

**Michigan  
Commission**

**on**

**Genetic**

**Privacy**

**and**

**Progress**

**Final Report and Recommendations**

**February 1999**



# Genetics Commission Report

The Governor's Commission on Genetic Privacy and Progress was created in November 1997 by Governor Engler to examine specific issues in genetics and report on potential state involvement or intervention.

This document contains background on genetics and the commission's specific recommendations.

Our work would not have been possible without support from the Governor's Office, Michigan Department of Community Health (MDCH), Department of Civil Rights, and other units of state government. We want to thank Dennis Schornack, Jim Haveman, Carol Isaacs, Nan Reynolds, and Art Stein. We also want to thank the hundreds of people listed in the acknowledgment section for their important assistance and contributions. All were gracious with their time and help.

The project had valuable student support from Rosemary Quigley, Allison Shuren, Anita Bhama, and Anna Rath. It also benefited from prior work done by a joint University of Michigan/Michigan State University Genome Policy Project and from public forums held throughout the state.

The project could not have been completed without critical staff work from Janet Graham, executive assistant, Rhoda Powsner, project director, and my secretary, Nancy Clark.

Finally, we wish to thank Governor Engler for the opportunity to serve and consider these critical issues. As chair of the commission, I want to personally thank all the members for their lively discussions, insightful comments and zeal to create a thorough report for the citizens of Michigan.

On behalf of the commission, I hereby present this report to Governor Engler this fifth day of February, 1999.

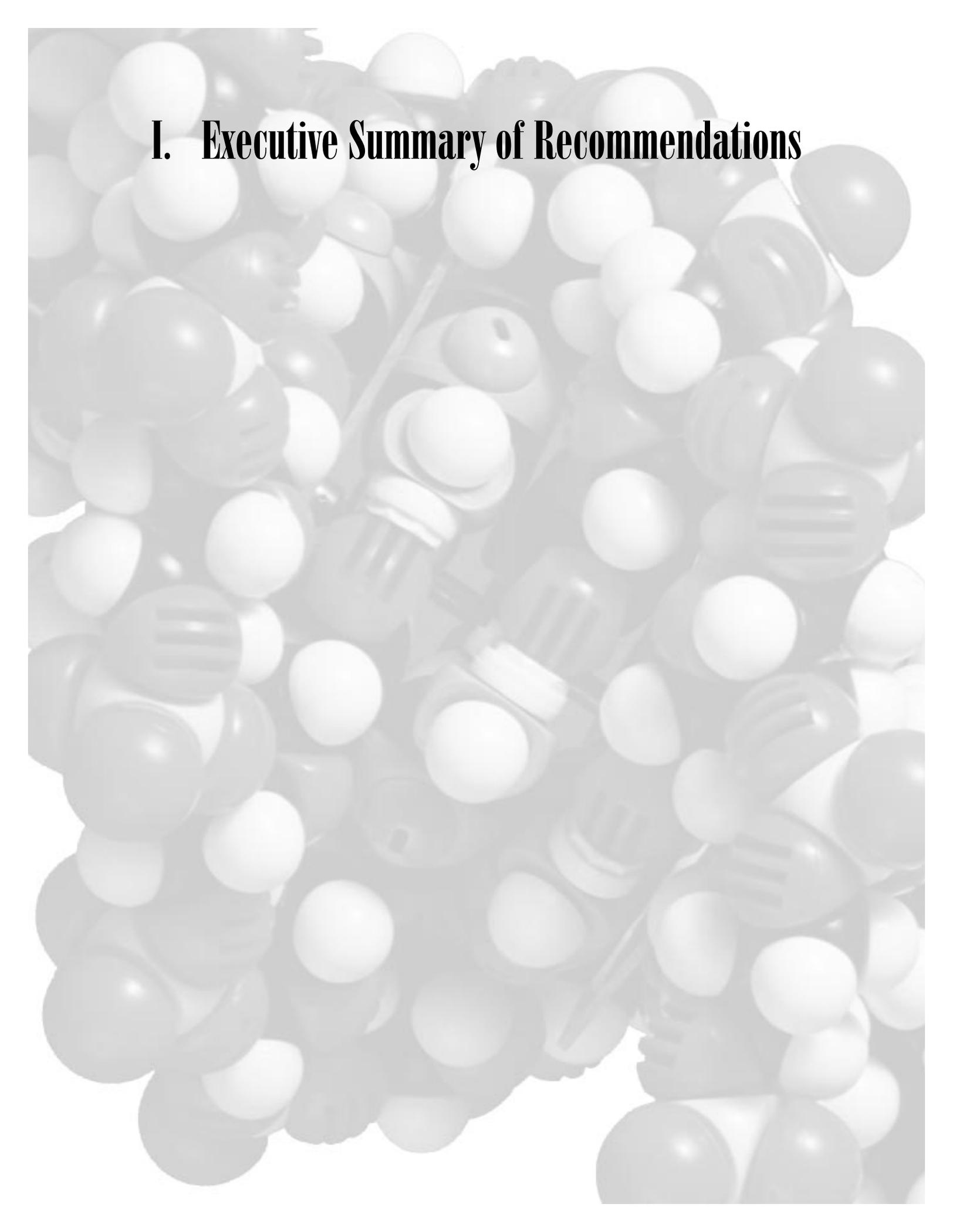
Edward B. Goldman  
Chair



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# **I. Executive Summary of Recommendations**



# Summary of Genetic Commission Recommendations

## 1. General Recommendations

- a. The commission recognizes that remarkable advances in basic knowledge in genetics as well as in genetic technology are occurring at a rapid rate. While the public has not indicated a strong interest in legislation generally, they have indicated a strong interest in privacy protection and protection from discrimination.
- b. Any legislation should consider genetics in the context of medical issues as a whole. Thus, in the areas of privacy it is important to protect all confidential medical information.
- c. For the reasons discussed in this report, including the rapid advancement of genetics technology, we believe that legislation should be as flexible as possible to account for the inevitable changes in technology and the corresponding challenges the technology will present. Legislation should be limited to areas in which professional standards and codes of ethics are insufficient to protect the public good and individual rights. In addition, legislators should take care to avoid legislation that inappropriately prohibits or hinders beneficial genetic testing and research.
- d. Ongoing expert advice and analysis are needed. The Governor should provide a mechanism for continuing access to expertise that can assist in the creation of policy as the field of genetics evolves.

## 2. Privacy

The federal government, by September of 1999, is required to adopt privacy regulations on medical information. These regulations will set a floor for all state regulations. The commission's recommendation is to wait until the federal legislation is passed before determining whether legislative response at the state level is needed to confer additional protections. An expert advisory committee could assist at that time.

The commission does have the following specific recommendations concerning privacy:

- a. Privacy protections should encompass all medical information, not just information related to genetic matters.
- b. We recognize that there are federal and institutional guidelines that protect the privacy of individuals who take part in research, and the commission does not want to recommend more stringent regulations which would unreasonably hamper the conduct of research in genetics.
- c. There may be a need for a very limited exception to general respect for privacy in the case that follows: The commission recommends that a physician be permitted, but not obligated, to disclose information to family members in the event that failure to disclose the information could reasonably lead to preventable serious harm to that person, and the patient refuses, even after counseling, to disclose that information.

- d. The commission recommends that after the federal government acts, the state should consider the need for additional protections in the context of general protection of medical information.

## 3. Ownership

The commission recommends that there be no law creating special property rights in DNA or genetic samples, tissue or information. These laws have not been useful in other states and may introduce confusion and conflict with other laws such as those governing malpractice and the Federal Clinical Laboratory Regulations. Patients should continue to have rights to access their medical information.

## 4. Collection, Use and Storage

The commission has recommendations in the areas of forensics, newborn screening, and paternity.

- a. Forensics. In criminal investigations, the commission recommends that if suspects are eliminated from further investigation, all of their DNA samples and records be destroyed in the presence of witnesses at a state-designated testing site. Audit records should be prepared.
- b. Newborn Screening. The commission recommends that newborn screening continue as it currently has with no requirement for informed consent due to the important public health benefit of screening. Any added newborn testing should be only for conditions for which diagnosis and treatment are both efficacious and effective in preventing irreversible physical or mental changes or in ameliorating a chronic condition. The commission also recommends that the newborn screening cards be retained in an appropriate environment that preserves the integrity of the samples so they can be used as a resource for future research, for individual identification of missing children, and for investigation of familial conditions. Research should be allowed only under stringent conditions to protect privacy and in accord with the federal rules governing medical research. Thus, the commission recommends that any new screening testing or any research on newborn screening samples be reviewed and approved by an expert advisory committee such as the Genetic Disease Advisory Committee currently in existence.

Finally, the commission recommends public education including state-created publications that notify parents how to refuse use of samples for future research.

- c. Paternity. The commission recommends that DNA-identifiable information not be included in paternity testing results that are forwarded to courts. The concern is to avoid placing genetic information in the public record. Other recommendations deal with clarifying technical aspects of existing law.

## 5. Discrimination

The commission considered issues of genetic discrimination in employment and discrimination that could compromise the ability to obtain, retain and afford health insurance. The commission was not charged with studying issues related to disability and life insurance, where separate considerations may apply.

- a. Health Insurance. The commission recommends legislation to prohibit health insurers from requiring predictive genetic testing or testing for carrier status of asymptomatic individuals.

The commission recommends that there should be no obligation to release genetic information to insurers if that information was obtained as part of participation in a research project. However, the commission was divided regarding the ability of the health insurer to obtain genetic information known to the patient and obtained in a clinical (non-research) setting.

- b. Employment. The commission recommends legislation to prevent use of genetic testing as a condition of employment.

## 6. Definitions

The commission recommends specific definitions of genetic testing and genetic information. The commission notes that definitions could be broad or narrow and the report makes specific recommendations about implications of definitions.

## 7. Education

In addition to specific education recommendations in the newborn screening section of this report, the commission recommends that education occur so that the citizens of the state of Michigan can be knowledgeable about genetics. Education should occur at the K-12 level and a model curriculum should be used. The commission believes that professional education should continue to occur through professional organizations. The commission recommends that educational material such as videotapes and publications should be made available with special emphasis on genetics in health care.

## 8. Research

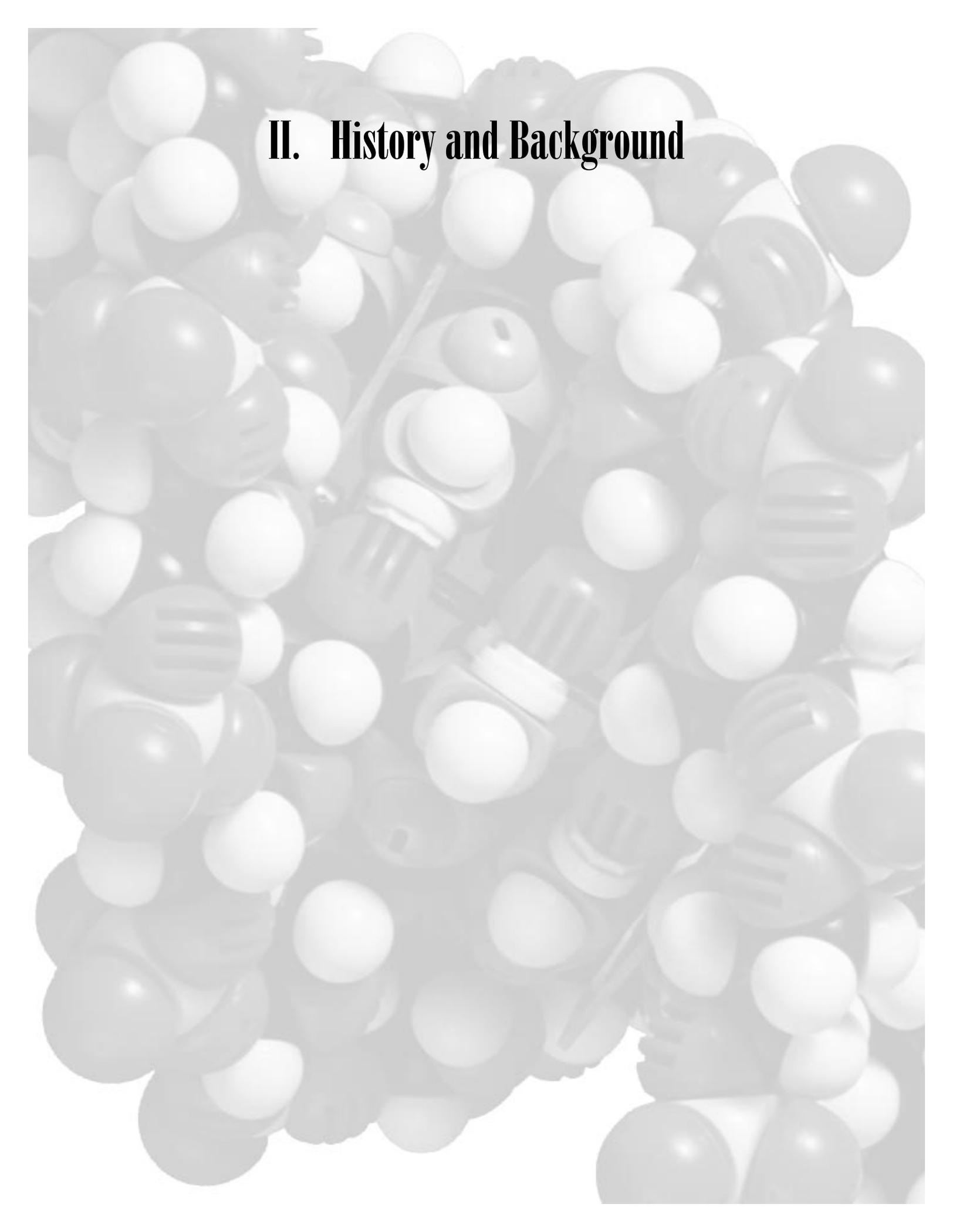
The commission recommends careful examination of any proposed laws to avoid any unintentional adverse impact on research.

## 9. Informed Consent

The commission recommends that for tests used to predict an individual's susceptibility to a disease or disorder, a policy be developed to inform the individual of the purpose of the test, relevant risks, benefits, alternatives, how the results will be used, who will have access, and how the results will be retained. All this information must be provided before the test occurs so that the individual can decide whether to proceed. Test results must be provided to the individual upon request. The exact content of information to be provided is best determined by the professional community since the content will necessarily change over time.

## 10. Telemedicine and Access

The commission recommends that physician-to-physician consultations be allowed across state lines because specialized genetic tests for many conditions are available at only a few sites in the United States.



## **II. History and Background**



# History and Background

## The Michigan Commission on Genetic Privacy and Progress

In his January 28, 1997 State of the State Address, Governor John Engler announced plans to appoint a Governor's Commission on Genetic Privacy and Progress "to recommend ways to protect genetic privacy, prevent discrimination and maximize the beneficial uses of new medical knowledge" resulting from the Human Genome Project. Anticipating the tremendous good that such technology would bring, but also the harm that might result from improper use of genetic information, the Governor indicated his desire to resolve proactively problems that would inevitably arise.

The commission was created September 26, 1997 by Executive Order 1997-14.

Various professional and special interest groups submitted names of candidates for the commission. Interviews were conducted and recommendations were made to the Governor. He made the final selection. The commission consists of the following members:

- Edward B. Goldman, JD, University of Michigan Health System, Ann Arbor, Chair
- David J. Aughton, MD, William Beaumont Hospital, Royal Oak
- Shirley Bach, PhD, Western Michigan University, Kalamazoo
- Howard Cash, President, Gene Codes, Ann Arbor
- James K. Haveman, Jr., Director, Michigan Department of Community Health
- Robert Lentner, Mid-Michigan Chapter of Huntington's Disease Society, Midland
- Thomas Meyer, JD, Jackson National Life Insurance Company, Lansing
- Elizabeth Petty, MD, University of Michigan Health System, Ann Arbor
- Nanette Lee Reynolds, EdD, Director, Michigan Department of Civil Rights
- Sonia Suter, MS, JD, Greenwall Fellow, Georgetown and Johns Hopkins Universities, Washington D. C.
- Helga Toriello, PhD, Butterworth Hospital, Grand Rapids

Staff members are Rhoda M. Powsner, MD, JD, project director, and Janet L. Graham, executive assistant.

The first meeting of the commission was held in November 1997. The commission reviewed the charge in Executive Order 1997-14. The charge stated that:

1. The commission shall recommend model state statutory and administrative policies that protect the privacy of genetic information, prevent discrimination based upon such genetic information in the areas of employment, health care, health care insurance, and government record keeping, or regulate certain uses of genetic information so as to safeguard the interests of the people of the state of Michigan.
2. The commission shall restrict its policy recommendations to those that are appropriate for adoption by state government. In addition, the commission may encourage the consideration and adoption of policies consistent with those it recommends for state government by other organizations and institutions within the state.
3. The commission shall recommend state policies concerning the collection, storage, use and destruction of human DNA samples so as to protect and secure the privacy of such human DNA samples against abuse or misuse by any person or organization, including government.
4. The commission shall recommend state policies concerning access to genetic information and the conditions for the release of genetic information by any person or organization, including government.
5. The commission shall recommend state policies concerning the receipt and management of genetic information from any person or organization, including government, and conditions for the use of genetic information by such recipients.

In December 1997 and January 1998 by-laws were drafted and subcommittees were formed to address the various issues in the charge. Thereafter, monthly commission meetings were held in accordance with agendas that were drawn up to cover specific topics. The commission held 14 meetings including a two-day retreat in September.

Public forums were advertised and held in Grand Rapids, Saginaw, Flint, Ann Arbor, Detroit, Traverse City and Okemos. The Okemos program was a video conference that included Hancock, Iron Mountain and Marquette. In addition to the general public, special interest groups were represented. Testimony was varied. Most notable was the fact that the opinions expressed did not indicate overwhelming concern with any one particular aspect of genetics, but rather revealed a collection of concerns that one might expect from a reasonably representative group. The forums are discussed in greater detail elsewhere in the report.

From 1996-1998 the University of Michigan and Michigan State University conducted a genome policy project to study development of genetic policy. The project was based on extensive community dialogues with Michigan citizens. The resulting report helped the commission in understanding citizens' concerns. The project found that, in general, the participants were reluctant to endorse any legislation except for legislation to prevent discrimination and protect the privacy of medical information.

The commission systematically studied current and proposed legislation concerning genetics and met with the various state agencies involved in genetics-related issues. In addition to accumulating information about the history and function of programs dealing with newborn screening, forensic DNA testing and paternity testing, commission members met with personnel from the Insurance Bureau, representatives of the insurance industry, and staffs of the Department of Community Health, the Michigan State Police Forensic Laboratory, and the Family Independence Agency, as well as attorneys general working with these departments and county prosecuting attorneys dealing with paternity testing.

The commission examined current and proposed future uses of genetic analysis. One concern the commission had was the singling out of genetic issues to the exclusion of other medical issues. For example, the commission felt that the best way to protect genetic privacy was to protect the privacy of medical information generally. The commission strongly urges the state to consider genetic issues in the broader context of medical questions.

The commission not only drew upon consultants within the state, but it also exchanged information with the head of the DNA Forensic Program in Great Britain, members of the U.S. National Institute of Justice, genetics groups throughout the country, laboratory directors of newborn screening programs, the National Bioethical Advisory Committee, the Ethics Foundation of the American Medical Association, the Michigan State Medical Society, the American Society of Clinical Pathologists and Congressional staff members.

Background information and a familiarity with the ongoing activities of state programs permitted discussion and debate of actual as well as anticipated issues. If, while conducting their work, the commissioners found areas that could be enhanced without legislative action, they worked with the appropriate agencies to achieve that goal. Notable examples were questions associated with newborn screening, forensic DNA testing and paternity testing.

Much credit is owed to the Department of Community Health, the Family Independence Agency, the Insurance Bureau, the State Police Forensic Laboratory, the assistant attorneys general and the prosecuting attorneys working with these agencies for their assistance.

On file at MDCH are all agendas and minutes of the commission's meetings as well as materials from the public forums, working documents and background papers. The commission established a web site at [www.mdch.state.mi.us/mcgpp/mcgpp.htm](http://www.mdch.state.mi.us/mcgpp/mcgpp.htm) with other background information.

### **III. Public Forums**





# PUBLIC FORUMS

**Background of the Forums:** To educate the public and solicit public interest and concerns, the commission conducted public forums at Grand Valley State University in Grand Rapids, the Sarvis Center in Flint, the Wayne County Medical Society in Detroit, Saginaw Valley State University in Saginaw, Washtenaw Community College in Ypsilanti and Northwestern Michigan College in Traverse City. In addition, a public forum for Lansing included a video conference conducted from the office of the Michigan Public Health Institute in Okemos. That forum was transmitted to several sites in the Upper Peninsula, including Marquette, Iron Mountain and Hancock.

Prior to the forums, the commission published a widely distributed brochure and letter that outlined the purpose of the forums and encouraged the public's attendance. Brochures were sent to hospitals, medical professionals, the lay public, support groups involved in genetic issues and the legislature. In addition, newspapers and radio stations in each of the participant cities were contacted to promote the forums. The Lansing State Journal ran a two-page story that addressed many of the issues before the commission. Various radio stations attended the forums.

Despite efforts to publicize the forums, attendance was primarily people who had a personal or business interest in the issues. Attendance ranged from one at the Detroit meeting to more than 30 at the Okemos meeting.

At the beginning of each forum, the moderator introduced the commission members present. In addition, the moderator provided a short explanation of the commission's goals and clarification of the issues under consideration. After the public testimony, the panel engaged in discussion with the audience.

**Summary of Testimony:** The testimony of the public can be categorized into several recurring topics. A common theme in most testimony was the need to protect personal privacy of medical information.

- **Privacy and Access:** One concern expressed repeatedly is that privacy should not interfere with properly conducted research. The need to manage our information systems to assure that risks to privacy and access to confidential information are minimized was also an issue.

There were mixed sentiments about the necessity or desirability of informing other family members of genetic conditions. Some suggested that there is a duty for physicians to inform family members of a genetic risk, while others felt that there were both a personal and a family right not to know. Some sessions discussed options for disclosure when there is imminent risk of injury to other family members.

Although some expressed the view that medical records should be treated differently from genetic information, many thought there was no need for separate genetic-specific laws.

- **Collection, Storage, Use:** Most people advocated informed consent for collection and use of samples, however, the manager of a lab that analyzes DNA for paternity testing expressed concern about being over-regulated.

A concern was raised regarding the process of reporting paternity results to the court system. Currently, positive results of paternity DNA testing, including both probability of paternity and genetic information, appear in court records that are open to public scrutiny.

Some worried that an employer could ask for hair, blood or tissue samples for the purpose of drug testing and then use results or the samples for undisclosed purposes.

- **Education:** It was the view at almost every public forum that educating the public about genetics in general and ensuring that citizens keep up with the swift changes and advances in genetic technology is a responsibility the state of Michigan should address.
- **Research:** The public and the research community are apprehensive that privacy concerns might impede research. As a safeguard, many participants advocated the requirement of informed consent for anything other than anonymous research. One participant advised that precautions be taken at the time research samples are anonymized to ensure that the information derived from that research does not find its way back into clinical medical records.

- **Discrimination:** The biggest concern the public expressed at the forums is tremendous fear of health insurance or employment discrimination based on genetic information.

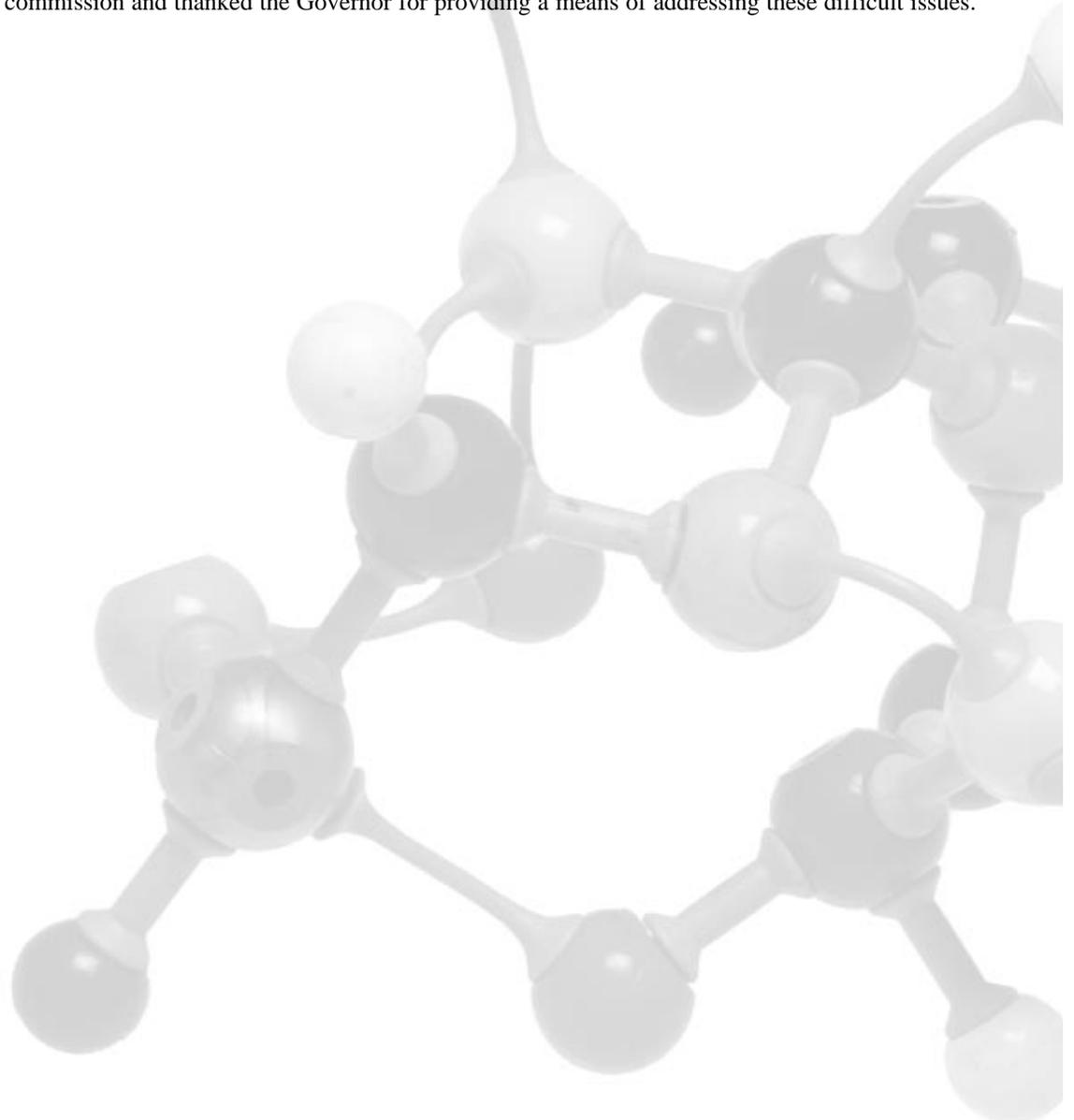
One participant testified that she was advised by her physician not to undergo genetic testing for fear of not being able to acquire health insurance in the future. Insurers at the forums stated that though they do not require genetic testing at this time, they believe that they should have the right to use any information, including genetic information, already known to an applicant.

