

A Report on Genetic Information and
How it is Currently Treated Under
Minnesota Law

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Executive Summary

Genetic information discloses facts about the person who has been tested. It also discloses facts about that person's relatives because each of us inherits our genetic makeup from our ancestors. Recognizing this potential impact on Minnesota citizens, the Legislature asked the Commissioner of Administration to assess how genetic information is currently protected in state agencies and offer any recommendations for legislative action. *See* 2005 Session Laws, Chapter 163, section 87.

There is protection for genetic information held in state agencies and some areas have been identified where changes could be made or further study pursued.

The recommendations can be summarized as follows:

Recommendation 1: Address access to DNA test results found in a civil or criminal case file in the courts by either enacting a statute or the judicial branch adopting a rule that makes DNA test results not available to the public.

Recommendation 2: Suggest to the Court that it require a protective order to prevent parties from making DNA test results available to those not involved in the court proceeding.

Recommendation 3: Amend section 176.231, subdivision 9, so that genetic information held by the workplace safety and health program in the Department of Labor and Industry can be released only with the consent of the individual.

Recommendation 4: Form a work group to study whether section 144.69 needs to be amended to require consent from certain individuals before epidemiologists contact the relatives of cancer patients.

Recommendation 5: Conduct further study about whether a relative should be able to access an entire data set. The issue is raised by data sets where there are multiple subjects of the data about a medical condition and current law only allows a subject of data to access this private data about him/herself.

Recommendation 6: Given the concern that law enforcement agencies or other parties outside the state agency can get access to genetic information with the permission of the person who is the subject of the information or a court order, conduct further study to determine what access is appropriate.

Recommendation 7: Clarify the language about the accessibility of DNA information in the forensic data collection at the BCA in sections 13.82 and 299C.155, after studying what access is appropriate for crime victims.

Recommendation 8: Create a work group to develop principles for use in evaluating legislative proposals about genetic information.

Recommendation 9: Develop a definition for “genetic information” that applies in both the public and private sectors and provide a general classification that applies unless there is a more specific provision in law.

Recommendation 10: There are a number of issues that are not covered by this report. The recommendation is that these issues be studied and proposals prepared for future legislative action.

Recommendation 11: Develop expertise among the members of the Legislature and staff in this area and use that expertise to ensure that careful consideration is given to all proposals that affect genetic information.

This report is submitted as required by 2005 Session Laws, Chapter 163, section 87 and addresses the State's handling of genetic information.

I. The Task Assigned by the Legislature

As part of the 2005 Omnibus Data Practices bill (Session Law Chapter 163/HF 225), the Legislature directed the Commissioner of Administration to prepare a report on genetic information. Specifically, the Legislature stated:

Sec. 87. [REVIEW OF STATE HANDLING OF GENETIC INFORMATION.]
The commissioner of administration shall review the applicable laws, rules, and policies to determine whether the state handles genetic information on individuals in a manner that appropriately takes into account the possible effect of release or nonrelease of that information on the genetic privacy of relatives of the individuals. The commissioner shall report the results of the review, including any recommendations for legislative changes, to the chairs of the house Civil Law Committee and the senate Judiciary Committee and the ranking minority members of those committees by January 15, 2006.

II. The Process

To begin the development of this report, state agencies with genetic information on individuals were identified. Representatives of those agencies and other interested parties participated in meetings with staff members from the Information Policy Analysis Division of the Department of Administration. Participants were asked to provide information, perspective and insight into the issues raised by the report. Neither minutes nor votes were taken and there was no attempt to create consensus on any issue. Discussions included how to define "genetic information" for purposes of this report, the focus of the report and pending issues in genetics and genomics.

Meetings were held on September 9, October 14 and November 17, 2005. Kristin Peterson Oehlke of the Department of Health provided background information on genetics. Jim Iverson of the Bureau of Criminal Apprehension in the Department of Public Safety provided background information on the forensic use of genetic information. These background presentations provided meeting participants with a common basis for discussion.

The participants in the meetings, and their affiliation are included in Appendix 1.

III. What is the significance of genetic information in today's world?

The general public understands "genetics" to be the study of what we inherit from our parents that make us who we are. More formally stated, it is the study of how living things grow and are changed or how biological variations cause differences among organisms of the same type. In other words, what makes a poodle different from a spaniel or a blonde human being different from a redhead.

