***Collection, Use, and Storage*.** The Commission made collection, use, and storage recommendations in the areas of forensics, paternity, and newborn screening. In criminal investigations, if suspects are eliminated from further investigation, the Commission recommended that all of their DNA samples and records be destroyed. In the area of paternity, the Commission recommended that DNA information that could identify individuals not be included in paternity testing results that are forwarded to a court, in order to avoid the placement of genetic information on the public record.

Regarding the screening of newborns, the Commission recommended that parental consent not be required for newborn screening of diseases that can be diagnosed and treated to prevent irreversible mental and physical changes (which is consistent with the current Public Health Code); that additional newborn screening be restricted to conditions for which diagnosis and treatment are effective in preventing irreversible changes or ameliorating chronic conditions; that newborn screening tests be retained indefinitely as a vital resource for the study and treatment of disease, though research on the samples should occur only in accordance with Federal research regulations and with the approval of the Department of Community Health; and that parents should be given an opportunity to deny the use of their newborn's screening test for future research.

***Privacy Protections*.** The Commission addressed the question of whether there is a specific need for a State privacy law concerning genetic information. The Commission found that it would not be useful to create a separate set of laws for genetic information, since it felt that the protection of all medical information is critically important. The Commission further expressed its belief that the use of genetic information for legitimate research should be allowed, with access controlled to protect confidentiality; thus, the Commission recommended that no law be enacted to prohibit legitimate research from occurring.

In addition, the Commission suggested that before the State moves to adopt specific privacy regulations, it should wait until Federal regulations are in place. The Federal Health Insurance Portability and Accountability Act of 1996 required Congress, before September 1999, to enact a privacy law to protect individuals' medical information and establish penalties for wrongful disclosure. Absent congressional action, the Secretary of Health and Human Services is directed to promulgate regulations regarding the privacy of health information, by February 21, 2000. (At the time of this article's publication, Congress had not acted; however, it has been reported that the Secretary has submitted a preliminary draft of regulations.) The Commission noted that after Federal regulations are in place, the State can determine whether it needs to establish further protections. Also, it is possible that the Federal law will preempt state action.

State Regulations

Currently, several Michigan statutes address issues regarding the use of genetic material. The DNA Identification Profiling System Act provides for the collection of DNA samples from certain prisoners, convicted offenders, and juvenile offenders, and requires the Department of State Police permanently to retain the DNA identification profile of a person convicted of attempted murder, first- or second-degree murder, kidnapping, criminal sexual conduct in any degree, or assault with intent to commit criminal sexual conduct. The Probate Code and the Michigan Penal Code both require the collection and testing of the DNA of a person convicted of or found responsible for one of the crimes cited in the Act above. The law governing the Department of Corrections forbids the release on parole or discharge of a prisoner serving a sentence for one of the crimes listed above, unless he or she provides a DNA sample. The Juvenile Facilities Act and the Youth Rehabilitation Services Act provide that a juvenile or public ward convicted of or found responsible for one of the crimes may not be placed in a community placement until he or she has provided a DNA sample.

The Sex Offenders Registration Act requires that a registration contain the individual's blood type and a DNA profile, if available.

The Public Health Code requires that certain samples be collected from newborns, to screen for certain serious, treatable diseases, without consent. The Code also requires the Department of Community Health to establish a chronic disease prevention and control program that, among several conditions, includes genetic disease and allows for genetic screening. The Michigan Adoption Code requires that prospective parents be informed of a child's genetic history and the genetic history of the biological parents. Under the Paternity Act, under certain circumstances, the parties involved may be ordered to submit DNA samples to determine paternity.

Proposed Legislation

In the current session, several bills have been introduced to address issues of genetic privacy or use of genetic material. Senate Bill 97 would create the "Health Information Privacy Act." Senate Bill 98 would amend the Elliot Larsen Civil Rights Act to prohibit discrimination based on an individual's genetic composition. Senate Bill 99 would amend the Insurance Code to declare discrimination against an individual on the basis of genetic information an unfair method of competition and an unfair or deceptive practice in the insurance business. Senate Bills 100 and 101 would amend the Nonprofit Health Care Corporation Reform Act and the Public Health Code, respectively, to prohibit Blue Cross and Blue Shield of Michigan (BCBSM) or a health maintenance organization (HMO) from excluding persons from coverage based on genetic characteristics.

Senate Bill 251 and House Bill 4556 would amend the Elliot Larsen Civil Rights Act to prohibit an employer from requiring an individual to submit to a genetic test as a condition of employment or promotion. Senate Bills 249, 250, and 252 would amend various acts to prohibit an HMO, BCBSM, or an insurer from refusing to issue a health insurance contract or policy if an applicant refused to have a genetic test, or because of the results of a genetic test.

Senate Bill 410 and House Bill 4440 would amend the DNA Identification Profiling System Act to require the Department of State Police to retain permanently the DNA profile of an individual convicted of any felony, if the court required a DNA profile.

Senate Bills 589, 590 and 591 would amend three acts to prohibit BCBSM, health insurers, and HMOs from requiring insured persons or applicants to submit to genetic testing, or to disclose genetic information. Senate Bill 593 would amend the Public Health Code to prohibit a genetic test without the written informed consent of the test subject. Senate Bill 594 would amend the DNA Identification Profiling System Act to provide that if the State Police forensic laboratory determined after analysis that a sample had been submitted by an individual who had been eliminated as a suspect in a crime, the laboratory would have to dispose of the sample and the corresponding DNA identification profile record. Senate Bill 595 would amend the Paternity Act to provide that if a DNA profile were conducted in a paternity proceeding, the person who produced the report would have to include in it only the probability of paternity, and not any other genetic information.

House Bill 4294 would create the “Health Care Information Act” to regulate access to and disclosure of health care information.

It is unknown at this time whether any of those proposals, or other bills not yet introduced, will be taken up by the Legislature or whether the State will otherwise respond to the Commission’s report.