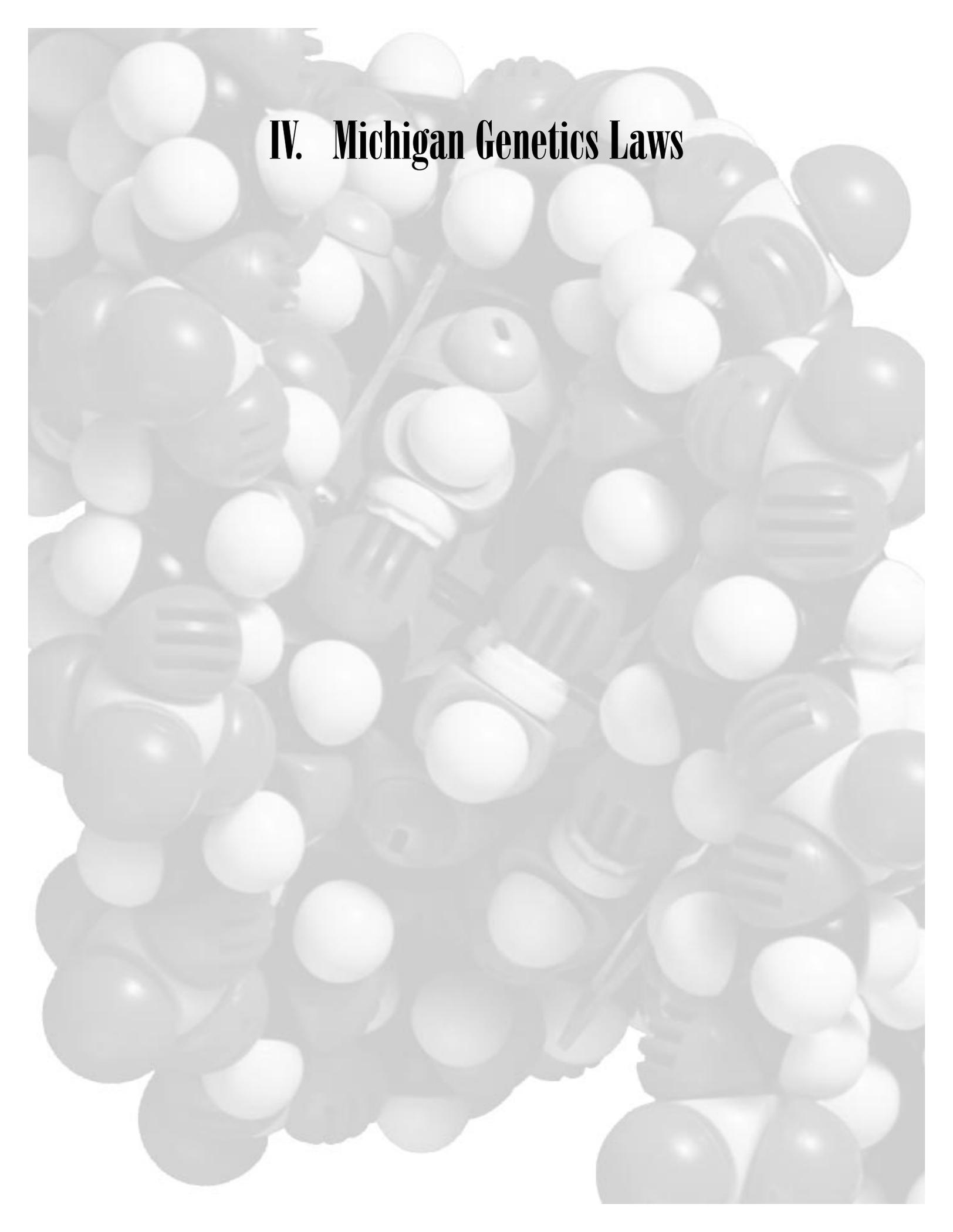
There was also a concern that insurance companies might use genetic test results that are not actuarially validated to set premiums.

Regarding employment discrimination, one common view is that “to condition employment on (genetic) information is to deprive capable individuals of the opportunity to be contributing members of the workforce.”

Two other issues addressed by the public that were not part of the commission’s mandate were (1) concerns about licensing technicians to perform DNA analyses, and (2) availability of medical information to adoptee and adoptive parents. The first issue is being addressed at the national level by professional organizations such as the American Society of Clinical Pathologists and the American Society of Crime Laboratory Directors. The second issue is already addressed in Michigan law.

In general, the views expressed by the public at the forums addressed both the risks and benefits of genetic testing. One participant said, “No matter what the cost, we must keep up with progress and technology.” Many of the participants expressed thanks for the opportunity to offer input to the commission and thanked the Governor for providing a means of addressing these difficult issues.





## **IV. Michigan Genetics Laws**



# Michigan Genetics Laws

1. MCLA 28.171 DNA Identification Profiling System Act effective June 17, 1994. State Police, pursuant to rules to be adopted, shall work with the FBI to develop the capability of conducting DNA identification and genetic-marker profiling.

State Police shall permanently retain the DNA identification profile of an individual convicted of:

attempt to murder 750.91

1st degree murder 750.316

2nd degree murder 750.317

kidnapping 750.349

criminal sexual conduct any degree 750.520 b, c, d, e, g

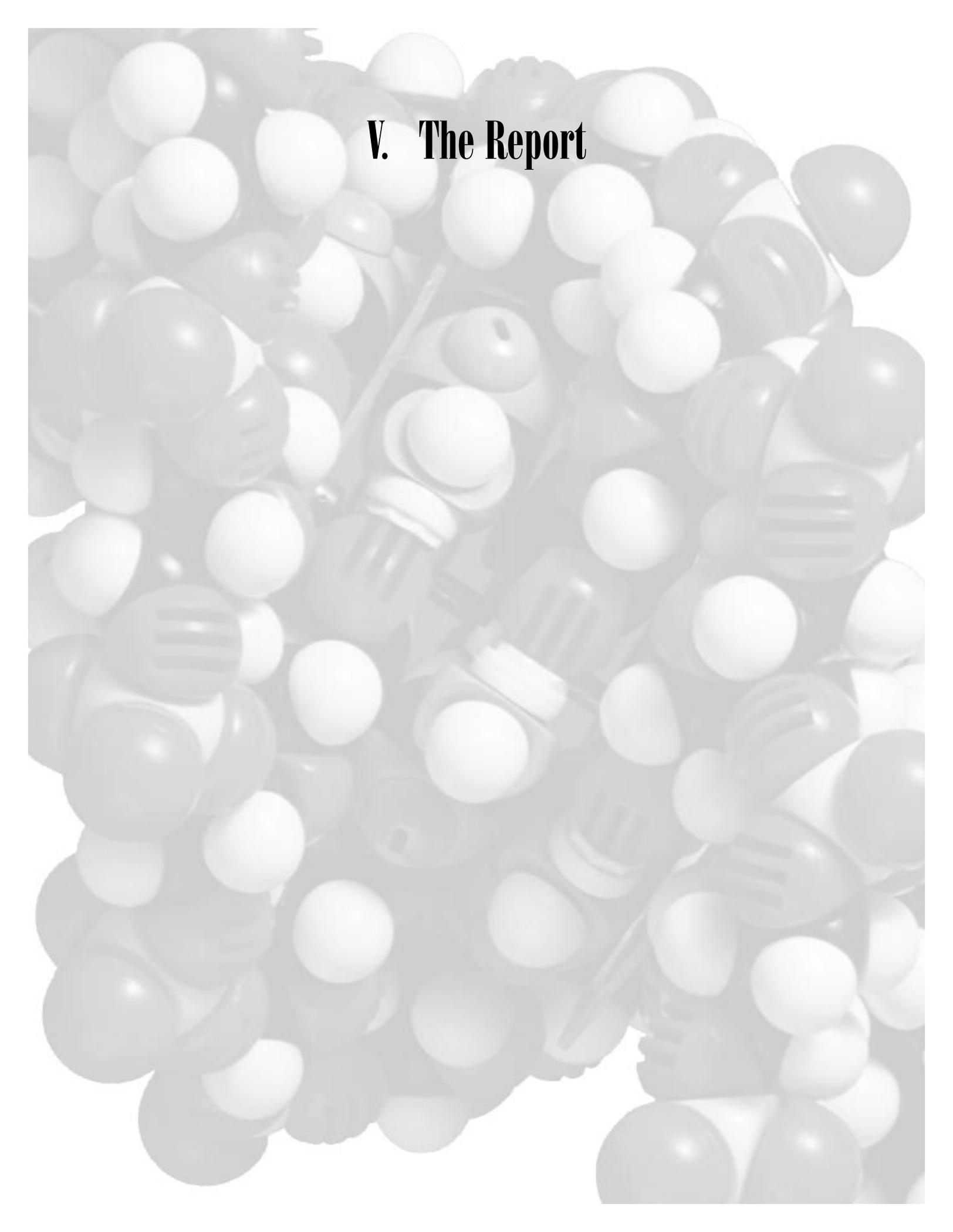
520b 1st ; 520c 2nd; 520d 3rd; 520e 4th; 520f (second offense) 520g assault with intent to commit criminal sexual conduct

2. Testing Newborns. MCLA 333.5431 (Since 1948). Health professionals in charge of newborns shall test for seven conditions (phenylketonuria, galactosemia, hypothyroidism, maple syrup urine disease, biotinidase deficiency, sickle cell anemia, and congenital adrenal hyperplasia) “and other treatable but otherwise handicapping conditions as designated by the department.”

Tests shall be administered and reported to the Department of Community Health. Parents shall be told if test results are positive. The law does not mandate any consent to obtain the samples.

3. Chronic Diseases. MCLA 333.5401 et seq. (1978). The Department of Community Health shall establish a chronic disease prevention and control program including genetic disease. The program includes: prevention, early detection and reporting, surveillance, treatment, education, rehabilitation and maintenance of patients.
4. Adoption Code. MCLA 710.68 (last amended 1994). This statute describes how to obtain biological information on an adopted child, including genetic information.





## V. The Report

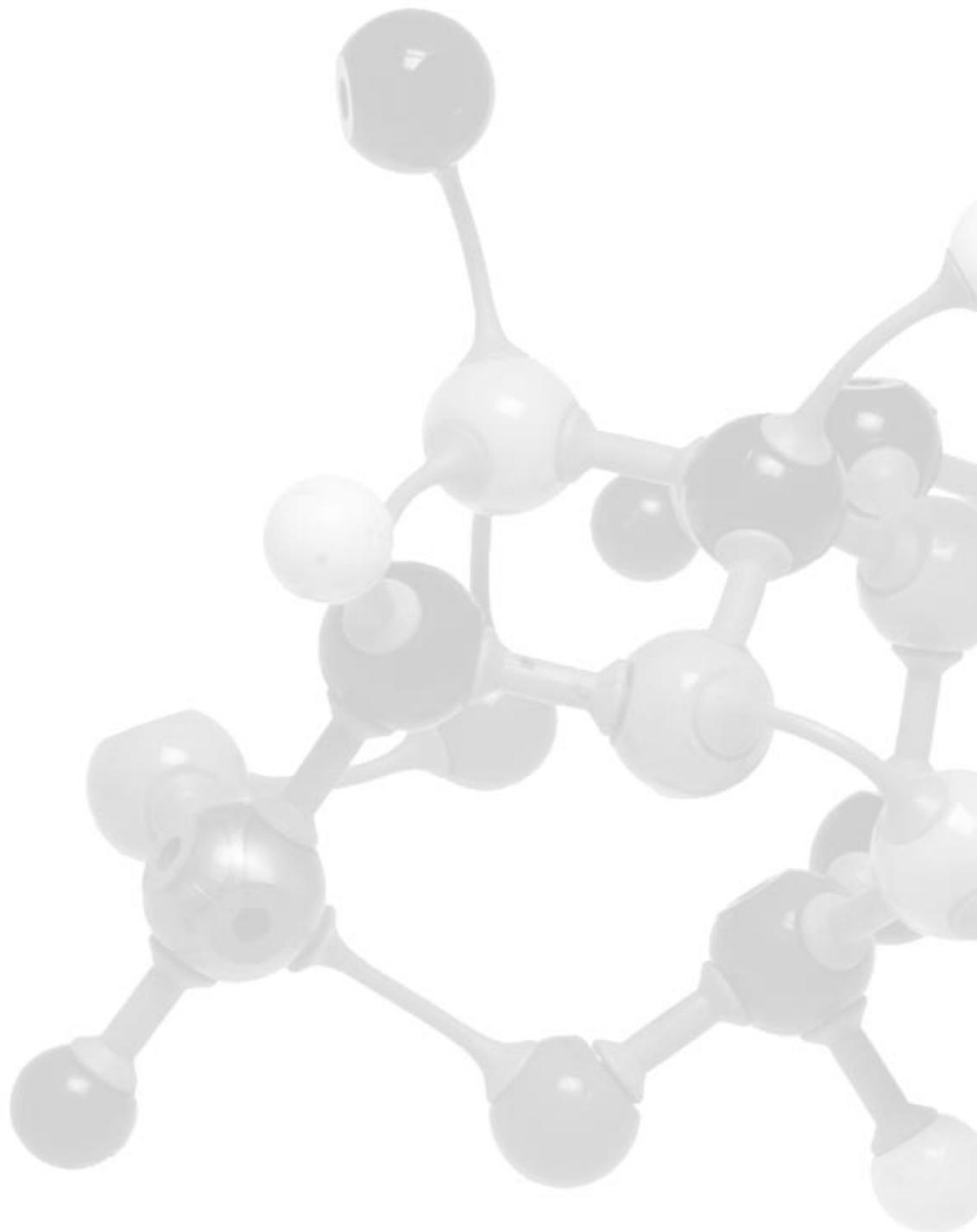


# The Report

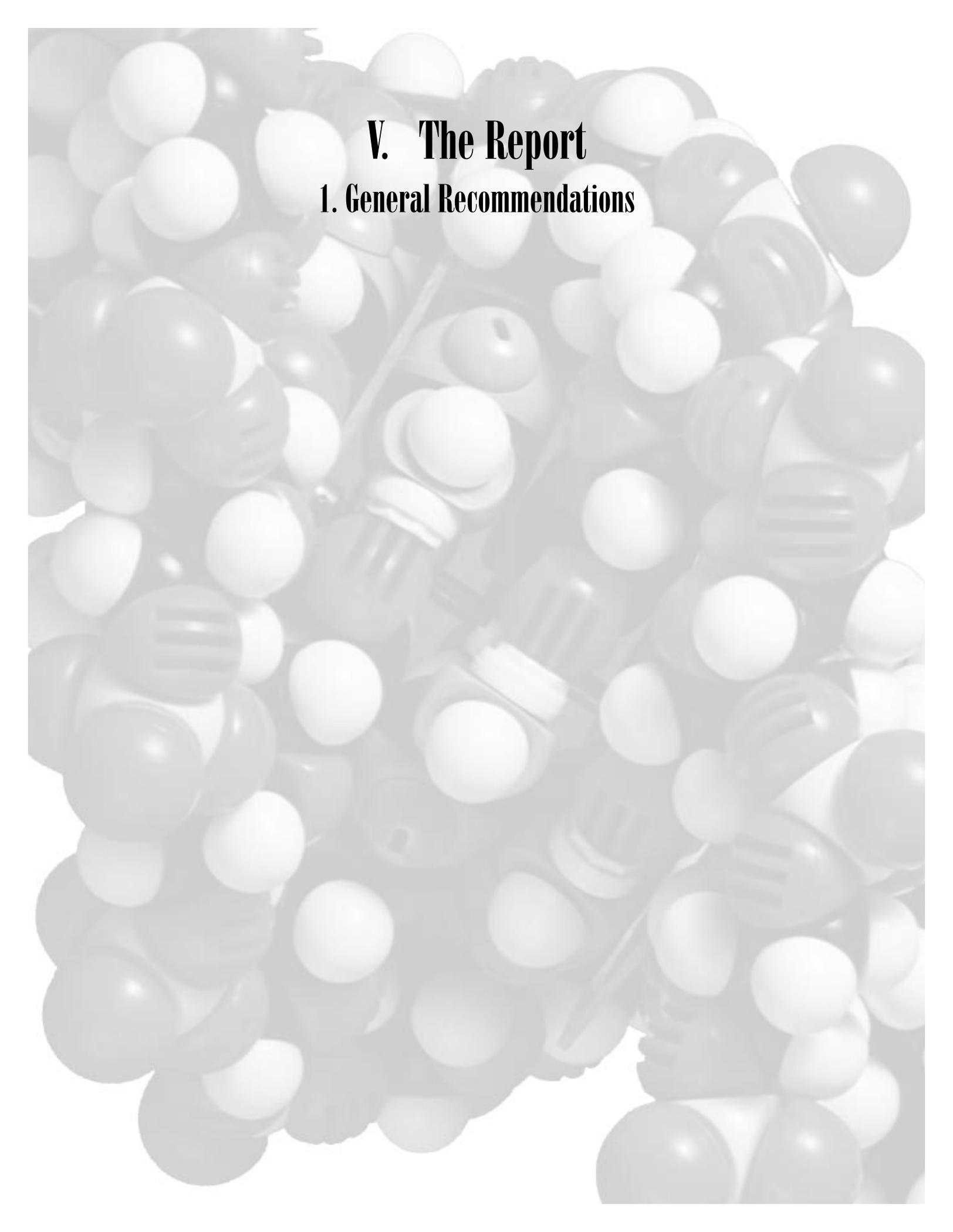
This report addresses the charges in Executive Order 1997-14.

Each section will set forth the issue to be considered, background and analysis and the commission recommendations. Substantial background material was collected and analyzed by the commission. To keep the size of this report reasonable, most of the background material is not included in this report but is referenced in the bibliography and list of articles in the appendix.

The report is based on substantial contributions by all commission members. In almost all cases, recommendations are the unanimous consensus of the members. For those few areas where consensus was not achieved, alternative minority recommendations are reflected.







# **V. The Report**

## **1. General Recommendations**



# General Recommendations

## Legislation

**Issue:** Is there a need for immediate legislative activity? Should genetics be a separate subject for legislation?

The commission recognizes that remarkable advances in genetics are occurring at a rapid rate. Although the public has not indicated a strong interest in legislation in this area generally, they have indicated a strong interest in privacy protection and protection from discrimination.

Any legislation should consider genetics in the context of medical issues generally because the commission is not persuaded that genetic information is substantively or substantially distinct from other medical information. Thus, in the area of privacy, it is important to protect all confidential medical information. Moreover, concerns with respect to genetics that arise in areas such as informed consent or insurance may be applicable to other medical information.

For the reasons discussed in this report, including the rapid advancement of genetics technology, we believe that legislation should be as flexible as possible to account for the inevitable changes in technology and the corresponding challenges the technology will present. Legislation should be limited to areas in which professional standards and codes of ethics are insufficient to protect the public good and individual rights. In addition, legislators should take care to avoid legislation that prohibits or hinders beneficial genetic testing and research.

## Continuing Expert Advice and Analysis

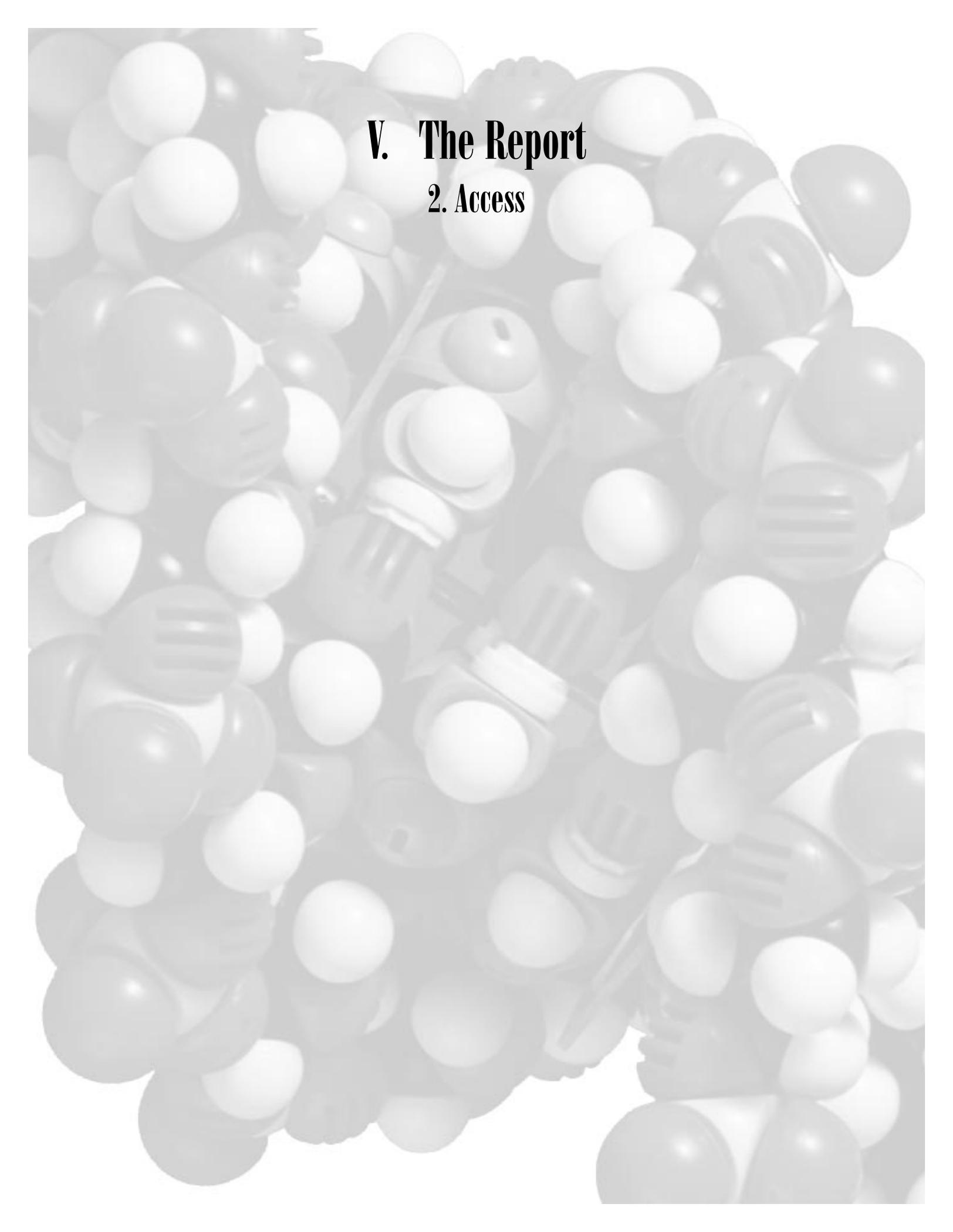
**Issue:** How should state government keep track of advances in genetics and their implications for possible legislation?

**Background:** The field of genetics is rapidly evolving. Scientific and medical advances in genetics have the potential to improve our health, identify criminals, provide new insights into human behavior, and improve our lives. At the same time, if misused, genetic information could result in discrimination and interfere with established civil liberties.

**Analysis:** The concerns associated with genetics are multi-disciplinary. Scientific, medical, legal and ethical analysis are important to understand the implications of genetic advances. Public input is critical to understand the concerns of Michigan citizens.

**Recommendation:** The commission recommends that the Governor provide a mechanism for continuing access to expertise that can assist in the creation and analysis of policy in the area of genetics. Analysis should be available to evaluate public concerns and to recommend approaches as genetic technology evolves. Expertise could be provided from research geneticists, clinical geneticists, physicians, lawyers, bioethicists, biotechnology representatives and other relevant stakeholders.