In some scientific circles, “genetics” is defined as the study of single genes and how they affect their host organism. “Genomics” is defined as the study of all genetic material and how environmental factors change how the genetic material operates. For purposes of this report, genomics is included as part of its content.

No matter how “genetic information” is defined (see section IV below), it has significance for all living things on Earth. Without delving into the science, deoxyribonucleic acid (DNA) contains all the directions for cells to follow in order to maintain life. The directions to cells are important because they are what separate flies from mice and from human beings. Medical or scientific advances based in genetics are being made almost daily. Samples of recent headlines include:

| Headline | Source | Date |
|--|------------------------------|----------------|
| <i>Havasupai Tribe Sues Genetics Researchers</i> | Privacy Journal | April 2005 |
| <i>Genes may play a role in politics</i> | St Paul Pioneer Press | June 21, 2005 |
| <i>Police are increasingly fighting crime with a swab</i> | Minneapolis Star Tribune | June 29, 2005 |
| <i>Study traces cancers’ genetic lines</i> | St Paul Pioneer Press | July 14, 2005 |
| <i>‘Smart tests’ can aid therapy; a genetic test created in Wisconsin can predict how patients will react to drugs</i> | Minneapolis Star Tribune | Aug. 28, 2005 |
| <i>Bill Would Permit DNA Collection From All Those Arrested</i> | Washington Post | Sept. 24, 2005 |
| <i>DNA detectives track the 0.1 percent degree of human separation</i> | Minneapolis Star Tribune | Oct. 27, 2005 |
| <i>Key to human variation at hand</i> | St Paul Pioneer Press | Oct. 27, 2005 |
| <i>Single gene linked to some dyslexia</i> | St Paul Pioneer Press | Oct. 29, 2005 |
| <i>Tension Grows Over Genetic Testing of Employees</i> | Law.com | Nov. 3, 2005 |
| <i>Gene raises blacks’ risk of heart attack</i> | St Paul Pioneer Press | Nov. 11, 2005 |
| <i>Feeling ravenous or just pucky? Genes have a say</i> | Minneapolis Star Tribune | Nov. 16, 2005 |
| <i>Stripped of one gene, mice become daring</i> | St Paul Pioneer Press | Nov. 18, 2005 |
| <i>Police: DNA key to cold rape case</i> | Minneapolis Star Tribune | Nov. 19, 2005 |
| <i>Dog DNA may offer insight into humans</i> | St Paul Pioneer Press | Dec. 8, 2005 |
| <i>Genome Atlas to map genetic errors that contribute to cancers</i> | Minneapolis Star Tribune | Dec. 14, 2005 |
| <i>New DNA testing by Governor Warner clears 2 men in rape</i> | Richmond (VA) Times Dispatch | Dec. 15, 2005 |
| <i>Genes responsible for cancer drug resistance</i> | Minneapolis Star Tribune | Dec. 17, 2005 |

As medicine and scientific research advance, physicians and scientists are better able to predict when an individual will have an inherited disease or condition. They are also able to use genetic

information to select medicines to treat the disease or condition that are more effective and have fewer side effects for a specific patient.

There are almost daily discoveries about genetics and the role this ‘building block of life’ plays in the organisms that inhabit the planet. This ever-growing store of knowledge is not without both negative and positive impacts.

One positive impact has been noted above. Examples of negative impacts include the following. Genetic screening of applicants for insurance might prevent coverage for some who don’t know they face a future medical challenge. (This practice is regulated in Minnesota by section 72A.139.) Genetic testing of job applicants could be used to avoid applicants with predispositions for expensive diseases thereby saving the business health care costs. (This practice is prohibited in Minnesota by section 181.974.)

As is suggested by the Legislature’s direction in Section 87 of Chapter 163, genetic information, and how it is used and disseminated, also affects the relatives of an individual. For example, DNA test results may exonerate someone as a criminal suspect but could implicate their sibling. Or, genetic test results used to learn whether a diagnosed disease has been passed to an individual’s children might include information that a child is not biologically related to the parent.

Genetic information is a powerful tool that can both assist and do harm. As a result, its collection, uses and disseminations should be controlled.

IV. How is “genetic information” defined?

For purposes of this study, “genetic information” is defined as:

any information about an identifiable human being that is derived from the presence, absence, alteration, or mutation of a gene or genes, or the presence or absence of a specific DNA or RNA marker or markers, and which has been obtained:

- (a) from an analysis of the individual’s biological information or specimen; or
- (b) from an analysis of the biological information or specimen of a person to whom the individual is related.

“Genetic information” also includes medical or biological information collected from an individual about a particular genetic condition that is or might be used to provide medical care to that individual or their family members.

The Department used several sources to create this working definition. Those sources are: The Human Genome Project’s 1995 legislative draft; Senate Bill 306 (109th Congress) and the Oregon Rules, Chapter 333, Division 25.

The working definition is used for this report because it reflects recent changes in the methods of analysis by which a heritable or congenital condition or disorder can be traced. The definition also recognizes that “genetic information” may be the result of data collected from individuals about their health and the health of their relatives rather than the testing of specimens that contain a cell with a nucleus from which DNA or RNA can be obtained.

This definition is intended to serve as a starting point for continued discussions of “genetic information” and how it affects the citizens of the State.

V. What are the current laws, regulations and guidelines used by state agencies?

Note: Unless stated otherwise, all references are to Minnesota Statutes.

The *Department of Human Services* (DHS) has three programs that may keep genetic information about individuals and their relatives.

The first is the program that determines the *parentage* of children. Sections 257.51 through 257.74. Parentage is established by order of the court according to statutory criteria and standards. DHS, in conjunction with county social/human services agencies, assists parties in obtaining the evidence needed to establish or deny parentage in certain cases.

Blood and genetic tests may be used to assist with the parentage determination. If these tests are needed, DHS and the counties collect the blood or other sample/specimen and send it to a private sector laboratory for testing. Samples/specimens are not returned. Data documenting the test results may be held at the court, by DHS or by the county.

Section 257.70(a) governs the treatment of these records:

Notwithstanding any other law concerning public hearings and records, any hearing or trial held under sections 257.51 to 257.74 shall be held in closed court without admittance of any person other than those necessary to the action or proceeding. All papers and records, other than the final judgment, pertaining to the action or proceeding, whether part of the permanent record of the court or of a file in the state Department of Human Services or elsewhere, are subject to inspection only upon consent of the court and all interested persons, or in exceptional cases only upon an order of the court for good cause shown.

If a court permits inspection of the records, the court would be able to decide whether to make a protective order that would restrict the use or dissemination of these records.

This statute is not clear, however, whether the individual parties to a parentage proceeding are provided with the test result records. Because these records are evidence in a legal proceeding, it is likely that the parties are provided with some or all of the test results. This would allow each party an opportunity to review the results and present argument about them. The statute does not address what limitations, if any, apply to the parties in a parentage case.

The second set of programs provides *services to people with disabilities*. Both federal and state statutes and rules apply and genetic information may or may not be held. When DHS holds genetic information, section 13.46 classifies those data as private.

The third program is the operation of a variety of *treatment centers/hospitals* to serve people with medical and/or mental health issues. (Most mental health services are provided through the counties and so are outside the scope of this report.) To the extent that medical or mental health issues have a genetic component and data about genetics are maintained in the records of the treatment center/hospital, those data are classified as private by section 13.46. If DHS has custody of juveniles, then the juvenile's parents would also have access to any genetic information kept about their child.

Patients in secure treatment facilities operated by DHS may be tested to determine if they have a "bloodborne pathogen." These pathogens include hepatitis B virus, hepatitis C virus and human immunodeficiency virus (HIV). Sections 246.71 through 246.722 provide procedures where patients and DHS employees can be tested for bloodborne pathogens in certain circumstances and how the test results can be shared with employees. The data are classified as private by section 246.719.

The ***Ombudsman for Mental Health and Developmental Disabilities*** has three general areas of responsibility. See sections 245.91 through 245.97. The Ombudsman serves people who have mental health issues or developmental disabilities and who have concerns about the services they have received, questions about their rights or are in need of information. Secondly, the Ombudsman does medical reviews when a person with a mental illness or developmental disability has been severely injured or died while receiving care. Finally, the Ombudsman operates a civil commitment training and resource center.

Data held by the Ombudsman is "mental health data" and are classified as private. Sections 13.46, subdivisions 1(d) and 7. In order to serve clients, the Ombudsman also gathers records that may contain genetic information. Generally, the data that are collected are classified as private in the originating agency and the Ombudsman maintains that classification. Section 13.03, subdivision 4(c). Data collected directly from witnesses are also classified as private according to section 245.94, subdivision 1(f).

The ***Department of Labor and Industry*** (DOLI) collects medical records to administer the workers compensation program. The data in this program are classified as private by section 176.138(a). Data needed to process a claim can be shared with the employee, the employer, the insurer and DOLI. Data not related to the current injury or disability can only be shared with the prior authorization of the employee. See section 176.138(b).