# V. The Report

## 2. Access



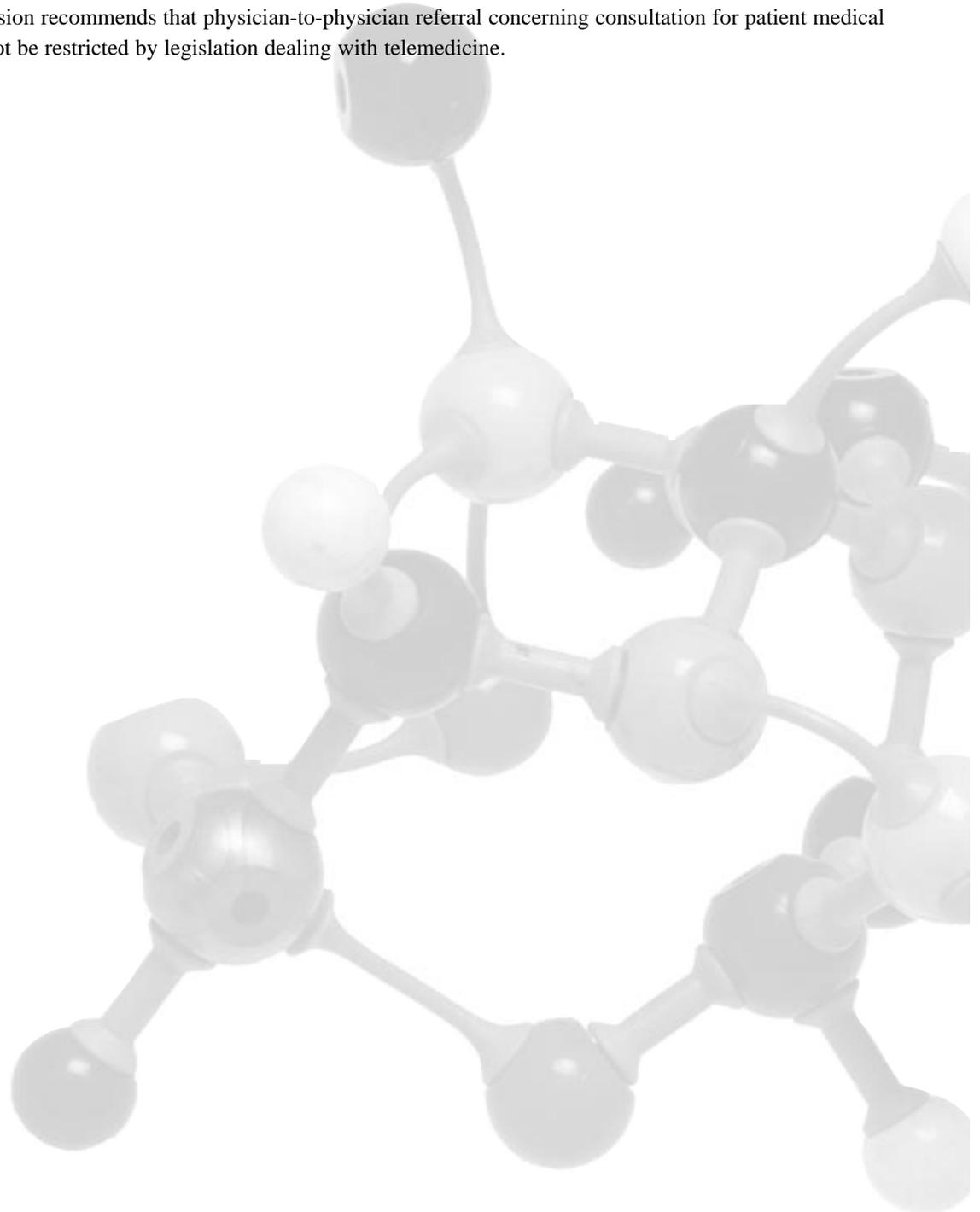
# Access: Genetics, DNA Testing and Telemedicine

**Issue:** Should there be a limitation against consultation and testing across state lines?

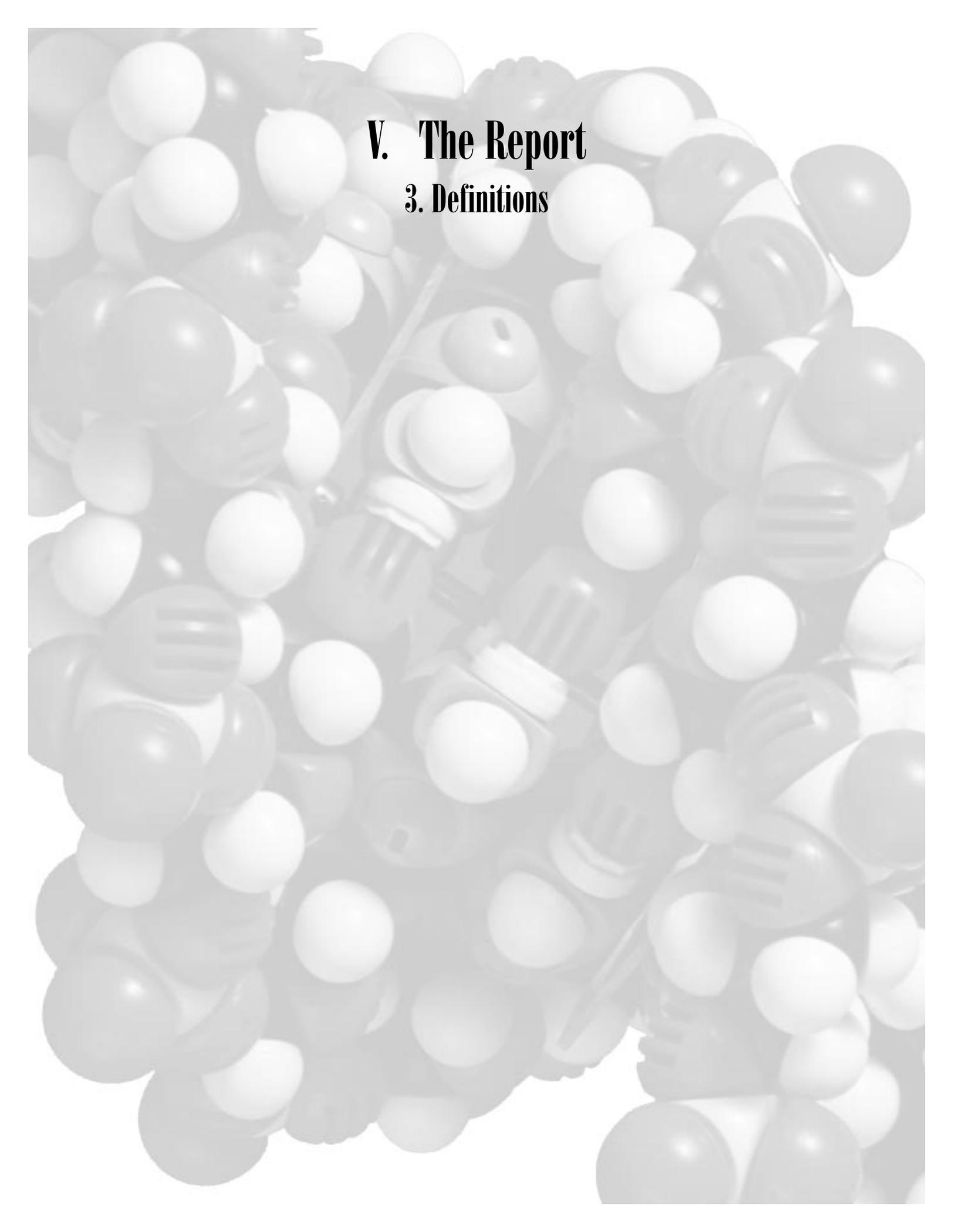
**Background:** With the development of technology that facilitates medical diagnosis and treatment across state lines and national boundaries, regulatory and legal issues have arisen.

**Analysis:** Certain specialized genetic tests and consultations are best performed at locations outside of Michigan. Legislation restricting access to out-of-state consultations and testing could interfere with Michigan physician referrals to national locations that serve as referral centers for genetic consultation and specific testing.

**Recommendation:** The commission recommends that physician-to-physician referral concerning consultation for patient medical care or analysis of specimens not be restricted by legislation dealing with telemedicine.







# **V. The Report**

## **3. Definitions**



# Definitions of Selected Terms

**Issue:** Are there terms that will need to be defined in legislation?

**Background:** Any legislation will require definitions of such terms as genes, genetic information, genetic testing, genetic sample, and genetic counseling.

The definitions will have significant implications. Genetic information can be defined narrowly as the result of genetic tests. But genetic information can also be obtained from a medical history, physical examination or other non-DNA tests. Therefore one might define genetic information more broadly to include information obtained from other sources in addition to genetic tests. Whether legislation uses the narrower or broader definitions will of course influence the scope and reach of the legislation. For example, legislation prohibiting insurance discrimination that defines genetic information narrowly will offer protection to a more limited group of individuals, but will have less impact on the insurance industry than broader definitions.

A recent Vermont law, 1997 Vermont Health Bill 89 entitled “an act relating to a state DNA data bank and to genetic testing,” exemplifies one approach to defining genetic information. It defines genetic information as a result of genetic testing. Genetic testing is defined as a test, examination or analysis that is diagnostic or predictive of a particular heritable disease or disorder and is of a human chromosome or gene, human DNA or RNA, or a human genetically encoded protein. The test must be generally accepted in the scientific and medical communities as being specifically determinative for the presence or absence of a mutation, alteration, or deletion of a gene or chromosome.

The commission believes that it is critical for legislators to understand the implications of the definition they choose in drafting legislation and to consider how the definition will affect the scope of the legislation

## Recommendations:

1. The commission recommends that the full implication of definitions be kept in mind when deciding on a definition. A broad definition would include the results of specific DNA testing as well as genetic family history and the results of other tests. A narrow definition would cover only specific DNA tests. For example, the broad definition of genetic information could include gender, eye color and other generally observed conditions.
2. The commission offers the following definitions:
  - a. **Deoxyribonucleic Acid (DNA).** DNA is the molecule that encodes genetic information. DNA is a double-stranded molecule held together by weak bonds between pairs of nucleotides. The four nucleotides in DNA contain the nitrogenous bases, adenine, thymine, cytosine, and guanine (A, T, C, and G). The sequence of bases in the coding regions of DNA determines the sequence of nucleotides in RNA molecules and of amino acids in proteins.
  - b. **Ribonucleic Acid (RNA).** RNA is a single-stranded molecule made up of four nucleotides containing the nitrogenous bases adenine, uracil, cytosine, and guanine (A, U, C and G). There are multiple cellular functions of RNA molecules, each served by one of several classes of RNA molecules, including messenger RNA, transfer RNA, ribosomal RNA and other small RNAs.
  - c. **Mutation.** A mutation is a change in the nucleotide sequence of DNA.
  - d. **Allele.** An allele is a specific variant found at a genetic locus.
  - e. **Locus.** A locus is a specific physical position on a chromosome.
  - f. **Chromosome.** Chromosomes are the autoreplicating structures of cells, containing the cellular DNA that bears in its nucleotide sequence the linear array of genes.
  - g. **Gene.** The gene is the fundamental physical and functional unit of heredity. A gene is an ordered sequence of nucleotides located in a particular chromosome that encodes a specific functional product, e.g., a protein or RNA molecule.

## **h. Genetic Information:**

**a. Narrow definition:** Genetic information is information about a gene, gene product, or inherited characteristic derived from a genetic test.

**b. Broad definition:** Genetic information about a gene, gene product or inherited characteristic derived from the individual or a family member of the individual, including information derived from tests that identify mutations in specific genes or chromosomes, other tests that are diagnostic of particular known genetic conditions, a physical medical examination, a family history or a direct analysis of genes or chromosomes. This definition would include physical characteristics.

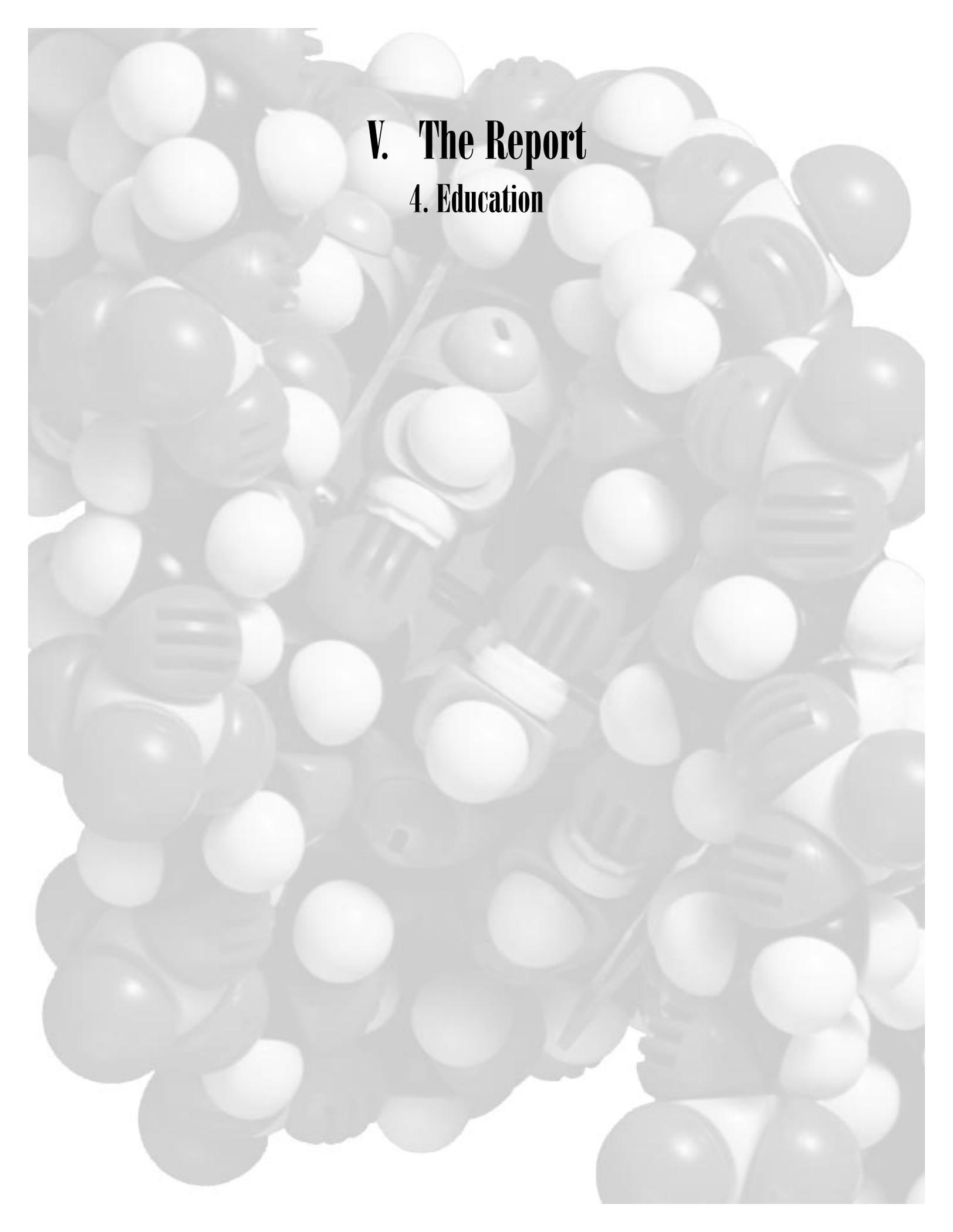
**i. Genetic Test.** Genetic testing is the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. Such purposes include predicted risk of diseases, identifying carriers for single-gene disorders, and establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn and other carrier screening, as well as testing in high-risk families, are included. Tests for metabolites are covered only when they are undertaken with high probability that an excess or deficiency of the metabolite indicates or suggests the presence of heritable mutations in single genes. Other tests are covered only when their intended purpose is diagnosis of a presymptomatic genetic condition. A genetic test must be generally accepted in the scientific and medical communities as being specifically determinative for the presence or absence of a mutation of a gene or chromosome in order to qualify under this definition.

**j. Genetic Sample.** A genetic sample is a sample of blood, tissue or body fluid or any derivatives obtained for the purpose of performing a genetic test. A sample or a portion of a sample of blood, tissue, or body fluid or any derivative that was neither obtained nor used for genetic testing is excluded from this definition.

**k. Genetic Counseling.** Genetic counseling is a communication process that deals with the human problems associated with the occurrence or the risk of occurrence of a genetic disorder in a family. The process involves an attempt by one or more appropriately trained persons to help the individual or family to (1) comprehend the medical facts, including the diagnosis, probable course of the disorder and the available management; (2) appreciate the way heredity contributes to the disorder, and the risk of recurrence in specified relatives; (3) understand the alternatives for dealing with the risk of recurrence; (4) choose the course of action that seems appropriate to them in view of their risk, their family goals and their ethical and religious standards, and to act in accordance with that decision; and (5) to make the best possible adjustment to the disorder in an affected family member or understand the risk of recurrence of that disorder.

**l. Family Genetic History.** Family genetic history is genetic information about the family of an individual obtained from the individual's or a relative's interview, testing, or review of medical records relevant to the individual or the individual's family members.

3. We recommend that genetic testing should be limited to analysis of DNA, RNA, etc. and should not include a history, physical, or other evaluation such as x-rays or blood tests unless the evaluation is designed to be specifically determinative for the presence or absence of the mutation, alteration, or deletion of the gene or chromosome.
4. We recommend the use of a narrow definition of genetic testing and genetic information unless otherwise stipulated in this document.



# V. The Report

## 4. Education



# Education

**Issue:** What are the educational needs for Michigan? How should state resources be allocated for educational issues? Should education be directed to the public, professionals and industry groups?

**Background:** The Human Genome Project and the rapid development of genetics have produced an explosion of information. The news media reports advances in genetics weekly.

The news reports can heighten public expectations or cause public anxiety. The public may not have adequate background to be able to put news reports in context.

**Analysis:** Based on the commission's public meetings and a review of the literature, the commission believes that the general public is significantly unaware or misinformed about the risks and benefits of genetics. This misinformation can result in widespread public concern and public mistrust. It is important for the public to be aware of the benefits of genetics, including identification of pre-symptomatic treatable conditions.

As a result of the commission's discussions and information from the public forums, the commission also believes that employers and the insurance industry need education about genetic issues.

The commission has discovered a wide variety of material that should be made available to the public. This material is captured in the bibliography to this report and on the commission's web site.

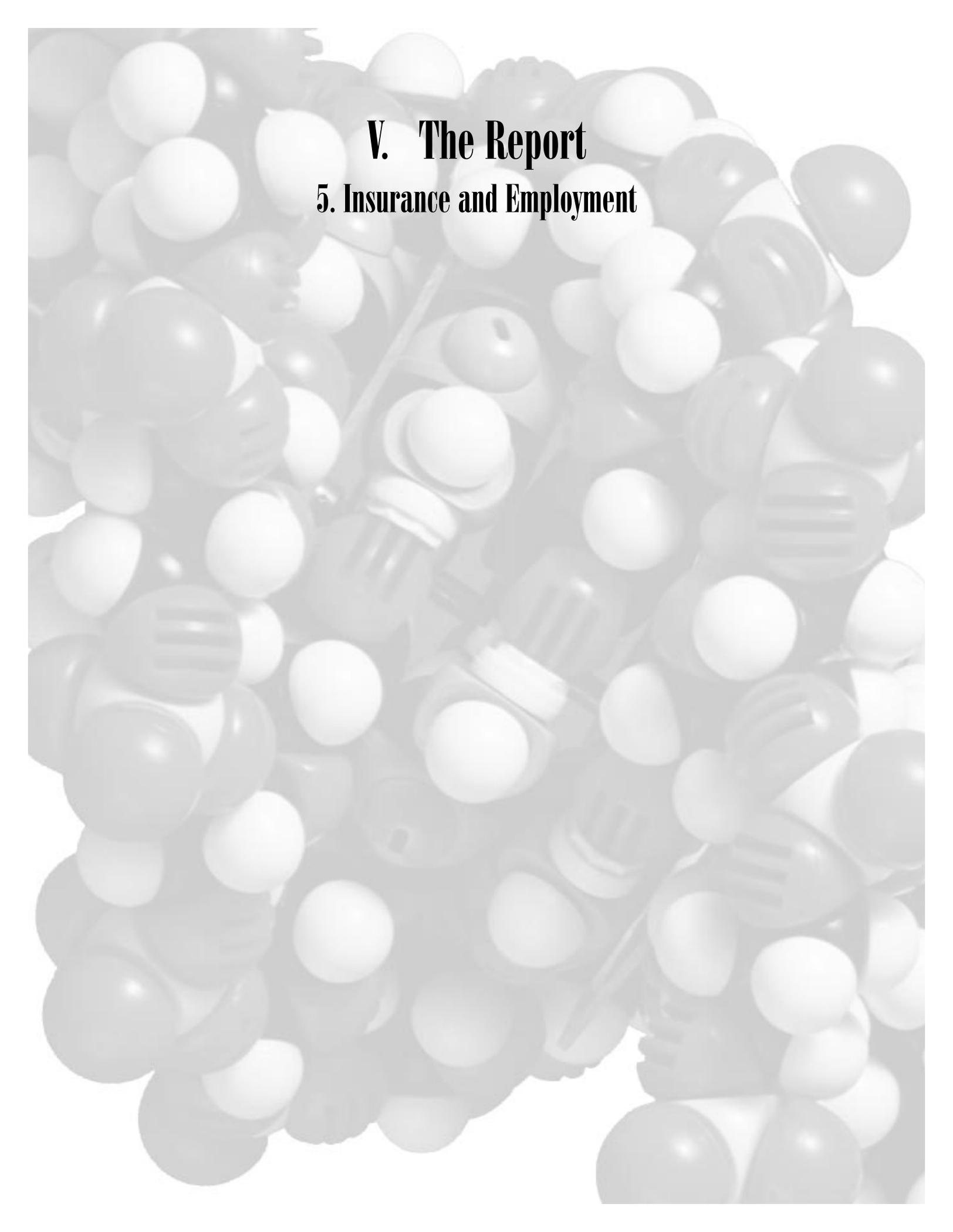
## Recommendations:

1. The commission recommends that the Michigan Department of Community Health provide education about genetics especially pre-symptomatic, predispositional, carrier status, inheritance and statistical issues. The commission recommends that genetics education be built into the K-12 school system set of core concepts.
2. The commission recommends that a state-wide educational resource be available to the judiciary, legislature, the school system and the general public. This resource could be used to create educational materials for specific issues, conduct seminars and help create public interest messages. Such a resource could be made up of educators from the state universities.
3. The commission recommends the creation of educational material for the general public. The general public material would include educational booklets about genetic testing and familial genetic disease. The commission believes that there needs to be an evaluation component to any curriculum to help measure if the material is achieving its intended results.
4. The commission recommends that the web site started by the commission be continued and updated so that it can be a resource to the citizens of the state.
5. Because the science of genetics is evolving so quickly, the commission recommends that a body with similar expertise to that of the commission be available to the state. This body could serve as an educational resource to state government as new legislation or rules are considered.

## Resources:

1. There is a public broadcasting system web site that goes along with the program, "A Question of Genes," a two-hour nationally-televised special that follows the lives of several individuals and families as they confront genetic testing issues. The address of that web site is [www.pbs.org/gene](http://www.pbs.org/gene). The program itself is sponsored by the DOE Human Genome Program.
2. "The DNA Files: Unraveling the Mysteries of Genetic Science" is a series of nine one-hour nationally syndicated documentaries created by National Public Radio. [Www.dnfiles.org](http://www.dnfiles.org).
3. The Human Genome News is available at the Human Genome Management Information System web site at [www.ornl.gov/hgmis/publicat/publications.html#hgn](http://www.ornl.gov/hgmis/publicat/publications.html#hgn).
4. The commission web site is [www.mdch.state.mi.us/mcgpp/mcgpp.htm](http://www.mdch.state.mi.us/mcgpp/mcgpp.htm).





# **V. The Report**

## **5. Insurance and Employment**



# Genetic Testing in Health Insurance and Employment

## Health Insurance

**ISSUE:** Should genetic testing be allowed to be part of the application process for health insurance and employment?

## Introduction

This report deals only with health or medical expense insurance as provided in the Governor's Executive Order. It does not address life, disability or long-term care insurance. The expressed fear at the public forums is that health insurance companies have been using, and will continue to use to an even greater extent, predictive genetic testing to deny insurance or restrict benefits.

While there is a lack of conclusive evidence that discrimination based on predictive genetic testing has decreased access to health insurance, the perception that such a problem exists has resulted in state and proposed national legislation addressing this issue. Currently, health insurers in Michigan do not require genetic testing to obtain or renew health insurance policies. Federal legislation passed in 1996, the Health Insurance Portability and Accountability Act (HIPAA), mandates that there can be no discrimination against asymptomatic persons based on genetic testing of applicants or participants in group health plans. While HIPAA addresses availability of insurance, it does not deal with rating and benefits.

There has been an effort at the federal level to expand the HIPAA mandates to individual health insurance policies. To date, this effort has not been successful.

Insurance issues include not just whether individuals can obtain and retain insurance policies, but whether it is appropriate for third-party payers to make decisions about coverage and premium rates based on genetic information. Insurance companies are concerned about adverse selection. Health care providers are concerned about the coverage of necessary medical tests and treatments in general.

## Background

**Group Versus Individual Health Insurance Coverage in Michigan:** As of 1994, 97 percent of those with health insurance in Michigan received their coverage through employer group health insurance plans. (U.S. GAO Report to the Chairman, Committee on Labor and Human Resources, U.S. Senate: PRIVATE HEALTH INSURANCE: Millions Relying on Individual Market Face Cost and Coverage Trade-Offs, November 1996.)

What of the remaining three percent of Michigan insureds who buy health insurance on their own? Some of these purchase health insurance from one of a small group of commercial insurers that place individual applicants into a group that is experience rated. Within the group, age and other factors modify each individual's premium. Individual applicants are subject to actuarial rating and potentially higher premiums than applicants for group plans.

For individuals unable or unwilling to purchase health insurance from a commercial carrier, Michigan law provides that Blue Cross Blue Shield of Michigan is the insurer of last resort and is required to make insurance available to all who apply. Thus, Michigan's problems are different from other states in that access to health insurance is, and has been, available to any resident.

## The Business of Health Insurance

As noted above, 97 percent of those in Michigan with health insurance are covered by employer group plans. Such plans generally do not require genetic testing or other forms of risk assessment of applicants. This is because the group is large enough to spread the risk among its members. Smaller employers usually pay higher premiums as the number of individuals among whom the risk is spread is limited. The difference in premium costs between large and small groups reflects the difference in the insurer's risk as well as the difference in administrative expense. Small employers attempt to compensate for this by joining trade organizations to allow individual risk to be spread among a larger group, thus potentially minimizing premiums.

The insurance industry points out that it is not common practice for health insurers to require genetic testing for obtaining or retaining policies. The Health Insurance Association of America (HIAA) stated in its May 20, 1998 memorandum to the commission

that “according to an HIAA survey of member companies, no insurer requires - or has any plans to require - genetic tests as a condition of acceptance or renewal of medical expense insurance.” Despite the fact that insurers do not require predictive genetic testing of applicants, they worry about adverse selection; that is, the sale of coverage to individuals who purchase insurance because they have special knowledge or suspicion of an increased medical risk that is not known to the insurer. While adverse selection is a concern in all forms of insurance, it is a less well- documented phenomenon in health insurance than, for example, in life insurance.

## Controlling Law

**State Law - General:** Regulation of insurance, including its accessibility, is primarily the responsibility of the states through their insurance commissioners. Prompted by concerns that advances in genetic technology may threaten privacy and lead to discrimination, some state legislatures have recently enacted statutes to prevent discrimination based on genetic test results or to protect the privacy of genetic information. These laws vary considerably in scope and have little impact on the vast majority of citizens covered by Medicare, Medicaid and employer group health insurance programs. It is estimated that only three to four percent of Americans with health insurance coverage will be affected by state statutes and this group is made up primarily of those who can afford to purchase their own coverage. (Reilly P: Genetic discrimination. in Long C (ed.) Genetic Testing and the Use of Information, Washington, D.C., AEI Press Inc., in press).

## Michigan Statutes:

- The Insurance Code of 1956 (Act No. 218 of the Public Acts of 1956) prohibits discrimination based on race, color, marital status, sex or national origin (MCLA 500.2027(a)(I)). MCLA 500.2020 does not permit discrimination between individuals of the same class and hazard. Neither provision addresses genetic testing.
- MCLA 500.2213b prohibits insurers from canceling or refusing to renew policies on the basis of illness or claims experience for both group and individual insureds. The only grounds for revocation or non-renewal of policies are non-payment of premiums, fraud and misrepresentation.
- MCLA 500.3438 and MCLA 500. 3439 limit insurers’ liabilities when multiple policies are purchased to cover the same event.