DOLI also operates a workplace safety and health program. To the extent that workplace safety and health may have a genetic component, section 176.231, subdivisions 8 and 9 make the data inaccessible to the general public. The employee, employer, or insurer may consent to any third party's inspection of the data.

The *Department of Public Safety's Bureau of Criminal Apprehension* (BCA) has three different collections of data that include genetic information in the form of DNA test results. Each data collection will be presented separately.

1. Missing Persons data

If law enforcement is working on a missing person case, relatives give permission for the collection and testing of their DNA and the resulting data are stored in what will be called the "missing persons data collection." The test results are used only with the written consent of the relatives. It is separate from the other data collections, is used only for missing person cases, and is currently the smallest of the collections.

2. Forensic data

DNA testing is done on evidence from a crime scene. Samples from the evidence are tested and the results are maintained in case records. DNA test results are also obtained from samples from suspect(s), victim(s) and other individuals involved in the crime scene and the results are also stored in the case record. The test results are compared and help investigators determine the source of the DNA found at the crime scene and so assist in determining who should be charged with the crime. The data created from these forensic tests are stored in what will be called the "forensic data collection." This data collection is used to solve individual crimes and the DNA test results of victims and other individuals are not used in other criminal investigations.

Most of the data created or collected and included in the forensic data collection are classified according to section 13.82. Therefore, the classification of the data may change over time and with particular circumstances, as there are different classifications when an investigation is active versus inactive. When an investigation is active, the data are confidential. The data become public when the investigation is inactive or the data have been introduced in court as part of a case. Section 13.82, subdivision 7. The DNA test result data are also classified by section 299C.155, subdivision 4 as private. According to that section, dissemination is limited to law enforcement personnel, the prosecutor and the subject of the data in any subsequent criminal proceeding. Thus, it appears that the suspect in a criminal matter gets access to some DNA test results according to section 299C.155. What is not clear is whose results are accessibly by the suspect and whether that section also controls access to the DNA test results for victims and other individuals. With these potentially conflicting provisions, it is difficult to determine how they should be reconciled.

Once DNA test results are introduced in court, they are public according to court rules. The judicial branch controls access to data in its records. *See* section 13.90 and the *Rules of Public Access to Records of the Judicial Branch* (effective July 1, 2005). As DNA test results would normally be admitted into evidence, Rule 4, subdivision 1, indicates that the results would be accessible to the public.

3. Offender data

The third data collection maintained by the BCA will be called the "offender data collection." This data collection consists of the DNA test results mandated by sections 299C.105 and 609.117. Section 299C.105 requires the collection of DNA samples from two major groups of

individuals: (a) patterned sex offenders; and (b) those adults or juveniles charged with one or more of the crimes listed in section 299C.105 and who have had a judge make a finding that probable cause exists for them to stand trial (if a juvenile, they will stand for adjudication whether they are delinquent) on the charges that have been brought against them. Section 609.117 requires DNA from convicted felons and these data are also maintained in the offender data collection. The test results consist of a certain part of the DNA and are used to identify individuals in criminal cases where no suspect has been identified.

As for the forensic data collection, section 299C.155, subdivisions 3 and 4 classify the data and limit access to them. Also, the data that are stored in the offender data collection are shared with law enforcement agencies across the country through a system operated by the Federal Bureau of Investigation.

4. Additional information

The BCA maintains the specimens that support the offender data collection. The samples are held in perpetuity and are used again when an active investigation results in a match with an existing record in the offender data collection. Once the match is found, the BCA checks to make sure that the individual's record should be in the offender data collection and then re-tests the sample to ensure that the results are accurate. Once the match is again obtained, the fact that there is a match is provided to the investigating law enforcement agency.

Samples are also maintained so that when DNA testing technology changes, the samples can be tested again and new results obtained. This process has already been used, as there was a change in the testing technology in 1998. When the existing offender specimens were re-tested, 39 cold cases were resolved.

The BCA lab tests other biological specimens to assist with criminal investigations. An example of this type of test is a blood test for the blood alcohol level of the driver of a motor vehicle, boat or snowmobile. The BCA does not currently conduct, and has no plan to conduct, DNA tests on these specimens.

The DNA tests used by the BCA are not currently known to have a link to information about heritable conditions or diseases.