## Federal Statutes:

- The Employee Retirement Income Security Act (ERISA) of 1974 (Pub. L. 93-406) regulates pension and benefit plans. Section 514 of ERISA protects employers’ self-insured health benefit plans from state regulation regarding mandated benefits, non-discrimination statutes and the formation of high-risk pools.
- The Health Insurance Portability and Accountability Act (HIPAA), Pub. L. No. 104-191, passed in 1996, severely limits insurer-imposed waiting periods for pre-existing conditions and prohibits discrimination in issuing or renewing coverage based on genetic test results. The law applies to those applicants who have been covered by previous employers under large or small group insurance health plans for 18 months, thus primarily affecting those who are changing jobs or relocating. While HIPAA assures access, it does not address the issues of premiums and coverage. In Michigan, 97 percent of insured people are covered under group insurance plans. The three percent who have individual health insurance are not protected by HIPAA.
- Joint Federal and State Programs: Title IV of the Children’s Health Insurance Program, the Balanced Budget Act of 1997, provides matching monies through federal and state funding for the years 1998-2007 for MICHild. The Department of Community Health has recently implemented a program to provide health insurance coverage for all eligible minors. Eligibility requirements include U.S. citizenship, Michigan residency, minor status and monthly income standards. Coverage is not conditioned on health status or genetic testing.

## Public Concerns

**Insurance Concerns of the Public:** During the public forums, the public expressed concern that insurers will deny or cancel health insurance policies based on the results of genetic testing. The perception is that insurers will use test results to deny or cancel policies of or make other underwriting decisions that affect asymptomatic individuals whose genetic patterns deviate from the normal.

The commissioners also heard that the fear of losing insurance coverage is having an impact on public participation in research projects and, to some extent, is discouraging the use of genetic diagnostic tests advised by individuals' physicians.

The insurance industry, in its public testimony and in written communications, stated that it does not require genetic testing as part of the application for health insurance at this time. Insurers are willing to forego genetic testing of asymptomatic applicants for health insurance if those who had genetic testing prior to their application make the results of testing available. Otherwise, it perceives an uneven playing field favoring those with abnormal tests who can purchase insurance at standard rates without adjustment for risk.

## **Recommendations:**

1. The majority of the members of the commission recommend that the Michigan Legislature prohibit health insurers from requiring predictive genetic testing (or testing for carrier status) of asymptomatic individuals. The prohibition against requiring predictive genetic testing of applicants for health insurance extends HIPAA's protections now afforded members of group health plans to those with individual health insurance policies.

There was a difference of opinion among the commissioners as to whether asymptomatic applicants should be required to disclose the results of previous genetic testing. Those favoring non-disclosure argue that insurers could use this information to discriminate against applicants. Those favoring disclosure believed insurers should have results of prior testing to prevent adverse selection. They noted that the agreement of insurers to forego testing has been predicated on their ability to obtain results of prior genetic testing. Such access would help protect insurers against adverse selection i.e., when applicants do not disclose known risks on a health insurance application.

In either case, applicants would continue to be able to disclose the results of genetic testing to insurers voluntarily.

2. The legislative definition of genetic testing used in the case of health insurance should be narrow enough to assure that only genetic testing of asymptomatic individuals is prohibited. It is not the intent of the commission to prohibit questions covering family history.
3. The commissioners recommend that applicants for health insurance should not be required to disclose the results of genetic testing or information derived from participation in medical research. The federal government defines research as "a systematic investigation designed to develop or contribute to generalized knowledge" (45 CFR § 46.102d).
4. The commissioners recommend that adequate steps be taken to assure the validity and appropriate use of genetic actuarial data used by the health insurance industry.
5. The commission recommends that information obtained by any party, including but not limited to insurers, be carefully guarded from improper use and re-disclosure to third parties without the written consent of the individual.
6. The commission recommends that there be adequate enforcement of the rules against discrimination and breaches of privacy.

## **Employment**

**Issue:** Should the use of genetic testing be permitted in the workplace to assess individual qualifications to perform a job and address workplace toxic reaction concerns?

## **Introduction**

Over the years, concerns have been raised about the potential for discrimination in the workplace based on health status. Federal and state governments have responded to these concerns with legislation prohibiting discrimination. Now, genetic advances raise similar questions, namely, should employers use information derived from genetic testing in hiring, work assignments and provision of benefits?

## Background

Employers have justified their use of genetic testing by citing their concerns about the health and suitability of employees and applicants for their particular workplace. They indicate such problems as inability to perform the job, public safety issues, retraining of individuals who incur disabling illnesses, and costs of absenteeism and health insurance.

## Controlling Law

Michigan Law: Act No. 20 of the Public Acts of 1998, the Persons with Disabilities Civil Rights Act of 1998, derives from Act 220 of the Public Acts of 1976 and is the controlling state law dealing with discriminatory employment practices. It amends the Michigan Handicappers' Civil Rights Act, substituting the word "disability" for "handicap" in both the title and the text. Although it does not contain specific language prohibiting discrimination based on the results of genetic testing, portions of the law dealing with physical and mental medical examinations, as well as medical records, have been interpreted by the Department of Civil Rights to include results of testing.

## Federal Law

The Rehabilitation Act of 1973 (29 USC § 701 et seq.) was the first major piece of federal legislation to deal with discrimination against the handicapped. It is limited to employers who have contracts with the federal government. Its definition of "individual with handicaps" and regulations adopted by federal agencies for enforcement were models for state legislation and the Americans with Disabilities Act passed in 1990.

According to the Rehabilitation Act of 1973, an individual with a handicap is a person who:

- 1) Has a physical or mental impairment that substantially limits one or more major life activities
- 2) Has a record of such impairment or
- 3) Is regarded as having such an impairment.

The Americans with Disabilities Act (ADA) of 1990 (42 USC § 12101 et seq.): This act is the most sweeping legislation concerning disability discrimination. It mandates equal access to private employment, public services and accommodations. In the area of employment, it does not deal with all workers, but only those who are "qualified." To be qualified, the individual must be capable of performing all the essential functions of a job with or without accommodation.

The ADA has no specific prohibition against discrimination based on predictive genetic testing. However, an Equal Employment Opportunity Commission (EEOC) ruling of March 15, 1995 interpreted the ADA as applying to those who have been found to have a mutation that may put them at greater risk for developing symptoms and signs of a genetic disorder.

The ADA prohibits a medical examination of prospective employees until after an offer of employment is made. The offer of employment can be conditioned upon a medical examination. This examination is the only one in the course of employment that may include evaluation of medical factors other than those which have a direct bearing on the job to be performed, and it may consist of all elements of a complete evaluation, including laboratory tests, X-rays and the like.

## Issues

**Medical:** There is little to be gained by employers, employees or applicants from predictive genetic testing that can not be better ascertained by appropriate clinical examinations. This holds true generally, and specifically when the public safety as well as heightened susceptibility to workplace toxins are a concern. These issues were discussed in a 1991 JAMA article on use of genetic testing by employers.

"As when used for other purposes, genetic tests will have poor predictive value when used to identify workers who might pose risks to public safety. A more effective approach to protecting the public's safety would be routine testing of a worker's actual capacity to function in a job that is safety-sensitive. Airline pilots, for example, undergo physical examinations every six months."  
JAMA 266: 1826 (Oct. 2 1991)

Concerns about increased susceptibility to certain workplace toxins led to testing of black males for sickle cell trait for fear that exposure to certain compounds would precipitate sickling of blood cells. Likewise, there have been attempts to identify workers with alpha1 antitrypsin deficiency because of the concern that respiratory irritants might cause chronic obstructive lung disease. However attractive these concepts may have been on a theoretical basis, they have not been scientifically validated.

“Although these genetic tests have been used for research and to advise workers of potential risks, they also may have been inappropriately used to exclude affected workers from the workplace. For instance, the apparent exclusion of workers with sickle cell trait was based on theoretical considerations that had no basis in fact. To date, there is insufficient evidence to justify the use of any existing test for genetic susceptibility as a basis for employment decisions.” Id.

**Legal:** The major issues that genetic testing has brought to the workplace is fear of discrimination and loss of privacy and confidentiality. The commission addresses the privacy and confidentiality of medical records, including genetic information, elsewhere in this report.

State law has not specifically addressed the use of genetic test results to discriminate against individuals who are qualified to perform jobs with or without accommodation.

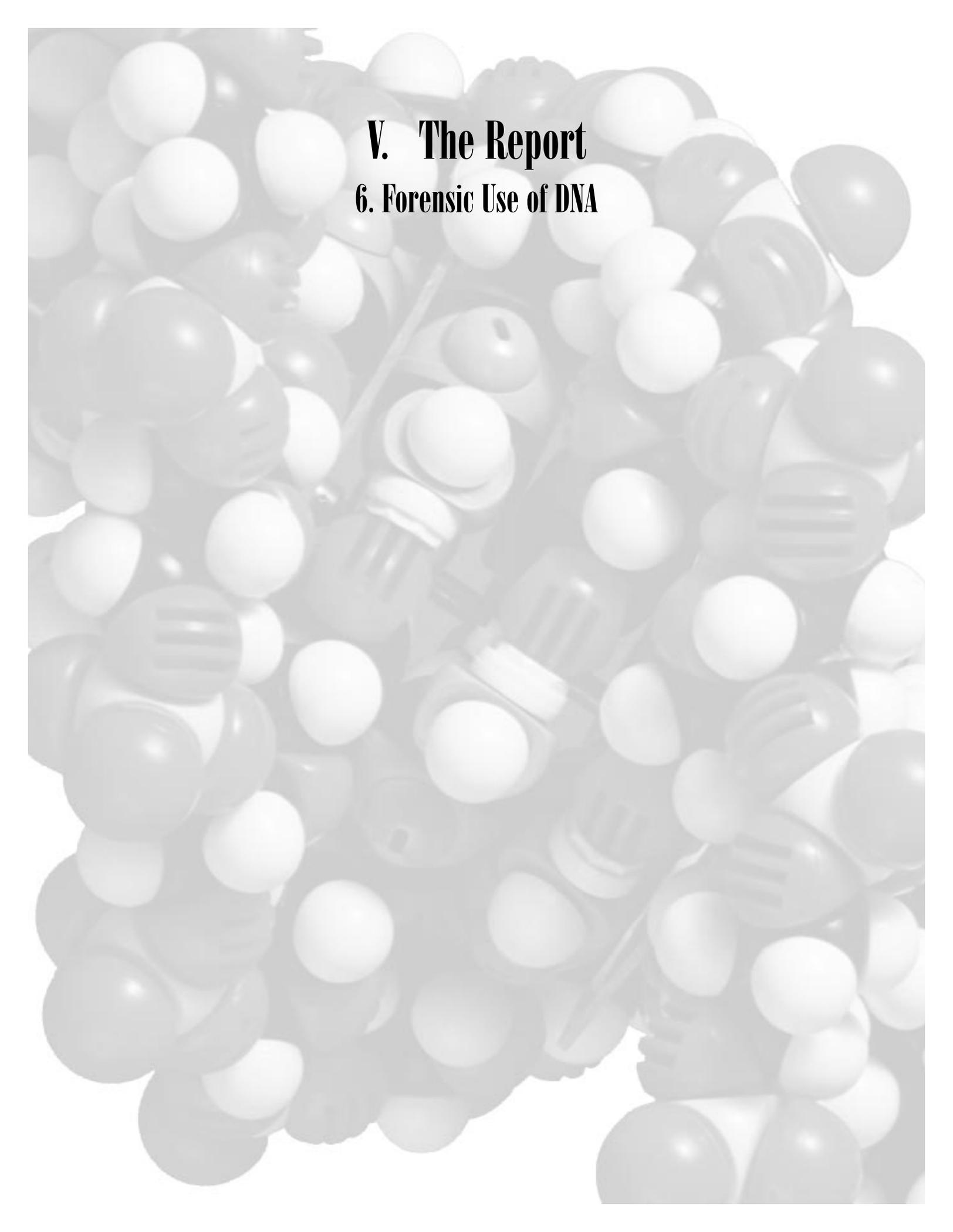
## Analysis

The Occupational Safety and Health Act (29 USC §651 et seq.) provides federal guidelines for maintenance of health and safety in the workplace in addition to the state-mandated guidelines. Genetic testing of employees for possible susceptibility to a workplace toxin is no substitute for the maintenance of a healthy work environment. As shown above, the reliability of these tests is not great enough to assure that valid employment decisions are facilitated by their use. Employers should remove toxic agents or adequately protect workers who are in contact with them. Genetic screening would not assist an employer in determining an employee's ability to perform a job.

## Recommendations

1. The commission finds that genetic screening has not been scientifically validated as a means of predicting the onset of clinical disease and therefore recommends that genetic testing not be relied on in assessing qualifications of an individual to perform a job.
2. The commission believes that employers' concerns about toxic exposures are best approached by making the workplace safe for all employees and therefore recommends the prohibition of genetic testing or the use of genetic information as a condition of employment.





# **V. The Report**

## **6. Forensic Use of DNA**



# Forensic Use of DNA

**Issue:** How should the state handle test samples, results and reports concerning elimination of suspects?

## Introduction

Federal and state governments have cooperated in the development and implementation of techniques and data retention related to DNA forensic testing. State legislation controlled the field in large part until Congress passed the federal DNA Identification Act of 1994. With the development of the Federal Bureau of Investigation's (FBI) Combined DNA Index System (CODIS) for the retention of data concerning convicted felons, direction has been given to the use and retention of information. Following is an overview of Michigan statutes and federal law for procedures governing forensic DNA testing.

## Existing Law and Background

1. **Controlling Law and Rules:** Michigan Law: Act No. 250 of the Public Acts of 1990 known as the DNA Identification Profiling Systems Act (MCLA §28.171 et seq.) calls for promulgation of rules for forensic testing concerning:

- Collection of samples in a medically approved manner by qualified persons and the types and numbers of samples to be collected by corrections departments, law enforcement agencies and the Family Independence Agency.
- Distribution of blood specimen vials, mailing tubes and labels and instructions for collecting samples.
- Storage and transmission of samples.
- Genetic profiling of samples.
- Development of a system, including computerization of filing, cataloging, retrieving and comparing DNA profiles, in cooperation with the Federal Bureau of Investigation (FBI) and other appropriate persons.
- Cooperation with the FBI in development of DNA identification and genetic marking profiling capability and training state police personnel.
- Protection of the privacy interests of individuals whose samples are analyzed under the act.

Other statutes deal with the procedures for DNA profiling and the categories of criminals whose DNA must be profiled.

- Act No. 507 of the Public Act of 1996 amended Chapter XII A of Act 288 of the Public Acts of 1939 by adding section 18k (MCLA §712.A18k) designated that individuals convicted or found responsible for violation of specified crimes shall provide samples for DNA profiling.
- Act No. 509 of the Public Acts of 1996 amended section 33d of Act No. 232 of the Public Acts of 1953 "to revise, consolidate and codify laws relating to probationers, probation officers..." (MCLA §791.233d). This ensured that prisoners required to provide samples for DNA testing did so prior to discharge, if they had not already done so.
- Act No. 510 of the Public Acts of 1996 amended §750.520(m) of the Michigan Penal Code regarding collection and forwarding of samples for DNA identification profiling according to rules promulgated by the state police.
- Act No. 511 of the Public Acts of 1996 amended Act No. 73 of the Public Acts of 1988 by adding section 5a (§803.225a) dealing with juvenile facilities. This action provides for testing of juveniles convicted or found responsible for certain crimes.
- Act No. 512 of the Public Acts of 1996 amended Act No. 150 of the Public Acts of 1974 by adding section 7a (§303.307a), which provides for DNA profiling of state wards convicted of specified crimes prior to discharge or being placed in any community. The rules developed in accordance with PA 250 and amending statutes are the foundation of genetic profiling procedures in various contexts and are found in the Michigan Administrative Code (R28.5051-5059).

**Qualifying Offenses for DNA Testing in Michigan:** Crimes for which DNA identification profiling is mandated include sex offenses, murder, assault and kidnapping. Testing applies to juveniles and adults who are convicted of or found responsible for committing or attempting to commit those crimes.

**Consent for Obtaining Samples for DNA Profiling:** Provision of samples for DNA profiling is mandatory for those convicted of the crimes delineated under Michigan law. Provision of samples may be voluntary or under warrant during the course of a criminal investigation.

**Laboratory Oversight:** The American Society of Crime Laboratory Directors establishes standards and monitors quality. Proficiency testing of technicians who perform DNA analyses is done under its auspices at least yearly.

**Federal Law:** DNA Identification Act of 1994 provides for the following:

- 42 USC §14131 - Quality assurance and proficiency testing standards that include the formation of a national DNA Advisory Board.
- 42 USC §14132 - The development of an index to facilitate law enforcement exchange of DNA identification information.
- 42 USC §14133 - Lists the duties of the Federal Bureau of Investigation relative to proficiency testing requirements, privacy protection standards and criminal penalty for abridgment of privacy protections, including fines up to \$100,000.
- 42 USC §14134 - Authorizes funding to the FBI for carrying out the above sections of this title.

## 2. Collection and Analysis of Samples

**Specimen Collection and Storage:** Originally, only blood samples were collected. Presently, the use of buccal smears (cells obtained by swabbing the inside of the mouth) is gaining in popularity. Blood samples are stored in freezers (controlled environment), while buccal smears can be stored appropriately at room temperature. Continued evolution of techniques for collection and storage is anticipated.

**DNA Analysis:** The object of forensic DNA identification profiling is to establish a pattern that is unique to the individual without identifying genes that are associated with specific diseases or disorders. Thus, a DNA profile does not establish the suspect's genetic predispositions.

**Access to Information:** Only authorized users in law enforcement agencies have access to the FBI's CODIS Indexing System for the identification of DNA profiles.

**Functioning of the Combined DNA Index System:** CODIS consists of three levels:

- National DNA Index System (NDIS) - maintained by the FBI
- State DNA Index System (SDIS) - each state has one designated SDIS
- Local DNA Index System (LDIS) - each law enforcement system participating in CODIS maintains an LDIS database that receives pertinent information from its local laboratory, the Local DNA Analysis System (LDAS)

The CODIS ensures that DNA data added to an index meet specific criteria. For example, before accepting LDAS data for transfer to LDIS, CODIS performs a series of checks to filter substandard or inappropriate data and to ensure appropriate user authority. An array of similar techniques permits transfer of DNA data from local to state to national levels only with carefully controlled access through selected user authority.

## 3. Issues Regarding Forensic Use of DNA

Over the years, a number of problems have arisen as DNA forensic technology has evolved. Relevant portions of state laws have been amended and the use of the databank in cooperation with the federal government has been instituted. What follows is a summary of problems that have been resolved and proposed solutions for those remaining.

### A. Resolved Issues

**Period of Sample Retention:** While not mandated by state law, DNA samples taken from convicted and responsible felons are retained indefinitely. Samples of elimination suspects are returned to the submitting local law enforcement agency upon conclusion of the investigation.

**Period of Record Retention:** DNA records of convicted individuals are retained and placed on the FBI CODIS system where they remain indefinitely. As required by Michigan Law (MCLA §28.176), records of elimination suspects that contain an individual's name are to be returned to the submitting agency at the conclusion of the investigation. The Michigan Department of State Police has implemented procedures that comply with this law. Unidentifiable evidence is retained in each casework file to assure compliance with the accrediting body's laboratory standards.

## **B. Outstanding Issues**

Questions have arisen about the manner in which local law enforcement agencies dispose of the returned elimination blood samples. Disposal of the blood samples returned to local law enforcement agencies is subject to Act No. 18 of the Public Acts of 1990 (Part 138 of the Public Health Code). Section 13811(b) of this act requires blood products and body fluids to be disposed of by one of the following methods:

- i Flushing down a sanitary sewer
- ii Decontaminating by autoclaving or incineration
- iii Solidifying
- iv If in solid form, transferring to a sanitary landfill
- v A process approved by the department

There is no provision, however, for monitoring this disposal.

## **Recommendation**

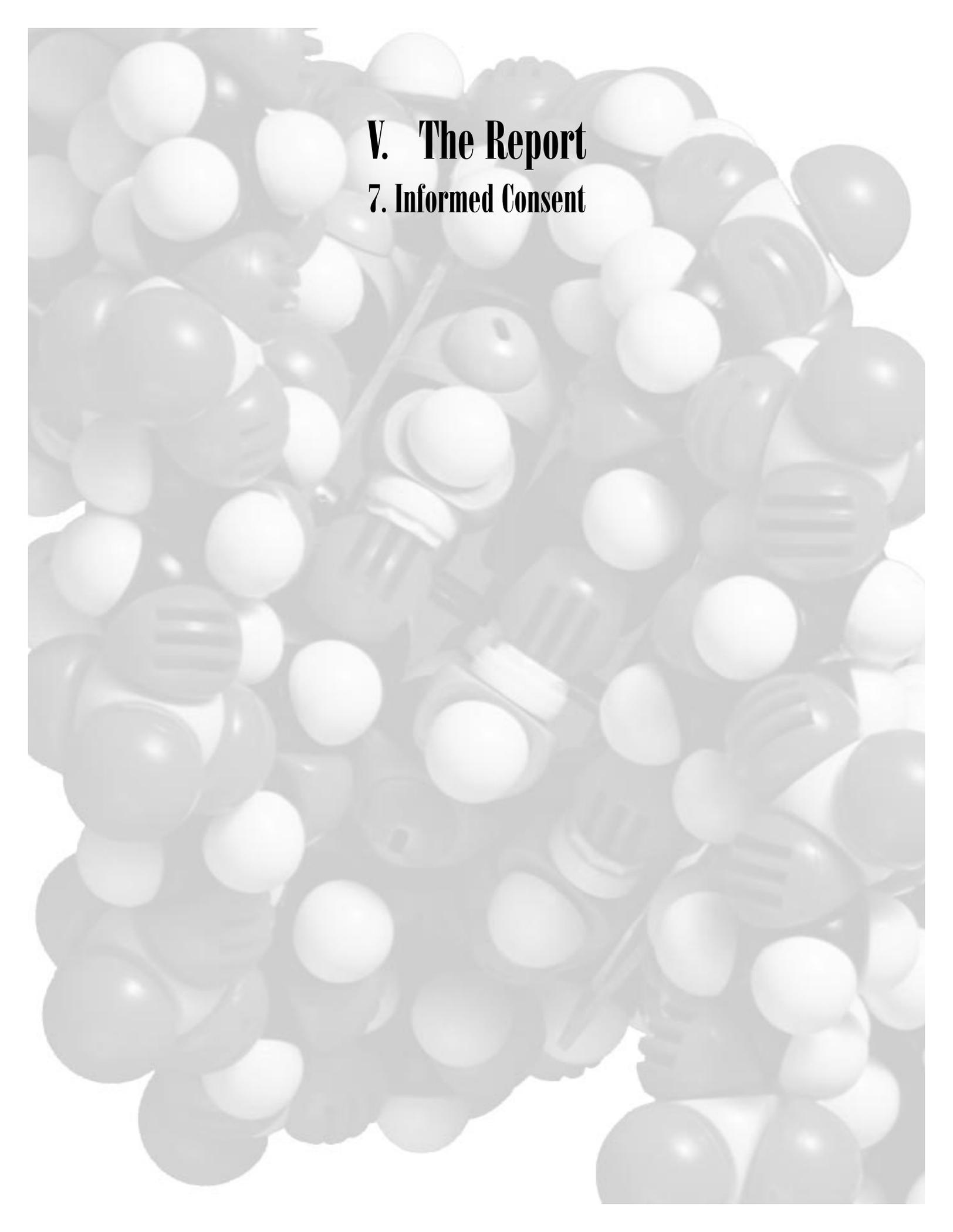
Since there is no assurance that returned elimination samples of blood and body fluids will be disposed of in an appropriate manner by local law enforcement agencies, the commission recommends that Michigan State Police protocol be modified to allow elimination specimens to be disposed of where the DNA analysis is conducted. This would require the State Police Forensic Laboratory to modify intra-departmental protocol for sample disposal as follows:

### **3. Elimination Samples/Purging Protocol**

- 3.1 Elimination samples and related records will be destroyed in accordance with 3.1.1 and 3.1.2, *infra*, after completion of the analysis so long as the laboratory concluded that the sample was submitted by a person who should be eliminated from consideration as a suspect.
  - 3.1.1 The destruction of samples will be performed in the presence of a witness.
  - 3.1.2 An audit record, signed by the witness, will document the destruction of such samples.

The destruction of elimination samples in the proposed manner would establish clear auditable rules for medical waste disposal.





# **V. The Report**

## **7. Informed Consent**



# Informed Consent

**Issue:** How should informed consent figure into genetic legislation?

**Background:** The informed consent doctrine states that health care professionals may not perform invasive tests or do studies on patients without first informing them of the nature of the procedure— its risks, benefits and alternatives. Health care professionals then need to obtain the uncoerced consent of a competent patient. This doctrine furthers patient autonomy and is an important keystone in medical law and ethics. In our discussions about privacy, discrimination and insurance we refer to the need to provide protection for patients. One important way to provide that protection is through an informed consent. Moreover, informed consent is an important way to protect individuals' privacy.

In considering informed consent, a review of case law may be useful to understand specific genetic issues.

Most courts require physicians to inform patients of the patient's physical condition, the purpose and advantages of the proposed treatment, the material risks of the proposed treatment and the material risks of alternatives, including no treatment. Plaintiffs, however, are increasingly asking courts to expand the scope of information that should be disclosed legally, and courts have reached differing conclusions.

A few courts have held that some physician-specific risk information is material information. The Wisconsin Supreme Court held that when physicians have "substantially different success rates with the same procedure and a reasonable person in the patient's position would consider such information material," this evidence may be admitted at trial<sup>1</sup>. Another court reasoned that a physician's HIV-positive status is a material risk when a physician performs invasive procedures<sup>2</sup>. Finally, the California Supreme Court held that a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment. Thus, in *Moore v. Regents of the University of California*<sup>3</sup>, the court found that a leukemia patient had a claim for violation of informed consent when the patient's physician failed to disclose his commercial and research interest in the patient's spleen cells at the time he sought consent for the patient's splenectomy.

Courts however, have not found statistical mortality information to be material. In *Arato v. Avedon*<sup>4</sup>, the California Supreme Court upheld a trial court's decision in favor of the defendant physician who failed to disclose the statistical life expectancy associated with a particular cancer treatment. The court reasoned that the information was outside the scope of material risks and that, even if the information were material to the patient's nonmedical interests, such as pending business affairs, the scope of information to be disclosed under the informed consent doctrine should be limited to therapeutic information.