The ***Department of Corrections*** (DOC) provides medical care to the individuals committed to its custody. The medical records that are maintained by DOC may include genetic information. An inmate's medical records are classified as private data. *See* section 13.85, subdivision 2. If DOC has custody of juveniles, then the juvenile's parents would also have access to the genetic information kept about their child.

Several state agencies test employees in a variety of circumstances using bodily substances that contain genetic information. Third party laboratories under contract with a state agency do the testing requested by the agency. The laboratory holds the samples/specimens and it is not clear if there are any laws or regulations that control the storage or disposal of these test results or the samples/specimens.

Employees who have an accident when using equipment or who use a commercial driver's license to perform their job may be tested. Pre-employment screening may also be done for some positions. Data about employees or applicants for employment are classified in section 13.43. While there are some data about public employees that are public (*see* subdivision 2(a)), most data about public employees are private according to subdivision 4. With one exception, any genetic information collected from employees is private data. The exception is if the results of the test are used to discipline the employee; once there is a final disposition of the discipline (defined term), then all data that document the basis for the discipline are public and this might include genetic information. The Department of Employee Relations has indicated that genetic information is not currently collected or used in the disciplinary process and that the issue of genetic information becoming public as a result of discipline has never arisen. Furthermore, they can think of no situation in which genetic information would be collected or used as part of employee discipline. While issues related to testing of state employees are not of immediate concern as the state agency controls the tests that are conducted, it may be appropriate to control how private sector laboratories maintain and store both data and samples/specimens. This issue has been included in the list of issues for future consideration found in Appendix 2.

Multiple state agencies may also have genetic information on people who are no longer alive or "data on decedents." According to section 13.10, data that were classified as private or confidential before a person's death become private or confidential data on decedents. Section 13.10, subdivision 2. As the person is no longer alive to give consent to the release of the private data on decedents, a "representative of the decedent" can provide that permission. Section 13.10, subdivisions 1(c) and 3. These provisions will permit relatives of individual to access genetic information, in some circumstances.

The **Department of Health** operates a number of programs that may maintain genetic information about individuals. The first program is the *Minnesota Birth Defects Information System*. Sections 144.2215 through 2219 direct the Commissioner of Health to maintain an information system that contains data on "...the cause, treatment, prevention, and cure of major birth defects." The statutory language became effective because the Department received a federal grant to establish the system. (*See* 2004 Session Laws, Chapter 288, article 6, section 11 and Chapter 290, section 15.)

Information is gathered to determine if a child's record meets specific birth defects case definitions established by the National Birth Defects Prevention Network and the Centers for Disease Control and Prevention. Only data on cases where the definition of the specific birth defect is met are retained by Health. Once the case is retained, Health is required to provide parents with information about the birth defects registry, its benefits and the parents' right to choose to have identifying data about their child removed from the system. At any time, the parents may choose to have the identifying data about their child removed from the database. *See* section 144.2216, subdivisions 1, 2 and 4. Data that are maintained are classified as private and may only be used for purposes of the program. *See* section 144.2217. There are also restrictions on dissemination. Section 144.2218 provides for sharing with government agencies in Minnesota or other states when the use will be for purposes of a birth defects registry and the other agency agrees to protect the data, as it would be in Minnesota. Section 144.2219 authorizes the sharing of data from the information system with research entities so long as the

identifying data have been removed. If the research entity desires identifying data, then the parent must provide prior informed consent.

The second program is the *Minnesota Cancer Surveillance System* (MCSS). Sections 144.671 through 144.69 direct the Commissioner of Health to perform several tasks. The one pertinent to this report is to monitor cancer incidence trends to "...detect potential public health problems, predict risks, and assist in investigating cancer clusters." (See section 144.671(1)) To facilitate the work of the Department, those licensed to practice the healing arts, hospitals, clinics and laboratories are required by law to report "...a detailed record of each case of cancer..." when requested to do so. (See section 144.68, subdivisions 1 and 2) The data are classified as private and can only be used for the purposes of MCSS. See section 144.69. Section 144.69 also authorizes the Department to interview the patient or the relatives of a patient named in a report, but only after the consent of the attending physician or surgeon is obtained. Consent from the patient is not required by state law but is required by the federal law governing research using human subjects.