Increasingly, genetics professionals or societies, bioethicists and policy makers are expanding the scope of the information they believe is crucial for informed consent for genetic testing in the clinical and research settings, such as:

- a. The manner in which samples will be collected;
- b. Psychosocial risks, such as discrimination, stigmatization, altered family dynamics, anxiety, guilt, etc.;
- c. The possibility of unexpected findings, such as non-paternity;
- d. Recontact and notification policies;
- e. Commercial or research interests the clinician or researcher may have in the samples;
- f. Who will have access to samples and results;
- g. Plans for storage and security of samples and test information, including whether samples will be anonymized, coded or identifiable;
- h. Likely secondary uses for the samples and who controls future use of samples;
- i. Opt-out provisions for future uses of samples;
- j. Plans and mechanisms for destruction of samples and who controls this process;
- k. The possibility of withdrawing consent and consequences of withdrawal from research studies;
- l. Uses of samples after death.

1 Johnson v. Kokemoor, 546 N.W.2d 495 (Wis. 1996).

2 Estate of Behringer v. Medical Center, 592 A.2d 1251 (N.J. Super. 1991).

3 793 P.2d 479 (Cal. 1990).

4 858 P.2d 598 (Cal. 1993).

Whether current informed consent law would require disclosure of all of the information described above is an open question. For example, it is not clear whether claims brought for failure to disclose information related to discrimination would be legally cognizable. Under the rationale of Arato, this sort of information might not be considered “therapeutic” and therefore would not be material. Risks related to psychological reactions, however, might be deemed therapeutic information and therefore within the scope of information that must be disclosed.

Legislatures have begun to mandate certain informed consent requirements for genetics testing. A main component of such legislation is to require authorization for testing and disclosure of genetic information. Many bills and statutes mandate that, prior to genetic testing, an individual be informed of the purpose of the test, the potential uses of the test, the limitations of the test, the meaning of the test results, the procedures for providing notice of test results, and the right to keep the results confidential. Much of this legislation also requires written authorization for disclosure of genetic information to third parties following a description of the information to be disclosed, the name of the individual or entity receiving the information, and the purpose of the disclosure. In addition, authorization may be required for continued retention of genetic information or samples, creating possible administrative difficulties for clinical investigators.

Although the law demands disclosure of material information to patients, it does little to ensure that physicians’ approach to informed consent is more than formalistic and legalistic. Many clinicians view informed consent law as requiring simply that the patient sign a document stating that she agrees to the procedure and understands the risks listed on the document. Many do not seem to view informed consent as a process to ensure that the patient sufficiently understands the information, options, and associated risks to make an intelligent decision about her choices. This is a problem in medicine generally. However, because the focus on information delivery is such a strong element of genetics, bioethicists and geneticists particularly worry about a formalistic approach to informed consent in many areas of genetics testing where the information can be complex and plentiful.

## Analysis

There is a clear consensus that informed consent should be required for genetic testing in most contexts. The extent and specifics of what should be included in the information for informed consent may vary depending on the nature of testing, the reasons for testing and the setting (clinical or research contexts, for example).

### 1. Clinical Genetics

The risks and issues in clinical genetic testing vary; thus we distinguish between routine diagnostic testing and more complex genetic testing.

#### a. Routine Diagnostic Testing

In the clinical context, there is a clear presumption that any medical procedure requires informed consent. Some types of genetic testing, such as routine diagnostic testing, may not require anything more than the sort of informed consent that is part of general medical care. Thus, patients should be informed of the differential diagnosis as well as the various options for establishing a diagnosis, and they should have the option not to participate in diagnostic testing. For example, when a clinician sees an infant with apparent trisomy 21 (Down syndrome), the parents should be informed about the diagnostic suspicion and the nature of information that can be obtained from chromosome studies. However, it may not be necessary to use formal informed consent documents that describe the specifics of the test, including how cytogenetic studies are done, risks of false negatives and positives, physical risks of venipuncture, etc. In other words, routine diagnostic genetic testing should be treated like other areas of general medical care.

However, when there is still some uncertainty about the value of diagnostic genetic testing, the informed consent process should be more complex and require documentation. For example, some clinicians use ApoE testing to establish an Alzheimer’s diagnosis. Clinicians disagree vociferously as to the value and propriety of using such tests for diagnostic purposes. In those cases, the patient should be informed of the disagreements, the concerns that opponents have with regard to such testing and the limitations of knowledge about the value of the test. In many ways, such testing is like offering experimental treatment, which requires complete and documented informed consent. When diagnostic genetic testing is not yet routine, detailed informed consent should be obtained and documented, similar to that required for experimental treatment.

## b. The Four Ps

In the context of presymptomatic, predictive, prenatal or preconceptional testing, complex issues and risks arise that require more involved informed consent. For example, the potential risks of insurance discrimination are greatest for those who are currently healthy but who want to know whether they are at an increased risk for a disease that will develop in the future. In addition, testing related to reproduction raises complex moral, psychological and deeply personal issues as well. In these cases, genetics testing is offered to help people make personal life-planning decisions, rather than to offer medical treatment per se. The focus is on information delivery and therefore informed consent requirements should be more stringent. We therefore believe that legislation should mandate documented and thorough informed consent for the four Ps — prenatal, preconceptional, presymptomatic and predictive genetic testing.

One of the issues this recommendation raises is whether such legislation should describe in detail specifically which pieces of information should be disclosed for informed consent. For a few reasons, it may not be practicable or desirable to establish such a list for all such tests. Each of these types of tests presents different types of psychosocial issues and risks and they may involve different approaches to or combinations of testing (DNA/RNA analysis, metabolic studies, medical history, physical examination, radiographs and standard laboratory tests). As a result, it would be virtually impossible to describe with sufficient nuance the material pieces of information relevant to each type of genetic testing. In addition, genetics technology and our understanding of genetics are ever changing, which means that even if such a nuanced list could be created today, it may well be out of date tomorrow.

While we do not recommend legislation articulating the specific pieces of information that must be disclosed, we do believe that legislation should set minimum standards about the kinds of information that should be disclosed in order for consent to be informed, such as:

- a. Nature and purpose of the test
- b. Effectiveness and limitations of the test, including clinical predictiveness, false positive rates (specificity) and false negative (sensitivity) rates
- c. Implications of taking the test, including the potential medical and non-medical risks and benefits
- d. Potential future uses of the sample and information
- e. Meaning of the test results and the procedure for providing notice of such results
- f. Who will have access to such samples and information (or the right to keep the information confidential).

The details of what should be included in these general categories should be defined by professional organizations, not by legislators, since the information may change over time and differ for different types of tests. Moreover, generating the details of these requirements requires technical and clinical expertise. Therefore, specific professional societies and professionals most familiar with these genetic tests and their uses should set the standard of care for the type of information that should be disclosed with respect to each test. They should also help draft the specific wording for informed consent documents.

Determining what information is material with respect to a test will vary based on the nature of the test and what is known about the magnitude (both in terms of probability and degree) of the risk and benefit. This raises the question of whether the risk must be demonstrated to be real, or whether it is enough that such a risk could exist. For example, it is not clear that the risk of insurance discrimination currently is that great. Nevertheless, there is some basis to think that insurance discrimination could become a real risk in the future. In the face of these uncertainties, we recommend leaving it to professional societies to define which risks would be material to a patient undergoing a particular genetic test. In addition, genetics professionals, scholars, ethicists and policy makers should continue to examine assumptions and gather empirical data about associated psychosocial and other risks and benefits to determine which risks and benefits are truly material. As our knowledge increases, the information that should be disclosed will likely alter to some extent.

Our concerns raise additional issues. First, the number of individuals trained to educate patients and consumers about the relevant material information related to genetic testing will increasingly be insufficient. Traditionally, genetic counselors have been trained to ensure that informed consent is obtained. All data suggest, however, that the number of trained genetic counselors cannot possibly meet the inevitable growth of demand for genetic testing. Therefore, we recommend that geneticists, psychologists, sociologists, ethicists, lawyers and other scholars examine whether and which alternative methods and educational resources can be used to obtain informed consent effectively.

While we urge a mandate for documented informed consent for the Four Ps, we emphasize that documentation should not overshadow the primary objective of providing comprehensible information to the patient. Therefore we stress that the foremost goal is to educate patients and the public, rather than simply to provide mechanisms with which professionals can avoid liability. Legislation or professional standards with respect to informed consent should be geared toward encouraging real informed consent, instead of formal, but empty, compliance with the requirements of informed consent.

## 2. Research

Publicly funded research or any research under assurance with the federal government that involves human subject research must be approved by an Institutional Review Board (IRB)<sup>5</sup>.

These review boards are responsible for evaluating the propriety of informed consent provisions. While the general requirements of IRBs are established by federal regulation, we nevertheless make the following suggestions about how IRBs should think about different kinds of research projects. When research involves identifiable samples, the informed consent provisions should be detailed and reviewed carefully to ensure that they address all of the relevant risks (physical and psychosocial) that subjects may face.

Other factors that IRBs should consider include whether there should be recontact provisions (and what their nature should be) and whether informed consent forms should have opt-out provisions allowing people to request destruction of samples after a certain point.

When research involves anonymous research samples, no specific informed consent should be required.

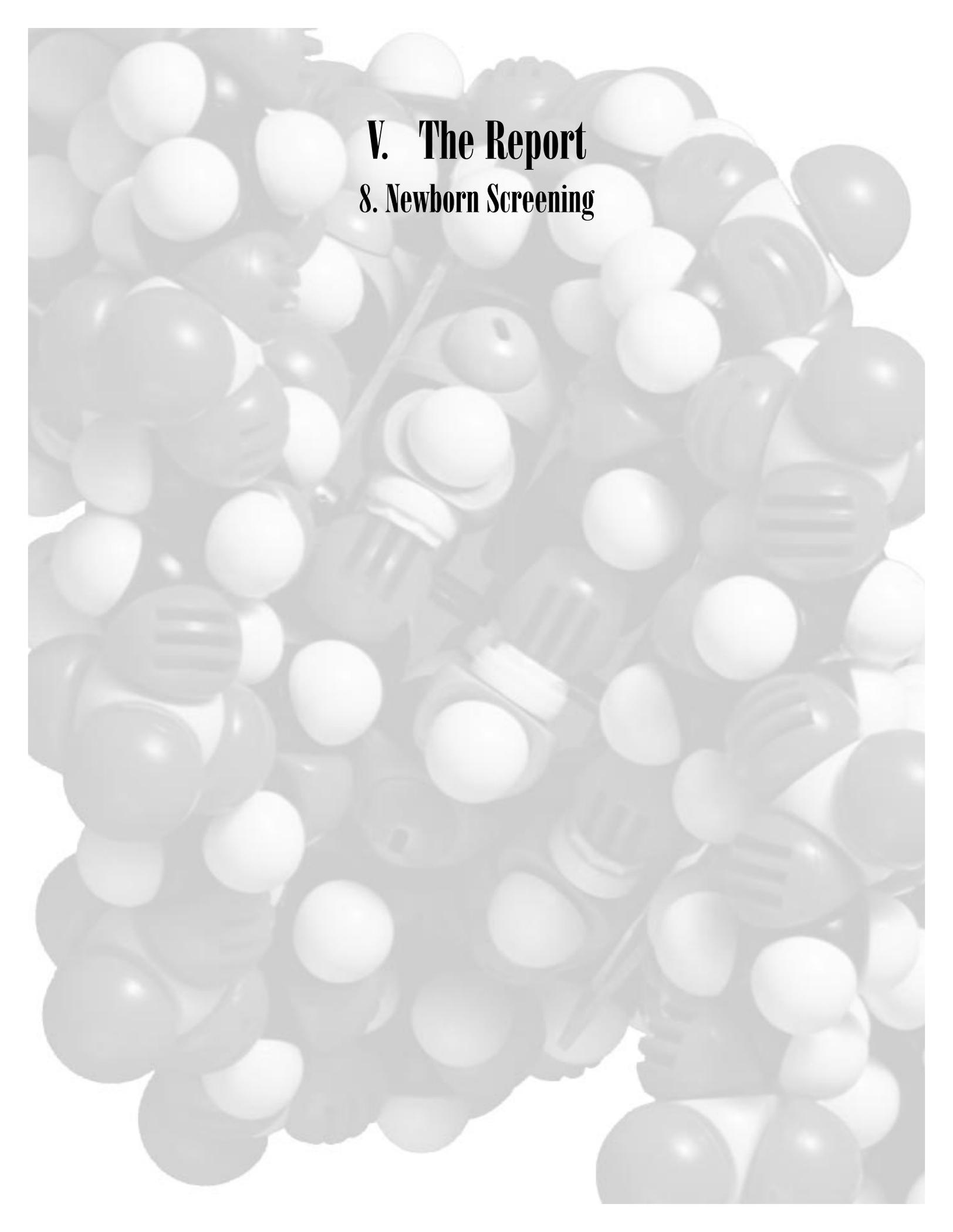
While IRBs offer some protection with respect to human subjects, their scope does not encompass research that is not publicly funded or under assurance with the federal government. This is a general human subjects research problem, but it is particularly important with respect to genetics research because such research is increasingly being conducted in the private sector. We therefore believe that IRB protections should apply to all human subjects research whether or not it is publicly funded. One solution would require IRB approval for any private research conducted in Michigan that would not otherwise be subject to IRB review.

## Recommendation

The commission recommends legislation that requires the following before a genetic test is performed or a study is conducted. The person proposing the test must:

1. Inform the patient of the purpose of taking the sample; what tests will be performed; what the risks, benefits and alternatives are; who will have access to the test results; what will be done with the information and how results will be retained.
2. Give the patient a chance to decline the test and inform the patient of any consequences of declining. For example, if the test were mandated by law (tuberculosis for hospital employees), refusal could result in loss of an employment opportunity.
3. Provide the test results to the patient, if the patient desires the results, so the patient can understand the results and whether there is any need for follow-up.
4. Consistent with Michigan law, keep the test results confidential, not share the results with third parties without consent, and inform the patient where and how results will be stored. The patient should be granted access to results so that the patient can determine whether the test results are stored in a secure and appropriate manner.
5. The professional community should determine the content of the informed consent since the content will change over time.

<sup>5</sup> CFR § 46.103.



# **V. The Report**

## **8. Newborn Screening**



# Newborn Screening

**Issue:** Should newborn screening only occur after parental consent is obtained? What rules should the state impose concerning subsequent use of newborn screening specimen cards?

## Introduction

Newborn screening for identification of specific diseases is compulsory in all states except Maryland and Wyoming. It is mandated under the parents patriae doctrine, which permits state intervention to protect the health and safety of its citizens. Newborn screening is limited primarily to diseases that can be effectively treated in the newborn period to prevent irreversible physical and mental changes. Implicit in the rationale for newborn screening is that the diseases for which newborns are screened can be effectively treated. Therefore, additional diseases should not be added to newborn screening panels without validation of diagnostic and treatment modalities.

## Background

**Controlling Law:** Act No. 81 Public Acts of 1992 (MCLA § 333. 5431) states that “A health professional in charge of care of a newborn infant shall administer or cause to be administered to the infant a test for phenylketonuria, galactosemia, hypothyroidism, maple syrup urine disease, biotinidase deficiency, sickle cell anemia, congenital adrenal hypoplasia and other treatable but otherwise handicapping conditions as designated by the department.”

**Laboratory Oversight:** Laboratory oversight of the State Newborn Screening Laboratory derives from federal law and regulation. (Clinical Laboratories Improvement Act of 1988, CLIA ‘88, 42 CFR 493, Federal Register, February 28, 1992.)

**Collection and Storage:** Since newborn screening is mandated under state law, parental consent is not required. The state has developed informational booklets describing newborn screening; however, these are not always available to or read by parents.

Specimens are collected prior to the newborn’s discharge from the hospital by means of heel pricks from which blood drops onto newborn screening cards. The blood spots are air-dried and forwarded on to the Michigan Department of Community Health’s Newborn Screening Laboratory where analyses are performed. When abnormalities are found, referral is made to the designated medical specialty site for further testing or evaluation of the infant.

The newborn screening cards are stored in an unheated warehouse. There is inadequate information about how long these specimens remain suitable for current methods of analysis, even under ideal storage conditions (see Therrell article in Appendix). However, it is clear that DNA samples stored under less than optimal conditions do remain stable for many years. Since it can be reasonably anticipated that in the near future DNA testing will largely replace the so-called bacterial inhibition assays and other methods for newborn screening, storage of samples can be anticipated to be less of a problem.

Some problems associated with storage include the fact that not all newborn screening cards, as they are sent to the newborn screening laboratory from the hospitals, are as well-separated from each other as they could be. Contamination of specimens may result if the samples have not been allowed to dry adequately prior to shipment. Inadequate separation of specimens, if it occurs while in warehouse storage, is not a serious problem because the specimens are already dry. Moreover, newer modifications of DNA testing should minimize contamination-related problems. The commission noted that correcting the problem of inadequate specimen storage does not necessarily require the introduction of new techniques, but rather careful use of current techniques.

**Period of Sample Retention:** Samples have been retained since the onset of the newborn screening program. The federal Clinical Laboratory Information Act (CLIA) requires that records of results be kept for two years and that samples be retained as long as is medically appropriate.

## Issues

**Consent:** As already noted, state law mandates newborn screening.

Research Use of Newborn Screening Cards: Not all of the sample spots on an individual newborn's screening cards are used for newborn screening. At present, some sample spots cleaned of any linkage to the babies' identification may be used for epidemiological studies under the aegis of MDCH. No parental consent is required for this; however, MDCH has rules for review and approval of the research proposals. Similarly, samples that are anonymous, but linked, are utilized without parental consent for the following purposes by MDCH:

- Research related to newborn screening at the time of collection
- Assessment of new technology
- Quality control
- Minimal risk research

Informed parental consent is required for research on identifiable samples. The samples may be used for familial research and forensic identification as requested or general research not associated with newborn screening.

**Storage:** Problems in the area of storage and sample retention relate to cost and effectiveness. For current methods of analyte testing of dried blood spots, the optimal storage temperature is believed to be at or below  $-20^{\circ}\text{C}$ , with a controlled humidity and adequate separation of specimen cards to prevent cross contamination. As noted previously, in Michigan newborn screening samples are stored in warehouses at ambient temperatures.

With evolving technology, especially as DNA analysis becomes more prevalent, simplified storage requirements are anticipated. For DNA testing of dried blood spots, ideal storage is at or below  $4^{\circ}\text{C}$ ; however, DNA from dried blood spots stored in the MDCH warehouse have been successfully performed years after collection.

As an indication of what changing technology is bringing to the area of sample retention, DNA analysis of buccal smears have been successfully used for forensic and paternity DNA specimens. These specimen cards can be readily stored at room temperature. Application to the area of newborn screening may be expected.

**Retention of Specimens:** As noted previously, there are conflicting views about how long newborn screening samples should be retained. As required by CLIA, laboratory records are retained for two years; however, the samples themselves are to be retained as long as medically necessary.

Newborn screening samples contain a wealth of information. Even though current storage methods are less than optimal for current analyte screening methods, the increasing use of DNA for screening, forensic identification and familial and medical research (for example, DNA markers in cases of childhood lymphoma in children whose newborn screens are still on file) suggests that these specimens should be retained for the present.

**Safeguarding data/samples:** The newborn screening laboratory has policies and procedures to assure that privacy and confidentiality are maintained. To maintain computer security, access is restricted to those who need to know. Staff education emphasizes the need for confidentiality and penalties for violations are enforced.

Newborn screening data are protected from third party access. Information about newborn screening is not provided to insurers. Family members other than parents who wish to obtain information about a child's newborn screening must obtain parental consent until the child reaches the age of majority, when the grown child may give consent. Generally, parental consent is obtained in the event of a court order for information, such as in cases of missing children.

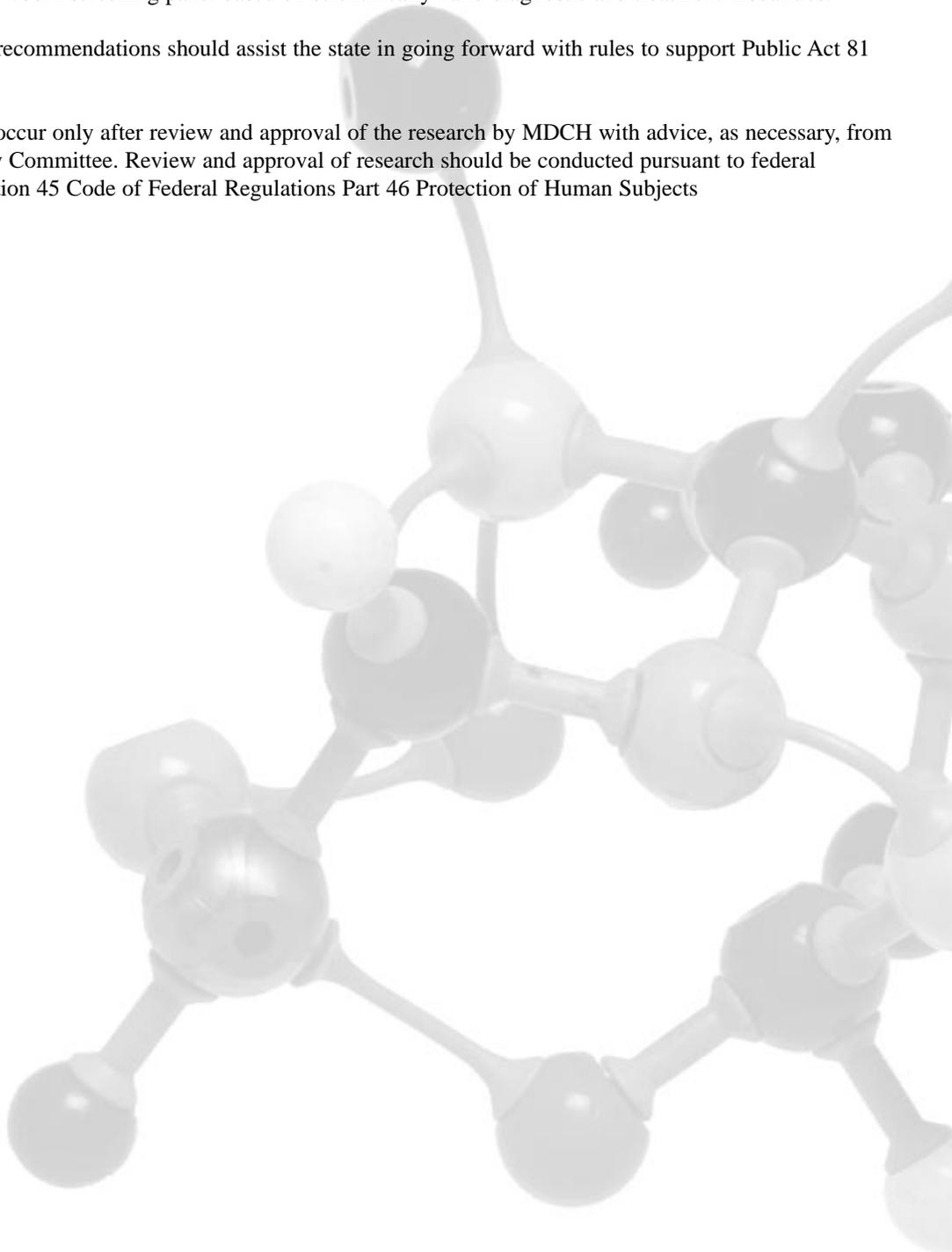
## Recommendations

1. The commission recommends that parental consent not be required for newborn screening for diseases that can be accurately diagnosed and effectively treated to prevent irreversible physical and mental changes or ameliorate a chronic condition.
2. Newborn screening should be restricted to conditions for which there is an accurate diagnosis and treatment that is both efficacious and effective to prevent irreversible physical or mental changes or ameliorate a chronic condition

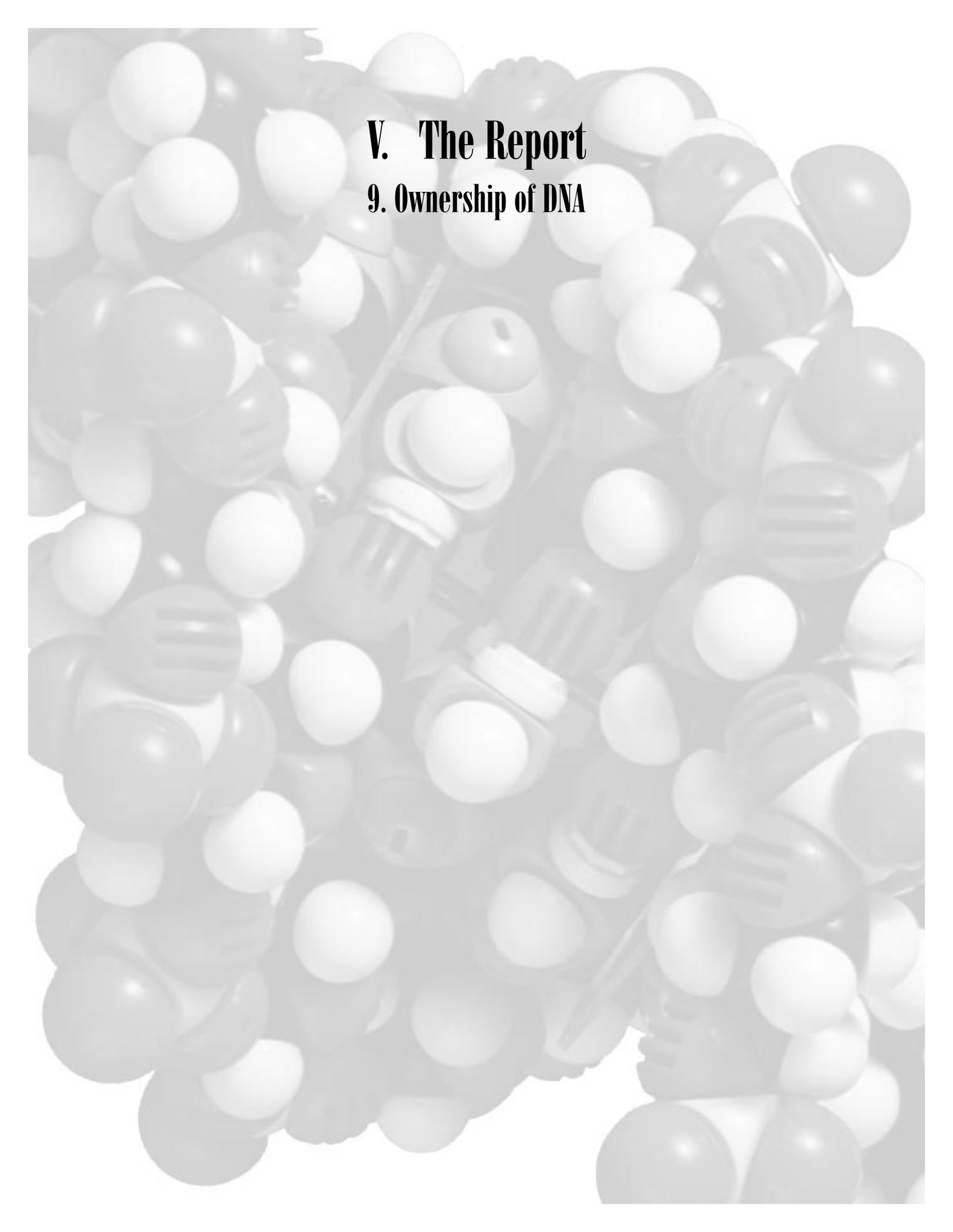
3. The commission recommends that parents be given an opportunity to opt out of having their newborn's screening test card used in future research. This could be done by distributing an informational pamphlet at the time of screening with information about the process. The pamphlet could contain an MDCH telephone number that parents could call to invoke the opt-out provision.
4. The commissioners believe that the newborn screening specimens represent a vital resource for the study and treatment of disease. Not only are these specimens potentially of value in our understanding of the public's health, but they can be used, with appropriate consent, by families with special or recurring medical problems and in the identification of missing persons.