The third program is *Newborn Screening*. Section 144.125 requires that all infants fewer than 28 days old be tested for heritable and congenital disorders. The Commissioner of Health determines what disorders will be included in the tests. At the time of this report, the Department tests for 51 disorders including amino acid disorders (e.g. PKU), endocrine disorders (e.g. congenital adrenal hyperplasia), hemoglobinopathies (e.g. sickle cell disease), fatty acid oxidation defects (e.g. medium-chain acyl-CoA dehydrogenase deficiency (MCAD)), and organic acidemias (e.g. methylmalonic acidemia (MMA)). A complete list of the disorders can be found at www.health.state.mn.us/divs/fh/mcshn/nbsdis.htm.

Parents can refuse to have their newborn tested. Parents can also agree to have the tests performed and then have the samples and test results destroyed within 24 months of the testing. Test results go to the newborn's physician and also go into a database operated by Health. The database is used to make follow up contact to determine how a child who has tested positive is progressing. See section 144.125, subdivision 3.

The fourth program is *communicable disease surveillance*, Minnesota Rules, sections 4605.7000 - 4605.7900. Submission of selected disease-causing microorganisms, such as Salmonella species, Bacillus anthracis (anthrax), or variola virus (smallpox) is required under these rules for the Department's disease monitoring and control activities. Microbial DNA or RNA, which do not contain genetic information about the patient, may be analyzed for diagnosis or disease tracking purposes. Specimens may also incidentally contain human DNA from the specimen source material (blood, stool, urine, cerebrospinal fluid), but the Department does not conduct or permit human DNA testing with these samples. All data are private as specified in section 13.3805.

Some programs operated by the Department receive information from individuals that are responsive to family history screening questions (e.g. Do either of your parents have heart disease?). In addition, clinical care provided at selected clinics may have resulted in the collection of information that was organized into a formal, three generation pedigree and these data are held in an individual's medical record. In either case, the data are classified as private according to section 13.3805.

Finally, the Health Department previously held data about individuals who were diagnosed with Huntington's disease. These data were classified as private (section 13.3805, subdivision 2) and have been transferred to the Hennepin County Medical Center (now known as the Hennepin Healthcare System, Inc.), as this is the location of the experts working with this disease. (*See* 1995 Session Laws, Chapter 259, article 1, section 58 for the authority to transfer the data.)

VI. Legislative Recommendations

Note: If a legislative change is recommended, language is provided using the legislative format where words to be deleted are shown with ~~strike through~~ and words to be added are underlined.

One of the primary questions posed by the Legislature is “What access do relatives have to genetic information maintained by state agencies?” The classification of the data in the various agencies provides part of the answer.

The predominant classification of data is as “private data on individuals.” Generally, private data are available to the individual who is the subject of that genetic information and those government employees whose work assignment requires them to have access. *See* section 13.02, subdivision 12 and Minnesota Rules, 1205.0400, subpart 2. Also, “individual” is defined so that the parent or guardian of a minor child also has access to the genetic information. *See* section 13.02, subdivision 8. The classification as private data means that genetic information is not accessible to relatives without the consent of the individual who is the subject of the data. The classification does not, however, control what the individual does with the results once they have them in their possession.

After reviewing the current state of the law in Minnesota, several recommendations are offered. They are intended to serve as a starting point for a discussion of these important public policy issues.

Recommendation 1: DNA test results in a civil or criminal case file in the courts are accessible by the public unless there is a statute that prevents that from occurring (e.g. parentage cases). Depending on the type of DNA test that was conducted, the data available in a court file may or may not have value to the relatives of an individual. Also, disclosure of the data may or may not pose a risk to the relatives of the individual. Therefore, these are issues that deserve consideration. There are two methods for addressing access at the courthouse: enactment of a statute by the Legislature or adoption of a rule by the judicial branch that makes DNA test results not available to the public.

Justice Paul H. Anderson, chair of the Supreme Court Advisory Committee on the Rules of Public Access to Records of the Judicial Branch will receive a copy of this report so that the committee's members can determine whether or not to propose a rule to address this issue.

For the legislative alternative, it is recommended that section 484.80 be created.

Section 484.80 [DNA evidence held in the judicial branch.] Those court records that document the results of DNA testing and that are maintained in the judicial branch are not accessible to anyone other than the person whose DNA was tested.

Recommendation 2: It is recommended that the Supreme Court consider whether it is appropriate to require the entry of protective orders to restrict the use and dissemination of DNA test results in those cases where the results are available to the parties.

By copy of this report, Justice Anderson is asked to convey this request to the appropriate parties within the judicial branch.