Because of their present and potential value, the commission recommends that newborn screening samples be retained indefinitely.

5. The commission recommends that the existing Genetic Disease Advisory Committee assist the Department of Community Health in making determinations regarding research, retention of specimens, as well as issues such as the advisability of adding new diseases to the newborn screening panel based on scientifically valid diagnostic and treatment modalities.
6. The commission believes its recommendations should assist the state in going forward with rules to support Public Act 81 of 1992.
7. Research on samples should occur only after review and approval of the research by MDCH with advice, as necessary, from the Genetic Disease Advisory Committee. Review and approval of research should be conducted pursuant to federal regulations on research. Section 45 Code of Federal Regulations Part 46 Protection of Human Subjects Section 46.101.et.seq.







# **V. The Report**

## **9. Ownership of DNA**



# Ownership

**Issue:** Should individuals have an exclusive property interest in their DNA samples or genetic information?

**Background:** Statutes in some states have created property rights in genetic samples and information. The expressed rationale is to allow patients to protect their samples and to avoid commercial use of the samples. The laws do not specify the nature and extent of such rights.

Presently the full implications of creating such rights are unclear. At worst, these rights will lead to exceedingly complex and unnecessary legal entanglements as well as increased research costs. The laws conflict with existing law, regulation and practice. For example, federal law on clinical laboratories requires that laboratories keep samples for at least two years. State law requires that hospitals keep pathology samples. State law in the area of medical malpractice allows malpractice cases to be brought for up to six years post date of treatment. Clearly a facility would need access to the pathology slides and tissue samples to defend itself in a case alleging misdiagnosis or failure to diagnose. If a patient were allowed to remove their tissue samples from the hospital, it would make it impossible for the hospital to comply with the Federal Clinical Laboratories Act and impossible to defend itself adequately against a claim of failure to diagnose or misdiagnosis. The commission believes that the creation of property rights will do little to serve, and may even contravene, the purpose of creating such rights.

The commission believes that protecting privacy of medical information in conjunction with adequate informed consent about the uses to which samples will be put is a better mechanism for protecting individuals than creating a new property right in genetic samples or genetic information. If, for example, a researcher intended to use genetic samples for commercial gain, the researcher would have to disclose this to the prospective subject and the subject would then decide whether to donate the samples.

**Analysis:** Whether individuals should have property interests in their genetic samples and genetic information is an area of particular interest. Increasingly, some ethicists, legislators, scholars and lawyers are considering the creation of genetics property rights.

The issue is not entirely straightforward since ownership is not an absolute concept. Ownership or property rights may be subject to restrictions or simply be limited. In the law, we frequently talk about a bundle of property interests, which may be shared among a number of different individuals. In other words, having a property interest in something only means that one has at least some of the sticks of interests in the bundle; it does not imply that one has the whole bundle of interests. Some of the key elements (or sticks) that make up the bundle of ownership interests include:

- a. The right of exclusion (right to exclusive possession or enjoyment)
- b. Control over how the object is used or kept from use (transferability)
- c. Devisability (transferring through will and testament)
- d. The right to use and manage the property
- e. The right to alter, destroy or alienate (transfer, often through sale)
- f. The right to the income, capital and security
- g. Length of terms of ownership interests
- h. Duty to forbear from harmful use

A claim that the law should recognize a property interest in genetic information could be based on the following reasons:

- a. An individual possesses the DNA in her body, and therefore the genetic information is physically located in her cells
- b. The information is uniquely hers.
- c. The individual can exclude others from using or benefiting from the use of her genetic material by restricting access to her cells—by controlling disposal of her hair, body fluids, waste products, etc.
- d. The genetic information can be wasted, modified, destroyed or alienated only by the person in whose cells the genetic material resides.
- e. The individual cannot be forced to expropriate the information encoded in her DNA; she controls who has access to that information
- f. Only the individual can give away the genetic information in her cells.

Some of the arguments used to defend genetic ownership rights are problematic, however. First, some of the discussions conflate the terms genetic information and genetic material, treating them too often as one and the same. In addition, people often point to the uniqueness of genetic information, forgetting that a vast majority of everyone's DNA is very similar to everyone else's. Only a small percentage of our genetic material is really unique.

A larger problem is that many proponents of property rights ignore the fact that the law treats body parts differently in terms of property interests, depending on whether the body parts are still part of you and whether the body parts are regenerative. One cannot be required to give up cells within one's body, in large part because the law recognizes an individual's right to bodily integrity. In fact, this is one of the principles underlying informed consent law. Yet, once you consent to have your body parts removed, you no longer have the same level of legal control over those body parts.

For example, in *Moore v. Regents of the University of California*, Moore consented to have his spleen removed. His spleen was used to create cell lines that generated lucrative pharmaceutical products and Moore sued for conversion of his property, including the cells and genetic material of his spleen. The California Supreme Court held that he did not have a property interest in the excised material, although he had a cause of action for lack of informed consent. As the court noted, California statutory law drastically limits any continuing interest of a patient in excised cells. In addition, the subject matter of the patented line was not Moore's property since it was factually and legally distinct from the excised cells.

The ruling was in line with the general legal trend to allow individuals to sell regenerative materials — such as hair, blood, and semen — but not solid organs. The court's ruling, however, was largely influenced by policy considerations, in particular the need to balance the patient's rights of privacy and autonomy against the public interest in promoting research. The court concluded that recognizing property rights in this case would severely hinder research since biological materials are routinely distributed to other researchers. All of the researchers could therefore potentially become part of a long chain of individuals sued for claims like conversion, and tracing the title of ownership would be exceedingly complex, if even possible. The likely effect might be reluctance on the part of companies to invest in product development and researchers to avoid research, given the difficulties of establishing whether a clear title exists. The court reasoned that informed consent principles would protect the patient's autonomy interests in protecting bodily integrity by requiring a researcher to disclose her commercial interests in the material.

We need not adopt the rationale of the *Moore* court. That case reflects the evolving common law in California, not Michigan. Nevertheless, the commission supports the *Moore* line of thought with regard to property rights in genetic samples and information for several reasons. First, it is never fully clear what individuals mean when they say that there should be property rights in genetic information and samples. Which specific bundles of interests would they protect? This is highly relevant since it would greatly influence the hurdles or barriers that researchers, clinicians, insurers, etc. would need to overcome in order to obtain genetic information or tissue samples.

Second, creating property interests would dramatically change the legal landscape and would likely conflict with many state and federal statutes and regulations that govern the control and management of both medical information and tissue samples. Too little attention is paid to the issue of whether proposed legislation would impose conflicting duties on researchers and clinicians.

Third, we have yet to find a persuasive argument that property interests necessarily do a better job of protecting autonomy interests than informed consent law. This is particularly important, given the large uncertainty about precisely what it would mean to have a property interest in the genetic information and samples. If we are going to change the legal landscape so profoundly, we need to be fully cognizant of the long-term implications and fully clear about exactly which interests we are carving out.

Finally, this problem raises the very difficult issue of defining exactly what we mean by genetic information and genetic samples. If we head down the path of creating property interests in genetic information and samples, with all of the attendant difficulties that such legislation or common law would present in the area of research, clinical care, underwriting, etc., we need to recognize that careless descriptions of the property being protected only exacerbate those problems.

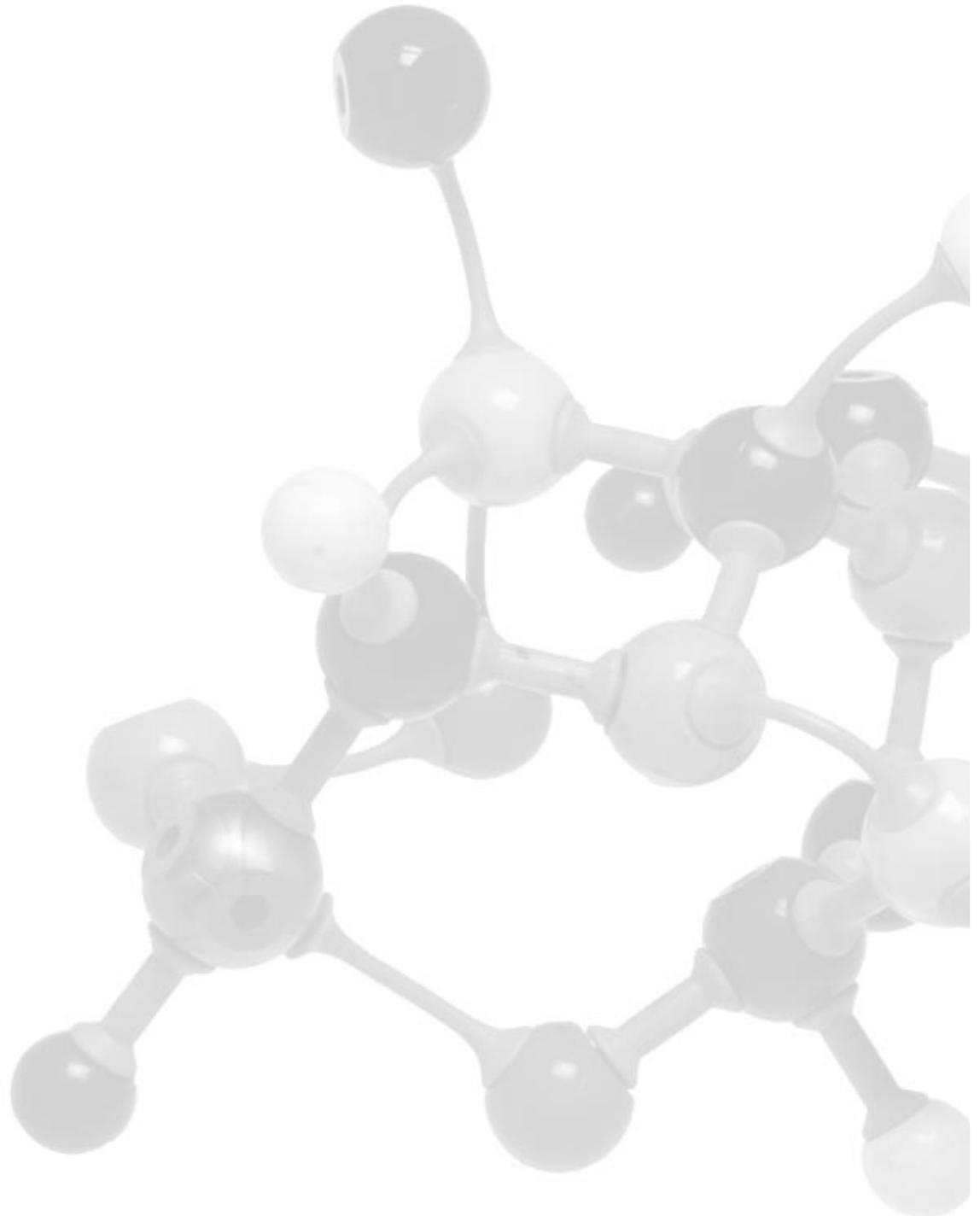
Thus, we propose that in order to protect individual's autonomy and privacy interests, we should focus on developing and honing legal mechanisms already in place rather than quickly restructuring the legal system in rather dramatic ways, at least at this point. We believe it is too early to go the "property" route, if ever we should take that route. Instead, we should focus on informed consent mechanisms, confidentiality protections of medical information and security mechanisms for storage of information and samples.

Many of the ownership concerns can be addressed through these mechanisms. For example, informed consent prior to obtaining samples can address who has access to samples, who has control over destruction of samples, what future uses will be allowed, and questions of research and commercial use. Most importantly, opt-out provisions when samples are collected in the clinical or research setting can allow individuals to have a say in whether their genetic material is used for genetic research. The real work of protecting individual autonomy, therefore, will turn on informed consent and the nature of information that a person must have prior to donating samples, and the nature of aspects of use to which the person must consent.

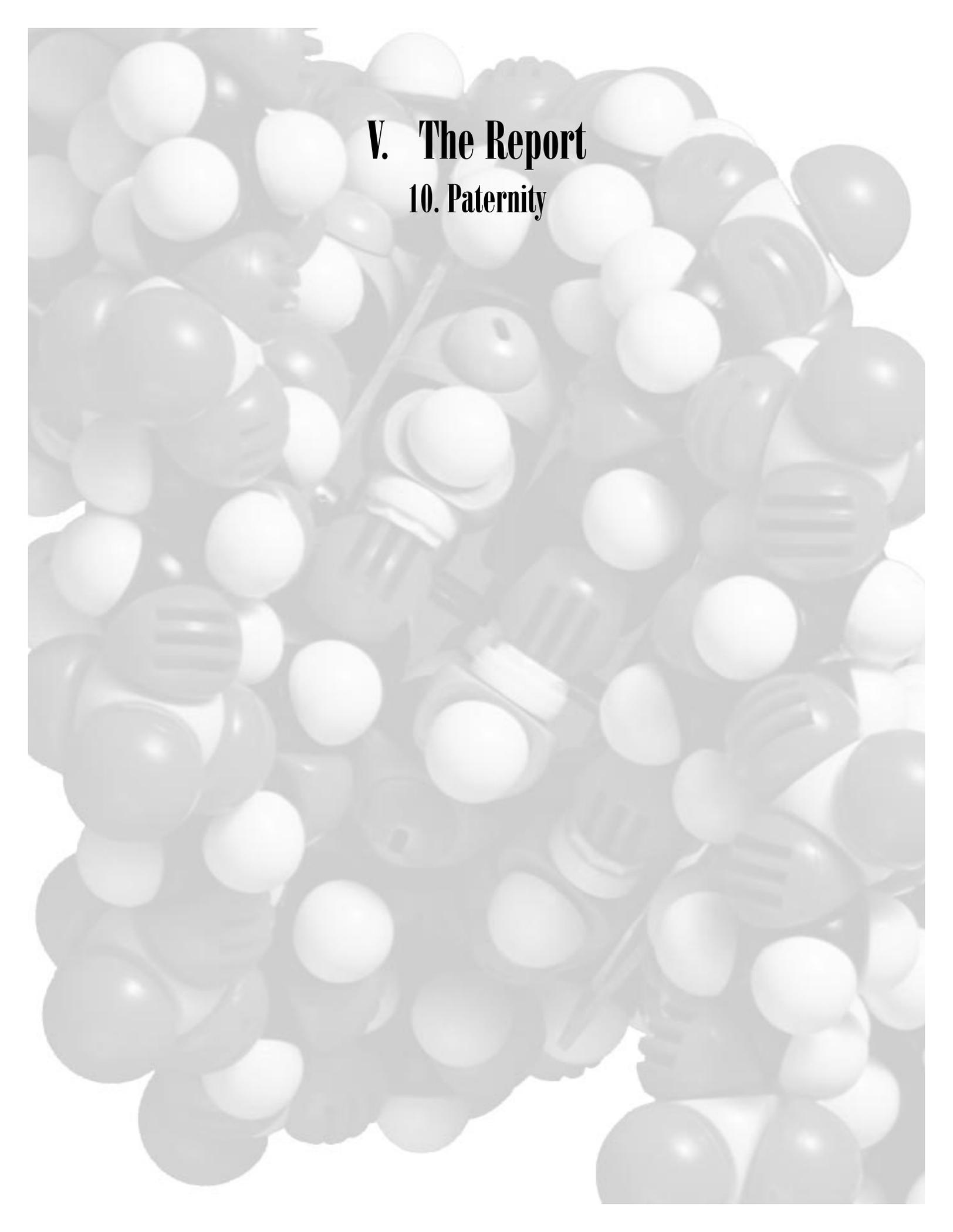
At this point, we favor maintaining the status quo because too little is currently known about many things, including 1) the magnitude of the potential harms that ownership interests are intended to avert, 2) whether ownership interests would solve the problems better than other legal mechanisms and 3) what the negative consequences might be in establishing ownership interests.

## **Recommendation**

The commission recommends that property rights in genetic samples and information not be created for the individual providing the samples.







# V. The Report

## 10. Paternity



# DNA in Paternity Testing

**Issue:** How should genetic information and materials taken for paternity testing be protected?

## Introduction

A large number of paternity tests are obtained voluntarily by the mother or putative father wishing to establish paternity. The remainder of the tests are initiated by the Family Independence Agency (FIA) through county prosecuting attorneys' offices in confirming eligibility for public assistance pursuant to Title IV-D of the Social Security Act.

## Background

In June 1998, the Michigan legislature passed Act No. 113 of the Public Acts of 1998 (MCLA §722.711 et seq.), amending the older Paternity Act (Act No. 205 of the Public Acts of 1956). Among other provisions, the 1998 statute deals with DNA paternity identification and specifies procedures for collection of specimens, reporting results of DNA testing, destruction of samples and ensuring individual privacy. The law is discussed below.

As of this writing, the state has concerns about the destruction of samples in cases in which paternity is excluded, privacy and confidentiality, expungement of records, and ambiguities caused by incomplete definitions.

## Elements of Act No. 113 of the Public Acts of 1998

**Consent:** The putative father may either acknowledge the child or undergo DNA testing, which is either voluntary or court ordered. When testing is ordered by the court, MCLA §722.714a (2) requires that the prosecuting attorney's office provide information about the nature of the test, the purposes for which it is being done, its uses, the reporting of the test results and the putative father's right to have the test results kept confidential, except as provided in section 6a.

**Testing:** MCLA §722.716(2) provides that a "DNA profile determination shall be conducted by a person accredited for paternity determinations by a nationally recognized scientific organization, including, but not limited to the American Association of Blood Banks." MCLA §722.716(a) (2) specifies that the national standards under which the testing laboratory is accredited shall determine the period for retention and destruction of paternity testing materials.

Most paternity testing ordered by the prosecuting attorneys is conducted by private laboratories, which have contracts with the state. To establish parentage, DNA profiling of blood is performed on samples of blood from the mother and child as well as the putative father. The child's genetic pattern is derived in equal portions from the mother and the father; the child's pattern is compared with both. As the first step, the bands that are present on both the mother's and child's patterns are marked. The next step is to compare the unmarked bands in the child's pattern with the bands in the father's DNA pattern. The number of matches between father and unmarked child bands is recorded. The probability of the putative father's having this number of bands matching those of the child's pattern is calculated. (Cellmark Diagnostics, DNA Fingerprinting<sup>SM</sup>: The Future of Identification [Germantown, MD]).

MCLA §722.716(5) provides that paternity shall be presumed if the probability of paternity is greater than 99 percent and states further that if "two or more persons shall have a probability of 99 percent or higher, paternity is presumed for the person with the highest probability."

**Reporting Results of DNA Profiling:** The American Association of Blood Banks (AABB), which accredits the laboratories doing the majority of paternity tests for the state of Michigan, has devised a standard form for reporting results of paternity testing.

The paternity report in its entirety, including the patterns of the mother, child and putative father, as well as the probability of paternity, is filed with the court according to MCLA §722.716(4).

Absent the timely filing of objections, the putative father is presumed to be the father of the child if the reported probability of paternity is higher than 99 percent. With this laboratory report for guidance, the court establishes paternity, usually in an Order or Judgment of Filiation.

The entire report of the case in which paternity is established appears on the court record. Court records are not sealed and they are open to public scrutiny. The report includes both the probability of paternity and information about the test patterns. The test result patterns are unique to the mother, father and child tested, although they don't reveal genetic predispositions.

**Retention of Samples and Results:** As noted earlier, MCLA §722.716(a) (2) specifies that the national standards under which the testing laboratory is accredited shall determine the period for retention and destruction of paternity testing materials. If as a result of DNA paternity testing the putative father is judged to be the child's father, then the genetic testing materials of the mother, child and father are required to be retained for the length of time set by national standards. If the putative father's test reveals he is not the child's father, his genetic testing material is required to be destroyed after the testing is completed. The mother's and child's blood must be retained for the prescribed period so that it may be used for further testing. When testing material is destroyed, the adult individual or the guardian of a minor individual whose blood has been tested is to be notified by certified mail.

**Confidentiality:** The Family Independence Agency or its designees and the contracting laboratories are required to maintain the confidentiality of the genetic testing material, which is defined as, "any substance or information used for or produced by genetic paternity testing under this act other than a report submitted to a court for a paternity determination."

## Recommendations

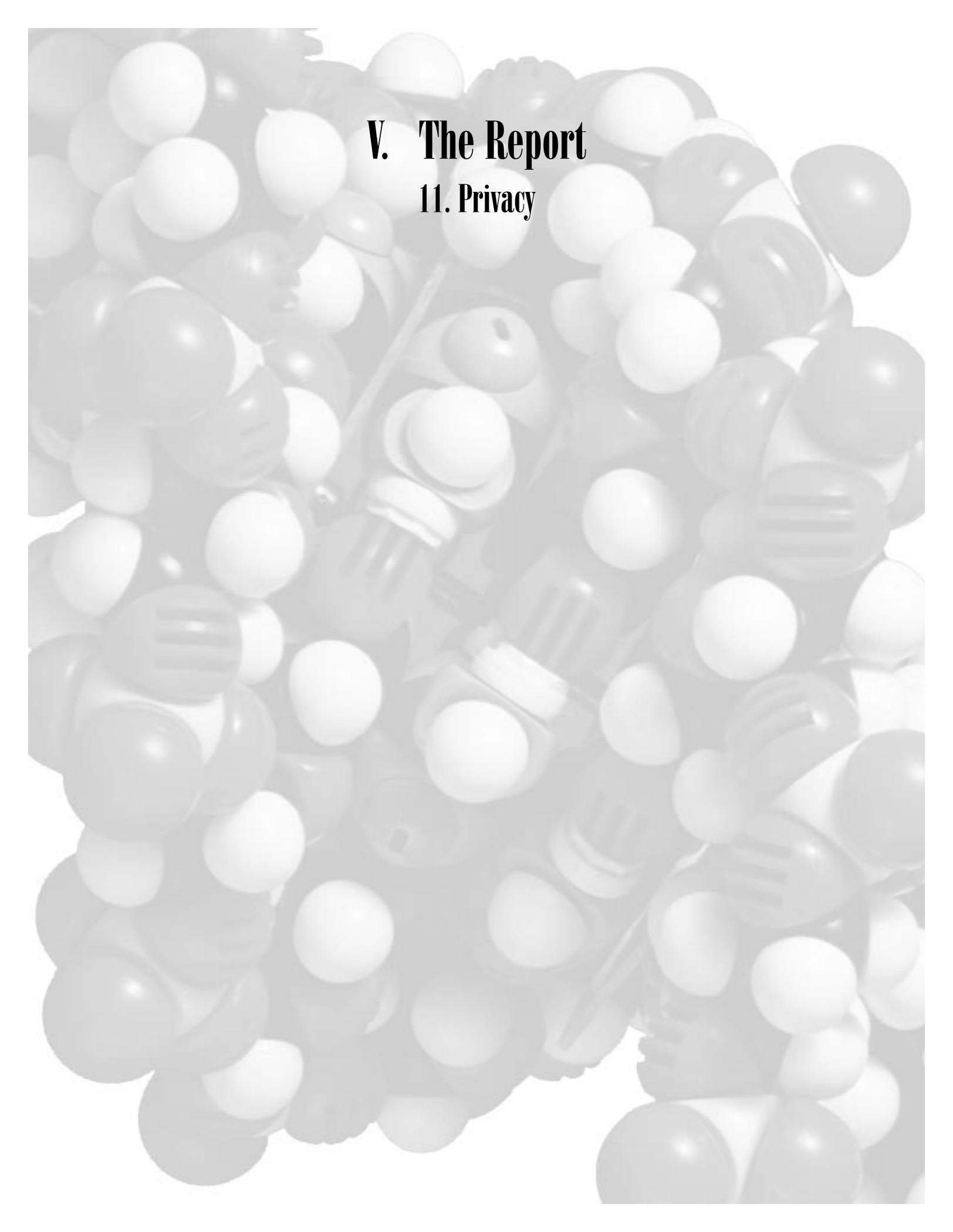
The commission makes the following recommendations:

1. Once the court establishes paternity, the report as it appears in the open court record should contain only the probability of paternity. The commission believes it is important to modify the form of the laboratory report so that the genetic information it contains does not become a matter of public information.
2. P.A. 113 deals with testing materials, which are defined in Sec 1.(d) as, "any substance or information used or produced by genetic paternity testing conducted under this act other than a report submitted to a court for a paternity determination." Substituting "genetic testing materials" for "testing material" would clarify that the samples are being referenced.
3. Provisions concerning elimination samples in Act No. 113 of the Public Acts of 1998 concern: (1) destruction of samples when an individual is not the father and (2) notification of destruction of these samples. The obvious intent of these provisions is to protect individual privacy.

To facilitate the process involved in protecting of privacy in the paternity act, the commission suggests that the testing laboratory be responsible for destruction of samples and the expungement of records in accordance with recognized national standards of the laboratory's accrediting body. The records detailing both the destruction of samples and the expungement of records for paternity tests performed in Michigan should be audited in accordance with rules promulgated by the state.

4. According to MCLA §722.716(5), paternity is presumed if the probability of fatherhood is greater than 99 percent. If two or more persons have a probability of paternity greater than 99 percent, paternity shall be presumed for the one with the highest probability. This may result in an incorrect identification. The commission recommends that testing be fully carried out until all but one of the putative fathers is eliminated.