Recommendation 3: In section 176.231, subdivision 9, workplace safety and health data in the Department of Labor and Industry about a specific individual can be released not only by the individual but by that individual's employer, insurer or a dependent if the individual is deceased. To the extent that genetic information on an individual is included in workplace safety and health data, too many parties are authorized to release the genetic information. It is recommended that this subdivision be amended as follows:

Subd. 9. **Uses which may be made of reports.** Reports filed with the commissioner under this section may be used in hearings held under this chapter, and for the purpose of state investigations and for statistics. These reports are available to the Department of Revenue for use in enforcing Minnesota income tax and property tax refund laws, and the information shall be protected as provided in chapter 270B.

The division or Office of Administrative Hearings or Workers' Compensation Court of Appeals may permit the examination of its file by the employer, insurer, employee, or dependent of a deceased employee or any person who furnishes written authorization to do so from the employer, insurer, employee, ~~or dependent of a deceased employee~~ or the representative of a deceased employee. Reports filed under this section and other information the commissioner has regarding injuries or deaths shall be made available to the Workers' Compensation Reinsurance Association for use by the association in carrying out its responsibilities under chapter 79. Data that document genetic diseases or conditions of the employee will not be provided to the Workers' Compensation Reinsurance Association without the prior written consent of the employee or the representative of a deceased employee. For purposes of this subdivision, "representative of a deceased employee" has the same definition as "representative of the decedent" in section 13.10, subdivision 1(c).

Recommendation 4: In section 144.69, the Department of Health can interview the relatives of a cancer patient with the consent of the physician but the consent of the patient is not needed under state law. This may be a transfer of genetic information to relatives of the individual who has been diagnosed with cancer and is generally the type of data dissemination that can only be made with the patient's consent. See section 144.335, subdivision 3a. Therefore, it is recommended that a work group of representatives of the Departments of Health and Administration, along with representatives of physicians and hospitals be formed to determine whether changes are needed to section 144.69 to address the issues raised in this report.

Recommendation 5: In some instances, more than one individual is the subject of the genetic information. This is particularly true of the formal, three-generation pedigrees created by the Health Department. Because the pedigree holds data about many people who are all related, there are multiple subjects of the data about the particular medical condition.

Under current data practices statutes, each data subject would be able to get access to data about her/him but not to data about anyone else. As the purpose of the pedigree is to help determine why a child has a particular cluster of medical conditions, it is recommended that there be further study about whether a relative should be able to access the entire set of data. One possible limitation to consider is whether access is only available to assist with diagnosis and/or treatment of a disease or condition.

Recommendation 6: One of the concerns raised by meeting participants was whether law enforcement agencies can get access to genetic information or specimens held by state agencies. For purposes of this report, the concern has been broadened to whether any outside party, including law enforcement or a private party, should get access to genetic information or specimens held by any government entity. Access to and control of specimens is one of the topics included in the list for further study in Appendix 2.

With respect to genetic information that are maintained as data in a state agency and are classified as private, any party would not be able to get access without the consent of the subject of the data or a court order.

The Health Department has some additional protection for data it holds. Section 144.053 provides that data collected as part of an epidemiological study to reduce disease or death are classified as confidential and cannot be introduced as evidence in a court proceeding. This language would not prevent law enforcement from obtaining a court order, but it arguably would prevent law enforcement from using the evidence in a subsequent proceeding.

Section 144.658 says that data held by epidemiologists to assist with the reduction of disease or death are not "...subject to discovery in a legal action." Again, this language would not prevent any outside party from obtaining a court order but it does prevent parties to litigation from using genetic information held by Health as part of their private lawsuit.

As more and more genetic information can be used to predict outcomes in the future, it is recommended that this topic of access for additional uses be studied. One option would be to enact legislation prohibiting secondary uses of genetic information. Another would be to create a process where the courts would balance the interests and needs of the requesting party, whether law enforcement or a private sector representative, with the needs and preferences of the person whose genetic information is sought. Including relatives of the person whose genetic information is sought in the process may also be appropriate as the genetic information is about them as well. A third option would be to establish different processes depending on the secondary use – i.e. law enforcement has one process while the private sector uses another. A fourth option would be to require informed consent before any secondary use is allowed.

Each option raises benefits and concerns and there may be additional options to explore. Further review would provide the Legislature with options from which to choose in addressing this issue.

Recommendation 7: One of the places where some DNA information may be accessible by the public is in the forensic data collection at the BCA. The DNA may be available both from the pieces of biological evidence from a crime scene and also from the victim and anyone else who is tested. Although the portion of the DNA currently used to identify people for law enforcement does not relate to diseases or disorders, that may not continue to be the case as science and medicine make advances in genetics.