To accomplish this, the law should be amended to read as follows: "If the results of the analysis of samples from two or more persons indicate a probability of paternity greater than 99 percent, subsequent tests should be performed until all but one of the putative fathers is eliminated."



# V. The Report

## 11. Privacy



# Privacy

**Issues:** Is there a specific need for state privacy laws concerning genetic information? Should there be any exceptions allowing physicians to disclose genetic information? Should there be considerations for research?

**Background:** Michigan has a comprehensive statutory scheme protecting access to health care information. Genetic information is thus protected under these rules. Special protection has been suggested because of the relevance of genetic information for family members, but special protection is unlikely to succeed. A preferred approach is to protect all health-related information.

Michigan has laws on professional-patient interaction, including doctor-patient, dentist-patient, social worker-patient, counselor-patient and psychologist-patient protection. Each of these laws balance social policies. For example, the doctor-patient law, MCLA 600.2157, states that all information necessary to diagnose and treat is confidential except as otherwise provided by law.

Michigan also has specific laws dealing with research confidentiality. For example, MCLA 333.2631 states that information shared with the Michigan Department of Community Health for medical research concerning mortality or morbidity is confidential and shall not be further disclosed.

Michigan has general medical privacy laws and also has specific laws in the areas of HIV and substance abuse. For example, MCLA 333.6111 states that records of the identity, diagnosis, treatment and prognosis of substance abuse patients are confidential.

Genetic information is just one part of a patient's total medical record and policies intended to protect genetic privacy must also cover the privacy of all health-related information.

Michigan also has specific laws concerning genetic information:

1. The DNA Identification Profiling System Act allows the Michigan State Police to retain DNA identification profiles of individuals convicted of attempted murder, first and second degree murder, kidnapping or criminal sexual conduct in any degree including assault with intent to commit criminal sexual conduct. MCLA 28.171.
2. The newborn testing law requires testing of newborns for seven specific genetic conditions. MCLA 333.5431. This information is kept by the state. The section of this report on newborn screening makes recommendations about these test results.
3. The law on chronic disease prevention and control requires the Department of Community Health to establish a chronic disease prevention and control program including genetic diseases. MCLA 333.5401.
4. The Michigan Adoption Code has provisions about obtaining biological information on an adopted child, including genetic conditions. MCLA 710.68(a).
5. Paternity testing can be done by blood or genetic testing and Michigan has a central paternity registry.

The federal government has been actively engaged in thinking about a federal privacy law for health information. In 1996, Congress passed the Health Insurance Portability and Accountability Act of 1996, which set a deadline for Congress to protect personal privacy. The law required the Secretary of Health and Human Services to recommend to Congress ways to protect individually identifiable information and establish penalties for wrongful disclosure of personal medical information. Secretary Shalala presented those recommendations to Congress September, 1997. Congress now has until August, 1999 to enact a privacy law. If Congress fails to act, the Secretary of Health and Human Services is directed to promulgate regulations relating to privacy of health information by February 21, 2000. Thus, the federal government will soon be creating federal privacy laws.

The secretary's report, submitted September 11, 1997, recommended that Congress enact national standards to provide fundamental privacy rights for patients and to define responsibilities for those who serve them. A summary of the recommendations is part of the commission's work papers.

It is likely that the federal government will pass medical privacy laws, including rules for genetic privacy, and that those laws will act as a floor for state legislation. It is, however, possible that the federal government will enact laws that preempt other state legislation.

An important balancing act must be considered here. Confidentiality is important to maintain trust between physicians and patients and to protect patients' health care information. At the same time, it is important to conduct health-related research including genetic linkage studies and outcome analyses. At the moment, the state and federal governments want both to improve the health care system and to increase privacy of health care information. This means that any privacy laws will need exceptions for authorized research.

**Analysis:** Given the major thrust for federal legislation, it is probably premature for the state to spend a great deal of time creating privacy laws that ultimately may be superseded by federal action.

It is important to balance the interest in ongoing research and protecting patient privacy.

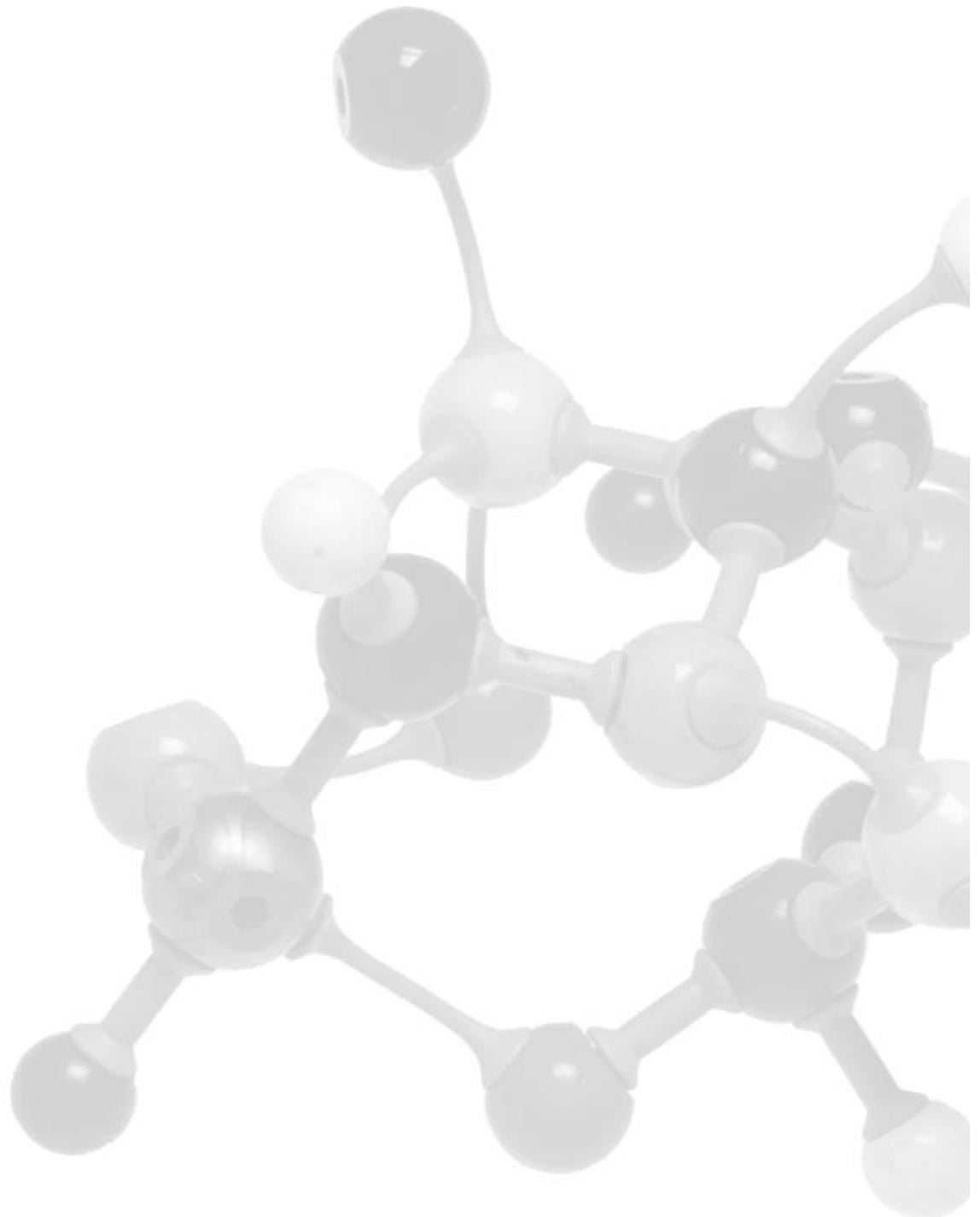
## Recommendations

1. The commission recommends that genetic information be protected just as all medical information is protected. The commission does not recommend special protection for genetic information since the commission feels that it is critically important to protect all medical information and it would not be useful to create a separate set of laws for genetic information. The commission believes it is important to consider both use of and access to information. The commission believes that research uses are important and access can be controlled in a way that keeps confidentiality intact. Exceptions to confidentiality should exist for criminal investigations, court proceedings, paternity disputes, decedent identification, convicted criminals and newborn screening. After the federal government enacts privacy legislation the state can conduct an analysis to determine the need for any state legislation.
2. The commission recommends that no state law be enacted that would prohibit legitimate research from occurring. Federal law will generally govern research, but the state can, through the use of existing laws such as MCLA 333.2631, provide added protection to genetic research. For example, MCLA 333.2631 states that information shared with the Michigan Department of Community Health while conducting medical research concerning mortality and morbidity is confidential and cannot be further disclosed. That law could be broadened to say that information shared with the department while conducting medical research concerning mortality and morbidity, genetic studies or other studies approved by the department would be confidential and could not be further disclosed.
3. The commission notes that in the area of genetics, family access to medical information may be important. Accordingly, the commission recommends that there be consideration for access to information about deceased family members when there is a demonstrated need by the living family members to have the information to conduct appropriate genetic studies. A law could indicate that for family members who have been deceased 100 years or more there should be open access. If the family member has been deceased fewer than 100 years, either an executor could grant access or, in the absence of an estate, a physician could obtain access to the records upon a showing that there was a need for the information to provide appropriate health care for living family members.
4. Further, the commission believes the state should enact a narrow law allowing, but not requiring, a physician to disclose information to a family member under the following limited circumstances:
  - a. A patient has a genetic variant that other family members could also have inherited.
  - b. The variant is associated with a condition that is either treatable or is important to be disclosed to avoid future injury.
  - c. The patient, after appropriate counseling, refuses to share the information or allow the information to be shared with other family members.
  - d. Failure to share the information could result in serious physical harm to the unknowing family member.

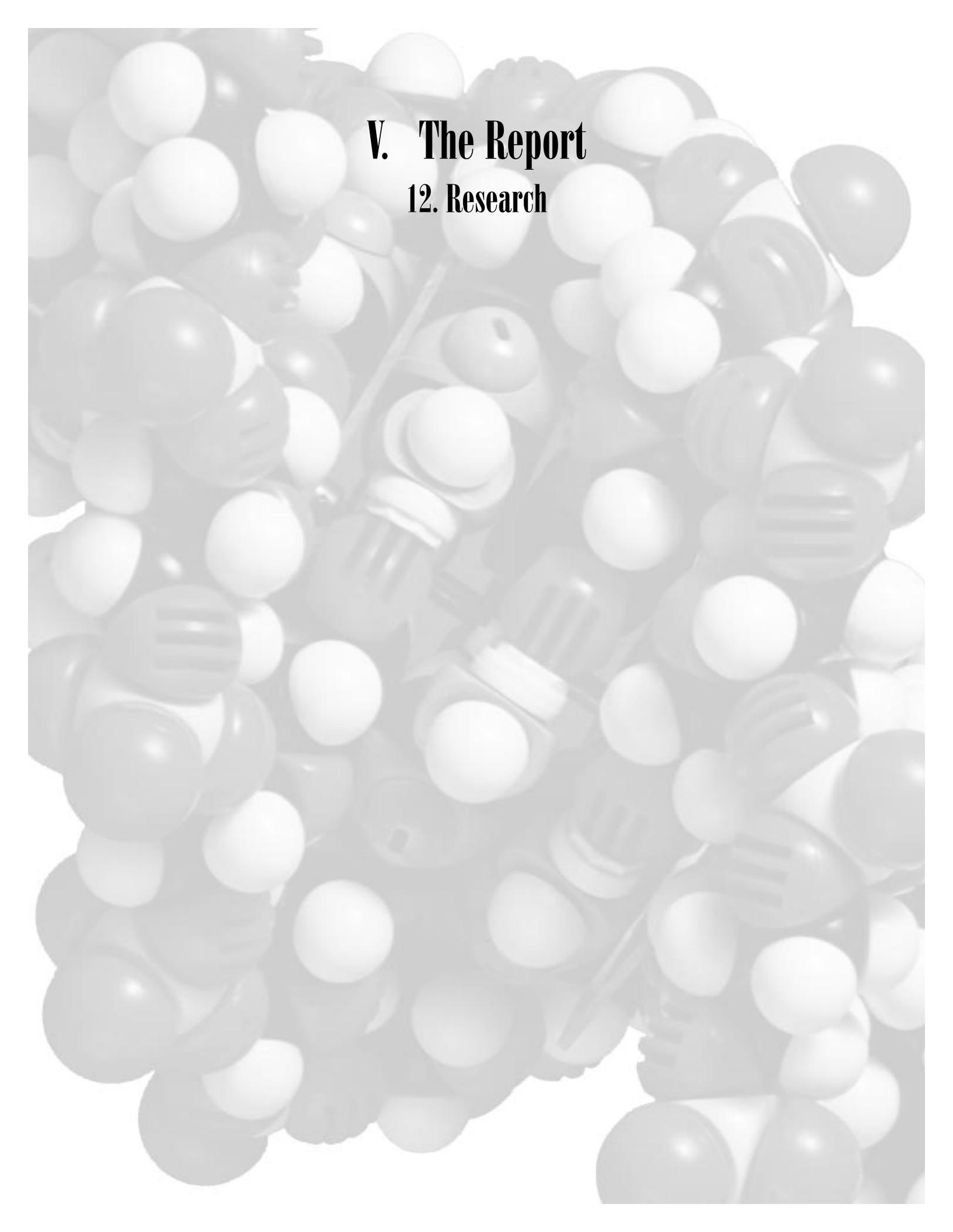
In these very limited circumstances, the commission believes that the health care professional (physician or counselor) should have the option to disclose the information and should be immune from liability for disclosing or not disclosing. This would require a limited exception to doctor-patient confidentiality.

5. The commission also recommends that any privacy laws should consider both release and re-disclosure of information. In some cases, as indicated above, it may be appropriate to disclose information to a third party but only on the condition that the third party cannot re-disclose the information.

6. Finally, the commission recommends that health care professionals, employers and anyone else with access to genetic information must provide full information to a patient or consumer so that the consumer can make an informed choice before submitting to any testing. This means that there would be a full discussion of the test, its implications, who would have access to the test results, how the test results would be used and how the results would be kept confidential. This is discussed in the section on informed consent.







# V. The Report

## 12. Research



# Research

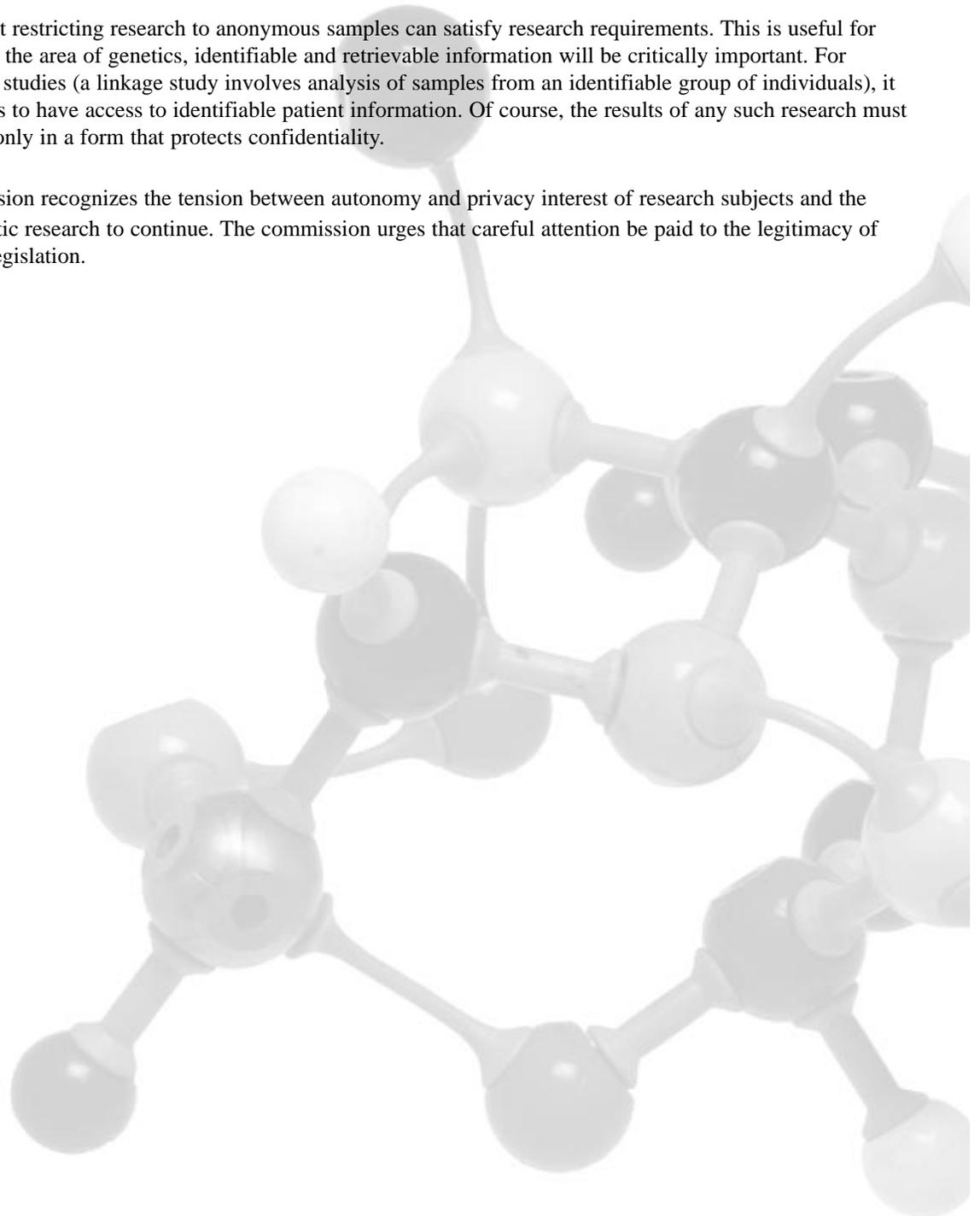
**Issue:** Should research and its implications be considered in constructing legislation?

**Background:** As noted throughout this report, genetics has provided significant advances in research over the past decade. These advances are expected to continue and accelerate as studies for therapeutic genetic treatment begin. The commission believes that research is important and the import of any potential legislation on research should always be considered.

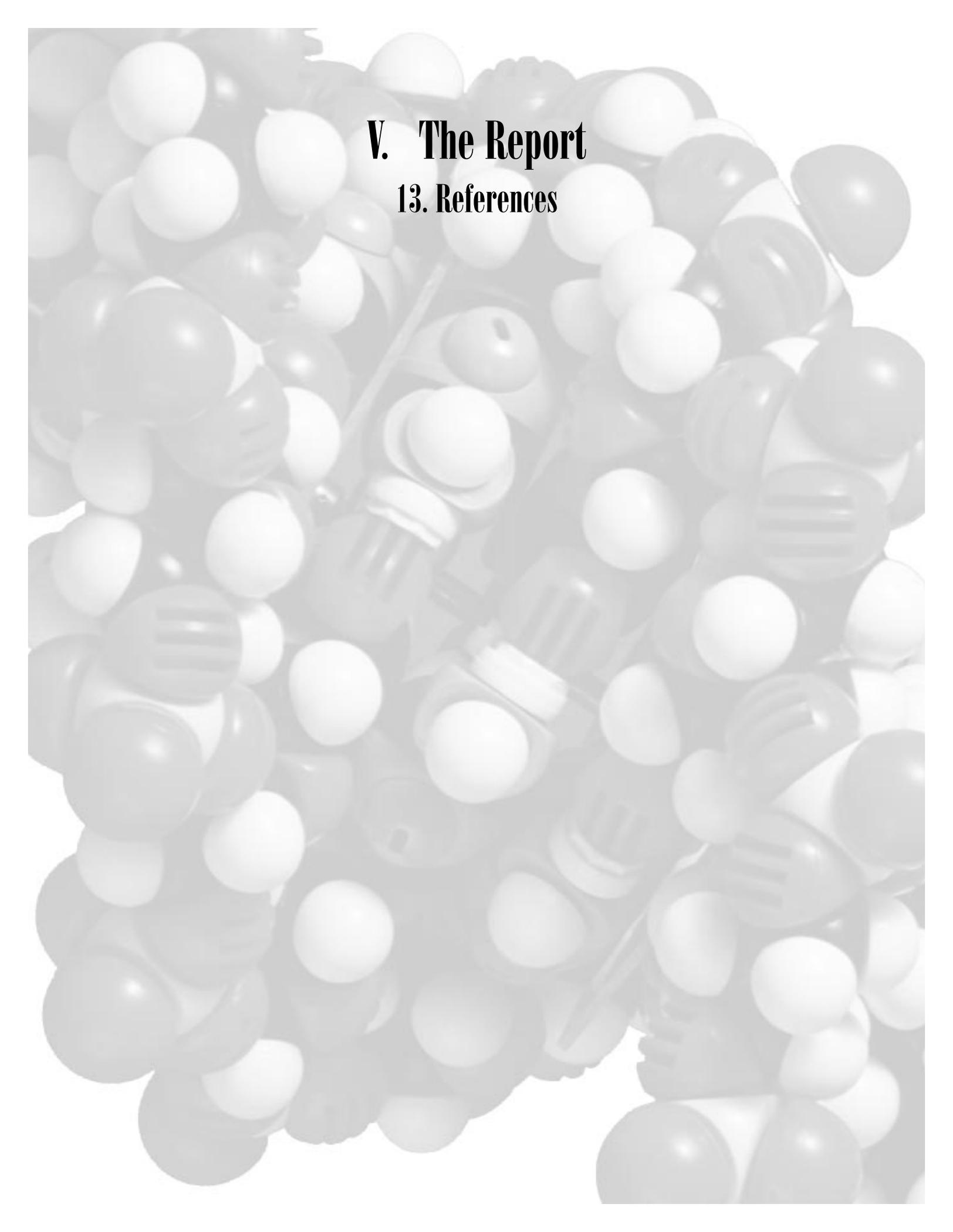
Given the values of genetic research, the commission urges the state legislature to consider the potential effects that certain policies might have on research. The commission believes that any limitations on research should be imposed only when necessary to further other important public interests.

Some commentators believe that restricting research to anonymous samples can satisfy research requirements. This is useful for some research, but especially in the area of genetics, identifiable and retrievable information will be critically important. For example in familial and linkage studies (a linkage study involves analysis of samples from an identifiable group of individuals), it will be important for researchers to have access to identifiable patient information. Of course, the results of any such research must be published and disseminated only in a form that protects confidentiality.

**Recommendation:** The commission recognizes the tension between autonomy and privacy interest of research subjects and the public interest in allowing genetic research to continue. The commission urges that careful attention be paid to the legitimacy of research issues in considering legislation.







# V. The Report

## 13. References



# References

1. Background on Genetics - an Overview by Dr. Elizabeth M. Petty
2. Selected References by Subjects
3. Bibliography
4. Acknowledgments

# Overview of Clinical or Medical Genetic Services

**Elizabeth M. Petty, M.D.**

Hereditary diseases have been described since biblical times but it wasn't until the last quarter of the 20th century that molecular and medical genetics blossomed into a recognized clinical subspecialty. The University of Michigan Medical Center was the first institution worldwide to establish and operate a university-based medical genetics clinic to serve individuals with and families concerned about inherited diseases. The doors of this unique clinic opened in 1941, three years before DNA was discovered as the basic chemical unit of heredity and over a decade before the double helix structure of DNA was described by Watson and Crick. Today's medical genetics evaluation has evolved and generally encompasses elements from both the general medical physical examination used routinely by all physicians and the specialized dysmorphology examinations used to define and characterize syndromes. The increasing availability of molecular genetic testing in all areas of medicine is expected to revolutionize the practice of medicine.

The medical genetics evaluation is one part of a specialized clinical service for individuals and families with concerns about genetic conditions that may run in their family, birth defects, genetic risk for adult-onset conditions, or issues regarding abnormal development. The field of medical genetics is a rapidly evolving and changing field reflecting our increasing knowledge about the human genome. Even within the specialty of medical genetics there are further specializations of various individuals who have expertise in a relatively focused and narrow area. The broad scope and complexity of disorders seen through medical genetics clinics necessitate a broad range of expertise to provide appropriate diagnosis and management for patients. Therefore, the genetics clinic is best served by a true team approach where genetic counselors, medical geneticists, laboratory geneticists, and other health care providers interact with the patient and patient's family to provide comprehensive care and appropriate evaluation. Other medical specialists who may be used for appropriate medical genetics evaluations include neurologists, cardiologists, oncologists, orthopedists and other surgery subspecialists, ophthalmologists, developmental pediatricians, physical medicine and rehabilitation specialists, pain management physicians, audiologists, plastic surgeons, psychiatrists and psychologists, social workers, pathologists, dermatologists, and radiologists. The interaction of all of these health care professionals together along with the genetics team is often necessary to provide patients with the most appropriate management for their multisystemic disorders.

## **Medical Genetics as a Clinical Medical Specialty**

As recent as the past few decades, medical genetics visits were largely geared towards making diagnoses based on physical examinations of patients and examination of detailed family histories. Clinic visits were focused on delineating and defining the cardinal or characteristic features of particular syndromes, describing new syndromes, and determining the inheritance pattern of these syndromes. With the discovery of particular chromosome abnormalities in the late 1950s, geneticists began to use cytogenetic testing as a means to identify the chromosomal basis for particular syndromes. In the early 1960s, increased knowledge regarding the biochemical basis of metabolic diseases, subsequent development of diagnostic assays and, ultimately, improved management of metabolic diseases sparked the development of newborn screening programs and biochemical genetics clinics to identify and treat individuals with inborn errors of metabolism. The recognition of restriction fragment length polymorphism and Southern blotting ushered in a new era of molecular genetics in the 1970s. In the late 1980s DNA diagnostics, as a means to augment clinical genetic diagnoses and enable DNA-based prenatal diagnoses, became more widely available and more regularly employed. The advent of the polymerase chain reaction in 1985 and the implementation of the Human Genome Project in 1990 have unquestionably revolutionized the field of molecular genetics and, as anticipated, significantly influenced the thinking of clinical geneticists and the evolution of the medical genetics evaluation.

The clinical geneticist now has a wide variety of auxiliary tests available to help confirm diagnoses, make predictive diagnoses in asymptomatic individuals, and provide prenatal diagnoses for interested individuals. These rapid advances in genetic discoveries, resulting technology and their subsequent media exposure have also changed, and likely will continue to change, the character of, public desire for, and the available services provided by a genetics clinic. Finally, the impact of an ever-changing health care reimbursement system is having, and will continue to have, a major role in determining how medical genetics evaluations are conducted and clinical services are provided. Medical genetics has evolved from a descriptive discipline to one with increasing emphasis on specific testing, counseling, education, prevention, and management.

Despite extensive growth of clinical genetic services over the latter half of the 20th century, medical genetics was not actually recognized as a bona fide medical specialty by the American Board of Medical Specialists until 1991. The American College of Medical Genetics was also established in 1991 and was formally recognized by the American Medical Association five years later in

1996 when it was admitted to their House of Delegates. Even before formal medical recognition, clinical geneticists believed in the importance and uniqueness of the specialty as well as their role in providing patients and their families with the most accurate diagnostic and prognostic information available and offering them the most up-to-date strategies for management.

## **The Role of Medical Geneticists**

To provide precise information to patients, families, and other health care providers about genetic disorders, it is absolutely essential that a thoughtful and comprehensive medical genetics evaluation by a trained clinician is fully integrated in the provision of today's clinical genetic services. Most often a formally trained clinical geneticist performs the medical genetics evaluation. Practicing clinical geneticists are, for the most part, physicians who have had their initial primary medical training in another area of medicine (usually pediatrics but sometimes internal medicine, obstetrics and gynecology, or even pathology or other specialties). They subsequently obtain at least two years of additional formal subspecialty training in clinical medical genetics. Traditionally, formal clinical genetics training was available through specialized fellowship training programs, accredited by the American Board of Medical Genetics (ABMG), for M.D.s and D.O.s. ABMG began certifying medical geneticists and genetic counselors in 1981, two years after the creation of the board. Beginning in 1997, the Accreditation Council for Graduate Medical Education (ACGME), rather than the ABMG, is granting accreditation for M.D. and D.O. clinical genetics training programs. In rare instances other professionals such as formally trained Ph.D. geneticists and dentists with interests in genetic syndromes have assumed active primary roles as clinical geneticists. After completion of a formal training program, physicians are eligible to sit for formal board examinations in clinical genetics, which are currently given every three years and must be renewed every 10 years. Thus, board-certified clinical geneticists are individuals who, after completing specialized training, have passed the ABMG Clinical Genetics examination.

## **The Role of Genetic Counselors**

Most clinical geneticists work very closely with genetic counselors and laboratory-based geneticists in providing and delivering comprehensive clinical genetic services. Formally trained genetic counselors have a master's degree from an accredited training program and are board-certified by the American College of Medical Genetics. Formally-trained genetic counselors provide appropriate genetic education and counseling to individuals and families about their genetic risk, the natural history of the condition, issues in management and treatment, diagnostic testing, and psychosocial support. During a clinic session the roles of the counselor and the clinical geneticists are often closely intertwined to fully optimize care for patients and their families. Thus, the medical genetics evaluation is intimately connected to and reliant upon superb genetic counseling services.

Genetic counseling traditionally involves time-intensive sessions with a patient not only to discuss diagnostic, prognostic, recurrence risk, and medical management strategies, but also to fully educate them about their disease process, discuss genetic testing issues, and to address psychosocial concerns related to their disorder. Patients are referred to appropriate support systems and educational resources as needed. Board-certified clinical geneticists in conjunction with board-certified genetic counselors conduct most formal genetic counseling. However, with the increasing recognition of genetic components of many medical disorders and the relative paucity of clinical genetic professionals, it is likely that all physicians and related health care professionals will need to understand and be able to provide some basic genetic counseling to a large number of their patients. Only the more complicated cases are likely to be referred to genetic clinics that are routinely available in all large medical centers and, increasingly, throughout smaller communities as outreach clinics associated with the larger centers are an increasing component of genetic counseling. Discussion of genetic testing counseling in the near future may also encompass issues regarding genetic therapy.

## **Purposes of Medical Genetics Evaluations**

There are several purposes of the medical genetics evaluation which may vary considerably depending on the particular disorder or the unique concerns of the patient or patient's family. Most often, a complete physical examination and clinical evaluation is used to help establish or confirm a particular diagnosis for an individual or for several individuals within a family. A good medical genetics evaluation should not only address what the disorder is but address other questions as well, such as: Why did it occur? When did it likely happen? Who else may be affected? What are the chances it may occur again in this family? What future problems should we anticipate? Can we avoid these problems? How can we optimize the individual's present and future health and psychological well being given this condition?

An accurate diagnosis enables precise genetic counseling and informative patient education. Specifically, recurrence risks can be more accurately provided given a confirmed and specific diagnosis. In addition, patients and their primary health care team can be specifically educated regarding the particular diagnosis and provided with anticipatory guidelines regarding potential problems as well as state-of-the-art therapeutic or management options. Once a diagnosis is formally established, or in individuals where routine follow-up is scheduled for a known diagnosis, the medical genetics examination helps determine the extent of systemic involvement

for individual patients to help provide focused medical management for their unique problems related to their particular disease. Necessary referrals to additional subspecialists who may be needed to help care for the patient should be made based on the individual's physical findings. A better sense about an individual's prognosis for morbidity or mortality may be made based on the medical genetics evaluation. Individualized counseling can be directed to focus on particular patient concerns. On follow-up visits for individuals with a genetic condition, a focused medical genetics evaluation is critically important to help identify any new problems and address any new patient concerns and questions.

Another important role of the medical genetics evaluation is to assess other family members for the condition that has been identified. There are often no cures to completely eradicate the genetic disease or disorder other than using family planning to avoid having a child with the condition. Frequently there are medical management strategies that can markedly improve an individual's condition and daily life. In addition, appropriate anticipation and watchful evaluation for potential problems will enable early detection, improving medical management and decreasing morbidity. Appropriate psychosocial support and education may enable affected individuals to manage their lives more effectively even given the physical symptoms of the condition. The ability to recognize a specific genetic disorder in a family followed by counseling may provide interested individuals with an opportunity for specific family planning.

A good clinical geneticist will do a thoughtful and comprehensive evaluation of a patient, even when a particular diagnosis at first glance seems quite likely. Sometimes this evaluation can be accomplished in one visit, while other times it may require a series of visits in a tiered fashion using additional genetic tests and specialized genetic examinations. As important as it is to give the patient a precise specific diagnosis, it is even more important not to mislabel an individual with an incorrect diagnosis based on a hasty evaluation or incomplete review of the patient's medical history, family history, and medical records. It is estimated that approximately one-third to one-half of patients presenting to a genetics clinic for a diagnosis leave the clinic without a specific diagnosis. It is a common and important practice in medical genetics clinics to continually re-evaluate these undiagnosed patients on a regular basis. Some syndromes or conditions become more easily recognizable with age and the rapid growth of genetic knowledge and resulting diagnostic technology may facilitate making a diagnosis in some patients.

The medical genetics evaluation is clearly rooted in and has evolved from the basic and important general components of physical examinations and diagnostic evaluations that are used in all areas of medical practice. Importantly, the past and present medical history of an individual, their family history and the physical examination remain critical components of a medical genetics evaluation just as they are in any medical diagnostic evaluation. As in any medical specialty where a wide variety of relatively rare conditions are diagnosed and managed, there is a great utility and benefit in having clinical genetic centers where physicians, genetic counselors, and other genetic professionals can review cases together. These conferences may be used to review cases before and following clinic visits to help make a diagnosis and discuss appropriate management. Such conferences are increasingly important given the evolving genetic technology to keep one another abreast of the most current diagnostic options and management strategies for patients. Some conditions are rare enough that any one clinical geneticist may only see a condition once in his or her lifetime, if at all, and, therefore, may have a difficult time recognizing a condition when first meeting a patient with it. Fortunately the clinical genetics community is well supplied with resident experts for virtually every disease. They are generally very open and willing to provide curbside consultations and expert advice.

## **Genetic Testing as a Clinical Diagnostic and Prognostic Tool**

Fortunately, DNA-based testing can now be offered for hundreds of conditions that have prominent medical manifestations. Testing can be used in a variety of situations servicing various purposes from molecular diagnostic confirmation of a disease process to facilitate more appropriate medical management and accurate recurrence risk counseling, as in the case of suspected hemochromatosis, or presymptomatically to more accurately predicting one's risk of developing colon cancer. The \$3 billion Human Genome Project was launched in 1990. Its goal is to sequence the entire human genome by the year 2005 and thus uncover the genetic codes for all of our estimated 70,000 to 90,000 human genes. Since there have been genetic discoveries revealed at an unprecedented pace, with the announcement of existing new disease gene discoveries occurring at least two to three times per month. This pace is predicted to skyrocket in the next century. Indeed, a new era of molecular genetics has ushered in a new and important component of clinical medicine. It has already made an undeniable impact in how medicine is practiced specifically and in how several diseases are diagnosed and managed. With the real prospect of increasing gene discoveries and related understanding of their function and regulation in health and disease, it is almost certain that the number of genetic tests available will continue to grow. Similarly, it is anticipated that the use of DNA diagnostic testing for more complex and perhaps polygenic or multifactorial traits will become readily available in the near future. The overall biomedical technology explosion has fostered the increased need and demand for specialized medical and molecular genetic services.

Accredited clinical molecular genetic diagnostic laboratories are directed by board-certified molecular geneticists holding M.D. or Ph.D. degrees or both. Similarly, cytogenetic and biochemical genetics laboratories are run by geneticists or pathologists board-certified in those specialties. General operating procedures for the laboratories are regulated by CLIA, a national diagnostic

laboratory board that oversees laboratory practices in all areas of clinical medicine. National organizations in pathology, genetics, oncology, obstetrics and gynecology, medicine and pediatrics have national committees that help develop profession guidelines for the development and use of various genetic tests. In particular, the American College of Medical Genetics, the American Society of Human Genetics, and the Association of Molecular Pathology continue to develop and provide specific position papers related to guidelines for genetic testing services.

Diagnostic genetic tests can be broken down into three large and sometimes overlapping categories. These include cytogenetic studies which may include routine karyotypes, high-resolution karyotypes, and molecular fluorescent insight to hybridization studies; biochemical tests, which may include screening urine or plasma samples for the recognition of specific classes of metabolic diseases or specialized quantitative tests to look precisely at some specific enzymatic function to yield a precise diagnosis; and DNA-based diagnostic tests. Biochemical tests, depending on the specific test, may be conducted in samples of urine, plasma, red or white blood cells and, in many cases, prenatal samples including placental tissue and amniocytes. Cytogenetic studies can be conducted from any cells that can be easily cultured. They are most often done from peripheral blood leukocytes (white blood cells) collected from a whole-blood specimen. Cytogenetic studies can also be conducted from bone marrow samples, amniocytes, chorionic villus samples, and skin biopsies. Abnormal fetuses that were miscarried can also be studied.

The type of genetic testing varies widely. These include: indirect methods of analysis such as linkage analysis; direct-mutation testing either by screening DNA sequences for unknown mutations or doing a specific DNA test to look for a known mutation; and functional analyses of gene expression by looking at resultant gene expression levels, protein products, or biochemical by-products. Each of the tests has its strengths and weaknesses. The specificity and sensitivity of any one test may vary considerably from another test for the same disorder. For some disorders, such as hereditary non-polyposis colon cancer, an adult-onset autosomal dominant disease where genetic heterogeneity exists, clinicians may have to choose between a number of different types of available genetic testing methods to identify the most appropriate, sensitive, specific and cost-effective test for any one individual or family. In many cases where a disease gene has been cloned, the resulting DNA test may indeed be the most appropriate test to offer a patient, though this is not always the case. Consider, for instance, a disease such as Neurofibromatosis type I (NFI, an autosomal dominant neurocutaneous disorder) where most affected adults have an easily recognizable disorder based on cutaneous examination. The gene for this disorder was cloned in 1990. At the time of this writing, clinical DNA-based testing is limited to an analysis of the size of the resulting NFI gene protein product. It is about 70% sensitive in identifying mutations in affected individuals (i.e. it is less sensitive in identifying the disease in affected adults than a good clinical examination). This test offers no particular clinical benefit, especially given the lack of any genotype/phenotype correlations that could offer insight into the patient's prognosis.

The types of molecular testing currently available can be divided into three main groups: indirect DNA analysis, direct mutation detection, and RNA-based functional assays. Technically, the analysis of protein products and functional assays could also be considered a form of indirect testing, as the specific disease-causing DNA mutation is not identified. However, given that the functional assays currently used in cancer diagnosis demonstrate a gene-specific abnormal product, it seems they are best left in their own classification. It is anticipated that functional-based genetic tests will be some of the most widely applied genetic diagnostic methods in the near future. They may be more readily applied to large population-based screening in diseases such as breast cancer where no predominant mutations have been identified in the cloned cancer genes. Indirect DNA testing, or linkage analysis, is used still in some cases where the precise mutation testing for a genetic mutation is not yet available or if a gene has only been very well localized and is not yet cloned. This is a method for tracking a disease gene on a chromosome through several family members without specifically analyzing the particular disease gene. For DNA diagnostic linkage studies to be effective it is important that the disease is most likely caused by one particular gene, that samples are available from multiple appropriate family members, and that patients undergoing such studies understand the ambiguities that may be associated with linkage studies. These ambiguities include the potential for recombination (chromosomes' regions mix with one another during formation of the egg or sperm of the parents' chromosome). As more disease genes are cloned, the availability of specific mutation testing and mutation screening for many disorders is becoming increasingly possible. DNA testing can be done on any nucleated cell specimen from which DNA can be obtained. Therefore, DNA testing can be used for prenatal diagnosis, routine clinical diagnosis, and can even be used to analyze achievable pathological specimens from deceased affected family members if necessary. Blood samples for DNA testing are most often requested to be sent in special tubes to ensure high-quality DNA for testing, but in reality DNA can often be extracted from body fluid or tissue stains the size of a dime. Some mutational studies are also based on functional assays of mutations. These require special specimen handling as for many of these tests it is important to have intact RNA as the sample source. Thus, for any special genetic tests, it is extremely important to know exactly what type of test is being done and how the sample should be sent. Failure to obtain, handle, or ship a specimen properly could result in no results, or worse, could potentially cause false-positive or false-negative results especially with sensitive biochemical assays.

It is anticipated with the advances made through the Human Genome Project that our ability to do predictive testing for adult-onset disorders will only continue to grow. It is important that the physicians and scientists responsibly translate this explosion of genetic information into molecular diagnostic tests. Specifically, in the area of predictive or presymptomatic testing the full implications of such testing should be well-understood. It is also important that, for each disease being tested for, the epidemiology, penetrance, clinical variability, and management of the disorder are understood. It is also important to remember that genetic testing is an

evolving process with the development of increasingly more sensitive, specific, and cost-effective methods. Genetic testing laboratory databases designed for health care professionals are maintained on-line. One currently available database, HELIX, provides information about which laboratories offer research or clinical genetic testing for all diseases with a genetic component. Thus, clinicians and researchers wanting to learn more about DNA testing can use on-line databases, consultation with local genetic centers, and information provided by national disease-associated organizations to ascertain current information about specific genetic testing for any disease in consideration.

It is also critically important to remember that genetic testing encompasses more than a simple laboratory and needs to include pre-testing counseling and education; provision of informed consent; accurate interpretation of the test results; and post-testing education, management and support. This is especially true when DNA-based testing is used to more accurately determine a healthy individual's genetic risk as in preconceptual testing to determine carrier status of parents for a given autosomal recessive disease, or in predictive testing of an asymptomatic individual who, by virtue of their family history or their ethnicity, are at risk of having inherited a particular mutation and seek to learn whether they have indeed inherited the mutation in question. In the future it is likely that this type of predictive testing will be readily available for a wide variety of conditions. Currently individuals with a family history of colorectal cancer are seeking such predictive testing in order to begin appropriate medical management.

In addition to specific genetic tests, a variety of diagnostic studies may be required in concert with a clinical evaluation and medical history in order to reach a particular diagnosis for a patient or to provide information about prognosis and medical management. These tests will include specific genetic-based testing but are not limited only to those genetic tests. For example, in a newborn boy who has excessive bleeding after a circumcision, a specialized precise DNA-based mutational analysis may reveal the molecular basis for his bleeding disorder and confirm his diagnosis of Hemophilia A. More routine hematology laboratory tests, such as clotting factor studies, will be most useful in making the initial diagnoses critical to the patient's immediate medical management. Thus, other routine laboratory studies may be required in the medical genetics evaluation to help reach a diagnosis or manage patient symptoms. Blood counts, clotting factors, liver function tests, kidney function tests, acid base status, and measurements of other breakdown products of metabolism may be useful. None of these laboratory studies are considered routine in the medical genetics evaluation but are used as necessary depending on the circumstances of individual cases. Various diagnostic imaging studies are often of great importance and help in the medical genetics evaluation. In addition to still photography and video imaging, various types of X-ray studies, including skeletal surveys, may be of specific help in determining various genetic conditions including skeletal dysplasia and to recognize any bony congenital anomalies that may point to a specific syndrome diagnosis. Specialized imaging studies such as CT scans, MRI scans, and echocardiograms may be required in the evaluation of certain conditions or to help make a specific diagnosis. For example in Marfan syndrome, where aortic root dilatation and aortic rupture may occur, an echocardiogram documenting aortic root size may be useful in helping to confirm a diagnosis. Once the diagnosis is made, routine echocardiograms or in some cases, other imaging studies such as transesophageal echocardiograms or spiral CT scans of the aorta, need to be done on a regular basis to monitor the patient for any signs of progression of aorta or aortic root problems necessitating more aggressive medical management. Therefore, diagnostic imaging studies in clinical patients can be quite useful not only in initial diagnosis but also in routine follow-up and management. Indeed in some cases such as cystic fibrosis a simple lab test at the patient's request can make the diagnosis as well as a DNA analysis. Specialized imaging studies in the prenatal period are routinely used to look for congenital anomalies such as detailed ultrasounds and fetal echocardiography.

## **Unique Areas of Genetic Testing and Counseling or the Four Ps: Preconceptual, Prenatal, Presymptomatic and Predictive Testing**

By its very nature, genetic testing has the potential power to determine what disorders may be most likely to occur in a family or in an asymptomatic healthy individual. The use of genetic testing for purposes of family planning to either prevent or better manage a child with a genetic disease has been available for decades. Preconceptual genetic counseling and testing can help determine which couples may be at highest risk of having a child with an inherited condition. Prenatal genetic counseling and testing which can occur any time between conception and the birth of the baby often is done between eight and 24 weeks of gestation to provide parents with information about the health of their baby so they can plan for the care of their infant.

The fields of predictive and presymptomatic molecular genetic testing for late childhood or adult-onset disorders such as cancer are relatively new areas in clinical medicine. Presymptomatic testing implies that an asymptomatic individual who has a positive genetic test for a disease gene will, at some time in their life, develop symptoms of the disease if they live as long as their average anticipated life span. Predictive testing implies that the test result will enable one to make a calculated prediction about the likelihood of an asymptomatic individual developing the disease over the course of their anticipated life span. Therefore, simply stated, presymptomatic testing implies that one will get the disease if one has the mutation, whereas predictive testing helps determine only the likelihood that one will develop the disease. In general, because of the incomplete penetrance of many genetic mutations, genetic testing of asymptomatic individuals is most often properly referred to as predictive testing. Sometimes the term susceptibility testing is used in discussions of predictive testing. Susceptibility testing also implies that one is able to calculate an individual's risk of developing the disease for which they have inherited the gene. In general, however, susceptibility testing refers

to testing for genetic mutations that have a very low penetrance or that do not follow clear Mendelian inheritance patterns of disease. It is important to bear in mind that the degree of penetrance will vary for each disease gene in question, and likely for different mutant alleles within the disease gene. Therefore, it is absolutely essential that both the patient and health care provider fully understand that predictive genetic tests are probabilistic rather than deterministic in nature. The test results only help determine the specific probability or odds that an individual will develop a specific type of cancer by a certain age. Most of the presymptomatic (e.g. Huntington Disease) and predictive (e.g. inherited breast cancer genes BRCA1, BRCA2) clinical tests currently available have been developed for testing in families with clearly inherited genetic syndromes rather than general population-based mutation screening efforts. Testing available today if used in the general population would likely lead to erroneous risk estimates. Both health care providers and consumers must understand basic information regarding the application of presymptomatic and predictive molecular genetic tests for these syndromes. Health care professionals must critically evaluate and appropriately use these molecular genetic tests, helping their patients consider not only what test might be most appropriate but also when testing might be most appropriate.

Presymptomatic and predictive genetic testing encompasses more than the actual DNA-based test. It includes genetic counseling and education for the individual, and possibly other family members who are considering testing, evaluation of the client for emotional stability and ability to understand the implications of positive and negative presymptomatic tests, and post-testing counseling and follow-up including therapeutic interventions and clinical referrals as needed. It is important that individuals remember that presymptomatic genetic testing does not predict the exact age of onset of the disease, the severity of symptoms, or the course of disease progression for specific individuals.

Because of the many issues involved in presymptomatic testing for an adult-onset disorder such as Huntington Disease (HD) or breast cancer, guidelines for testing have been developed by various groups. For HD, guidelines highlight the importance of pre- and post-testing genetic counseling, a neurological evaluation, a comprehensive psychological evaluation, and presence of a support person who will be with the client throughout the testing process. The support person can be a close friend, a spouse, or other individual identified by the client as someone who they can trust and depend on to provide support during the testing process especially when results are disclosed. It is not recommended that the support person be a sibling or other family member who is also undergoing testing at the same time. It is recommended that clients have contacted or identified a local counselor or therapist who will be able to help them deal with their emotions triggered by the test results. It is recommended that the results be disclosed only in person because of several questions that arise when the test results are given to the client whether they are positive or negative. It is also strongly recommended that minors be tested only if it is clinically indicated, such as when minors are having symptoms consistent with a possible diagnosis of HD. It is specifically recommended by the vast majority of geneticists that no presymptomatic testing of minors occur. Since there is no specific treatment or therapies to alter the course of the disease, this is no advantage or benefit for testing minors at this time. It is also widely recognized by the HD groups and geneticists that many at-risk adults choose not to undergo presymptomatic testing because they would rather not know this information given the fact that there are no specific therapeutic options. Thus, it is felt presymptomatic testing should only be done when individuals can reliably give informed consent for the testing.

## **Summary of Genetic Testing in Medical Practice**

The discovery of specific genes involved in human disease has grown at an exciting and unprecedented pace during the last decade of the 20th century. These discoveries were sparked by the 1990 launch of the Human Genome Project. Additionally, the explosion of innovative molecular genetic technology in the last quarter of the century, including development of recombinant DNA methods in the 1970s and the advent of the polymerase chain reaction in 1985, has allowed investigators to characterize cancer genes more rapidly. Many of the laudable scientific advances in characterizing novel human disease genes have been, and continue to be, translated into clinically useful diagnostic and prognostic tests. Some of the most widely discussed new types of clinical molecular testing in medical practice today involve the actual analysis of a specific DNA sequence or its resulting protein product. It is important to note, however, that other types of genetic tests have demonstrated significant utility in the investigation, detection, and management of human disease over the past several decades. Available genetic tests useful in medical practice vary considerably from those based on analysis of single nucleotide changes at the DNA level to those looking at large structural chromosome rearrangements.

To date, the major impact of modern molecular genetics in clinical medicine has been in the improvement of our ability to predict, diagnose, and classify human disease. Despite this, the actual number of proven cost-effective and clinically useful molecular genetic diagnostic tests available at the close of the 20th century is still relatively limited compared with the actual number of diseases identified as having some genetic basis. Until recently one of the largest roadblocks in the rapid and efficient translation of molecular genetic information into the development of sensitive, robust clinical DNA-based tests for diseases was secondary to limitations in the technology for cost-effective mutation screening. With innovative and increasingly automatable molecular genetic technology being developed, it is likely that these limitations will be significantly reduced. Armed with tremendous new knowledge about various genes and significant advances in technology to manipulate and analyze DNA, RNA and proteins, we are poised with

the real potential to develop molecular genetic tests not only for clinical predictive and diagnostic testing, but also for more specific prognostic testing and potentially as a rapid means of directing the development of specific gene therapies. With our deeper understanding of genetic mechanisms underlying the pathogenesis of human disease, the widespread use of DNA or molecular-based testing may become a practical reality for the rapid diagnosis and focused management of several human diseases, both inherited and sporadic. Future progress should provide new tools for predicting genetic risk and therapeutic responses, hopefully leading to a significant shift in medical therapy towards disease prevention. It is anticipated that our knowledge in this area will continue to skyrocket, ushering in a new era of molecular medicine that will significantly alter the practice of medicine in the next century especially in the areas of predictive risk analysis, preventive management strategies, and anticipatory guidance. One of the biggest challenges of the next millennium will be understanding, appropriately applying, and accurately interpreting the plethora of anticipated molecular diagnostic tests. It is critical in applying these tests cost-effectively to make sure that health care professionals understand basic genetic principles as applied to clinical molecular genetic diagnostic tests. It is equally vital to make sure that the benefits, ramifications and limitations of such testing are understood by the individual undergoing the testing and by society in general.

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*Beverly S. Hammerstrom, Representative, Michigan House of Representatives • Thomas F. Higby, MD, Michigan State Medical Society Advisory Committee on Genetic Technology • Mark Hughes, MD, Michigan State Medical Society Advisory Committee on Genetic Technology • Robert Ianni, Assistant in Charge, Criminal Division, Office of the Attorney General • Carol Isaacs, Director, Health Legislation and Policy Development, Department of Community Health*

*Russel S. Jelsema, MD, Michigan State Medical Society Advisory Committee on Genetic Technology • David Johnson, M.D., Deputy Director for Public Health and Chief Medical Executive, Community Public Health, Department of Community Health • Kevin Kelly, Managing Director, Michigan State Medical Society • Anthony Killeen, MD, PhD., Assistant Professor of Pathology, University of Michigan • Mark D. Kolins, MD, Chair of Legislative Committee, Board of Directors, Michigan State Medical Society*

*Helene Larson, Secretary to the Chief Operating Officer, Director's Office, Department of Community Health • Geralyn Lasher, Communications Administrator, Director's Office, Department of Community Health • Kirsten Lietz, Librarian, Library of Michigan • Ellen Lopez, Acting Director, Personnel, Department of Community Health • Richard Lowthian, Director, Forensic Science Division, Michigan State Police • Richard Lucas, Librarian, Law Library, Library of Michigan*

*Charlene McCallum, Director of Legislation and Operations, Senator Dale L. Shugars' Office • Mark Miller, Chief Operating Officer, Department of Community Health • Yvette Miller, MD, Michigan State Medical Society Advisory Committee on Genetic Technology • John Naber, Newborn Screening Unit, Department of Community Health • Michael L. Netzloff, MD, Michigan State Medical Society Advisory Committee on Genetic Technology • Christine Norris, Secretary to the Director, Department of Community Health*

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*Michigan Department  
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