In addition, the DNA in the forensic data collection at BCA may disclose genetic information about relatives of the individuals and so disclosure may pose a risk to these additional people as well. Therefore, it is recommended that this issue be studied further to determine what amendments would be appropriate to ensure the protection of DNA test results for everyone tested as part of a criminal investigation. Access by a suspect in order to protect his/her constitutional rights will also need to be considered and it may be appropriate to prevent the dissemination of DNA test results by anyone who receives them in connection with a criminal proceeding.

There is an additional issue to be considered – access by a crime victim to the DNA of the person suspected of perpetrating the crime against him or her. Currently, a crime victim has access to:

- ❑ all data gathered by a law enforcement agency investigating a crime (*see* section 13.82, subdivision 13); and
- ❑ data collected or created because an individual has been detained or confined and the data are needed to assert the victim’s right to restitution (section 13.85, subdivision 5).

There are some situations where a crime victim arguably should have access to the suspect’s DNA test results. As an example, a victim may need to prove responsibility in a personal injury lawsuit where the criminal charges were not pursued or the suspect was found not guilty. Another example is to obtain information about the father of the victim’s child in order to prove parentage. While access to DNA tests results in these situations is available by court order, it is also recommended that the issue of victim access be further studied and suggestions offered for legislative consideration.

Recommendation 8: Group participants briefly discussed the idea of developing principles that could be used to guide future legislative activity in this area. The Fair Information Practice Principles developed in the early 1970s were offered as an example of what could be developed. The Fair Information Practice Principles state:

- ❖ There must be no personal data record-keeping systems whose very existence is secret.
- ❖ There must be a way for individuals to find out what information about them is in a record and how it is used.
- ❖ There must be a way for individuals to prevent information about them that was obtained for one purpose from being used or made available for other purposes without their consent.
- ❖ There must be a way for individuals to correct or amend a record of identifiable information about them.

- ❖ Any organization creating, maintaining, using or disseminating records of identifiable personal data must assure the reliability of the data for their intended use and must take precautions to prevent misuse of the data.

(*Taken from: Records, Computers and the Rights of Citizens; A Report of the Secretary's Advisory Committee on Automated Personal Data Systems, U.S. Department of Health, Education & Welfare, July 1973.)

It is recommended that a work group be created to develop principles for use with genetic information. It is also recommended that the work group include representatives of other levels of government in Minnesota and that legislative staff provide support for this work. Suggested group members include representatives of:

- American Civil Liberties Union – Minnesota
- Citizens' Council on Health Care
- Data users including researchers, epidemiologists and citizens
- Employer representatives
- Government entities at the state, county and local levels
- Insurance company representatives
- Judicial branch
- Laboratory representatives
- March of Dimes
- Mayo Clinic and Foundation
- Minnesota Medical Association
- Prosecutors and public defenders
- University of Minnesota Center on Bioethics

Recommendation 9: Given the importance of genetics to society as a whole, the Legislature might consider beginning with the enactment of a definition for the term “genetic information.” The definition would apply in both the public and private sectors, give direction on how genetic information should be collected, stored, used and disseminated, and address those situations not already covered in existing law. It is recommended that this general provision classify any genetic information held by a government entity as private data and that similar restrictions be imposed on access to genetic information held in the private sector. The initial legislation should also provide other general guidance that would serve in those situations where there is no specific statutory authority.

Recommendation 10: There are a number of issues that are not covered by this report. To the extent that they were identified during the preparation of this report, they have been documented in Appendix 2. As part of the work outlined in Number 11 below, it is recommended that these issues be studied and proposals prepared for future legislative action.

As part of the consideration, some group participants were concerned that the benefits to society (solving crimes; decreasing the number of cases of a disease like tuberculosis; reducing obesity in the population) would be overshadowed by misuses of genetic information. There were also those who expressed the opposite concern that the potential for misuse would prompt restrictions on beneficial uses that would be detrimental to society. There was also concern that provision of

genetic information to government is not always voluntary. When the interaction with government is mandatory, consideration should be given to increased protections for the genetic information.

Recommendation 11: The final recommendation is for the Legislature to develop expertise among its members and staff in this area and use that expertise to ensure that careful consideration is given to all proposals that affect genetic information. While it will be up to you as legislators to determine whether and how to implement this recommendation, possible responses include (1) assignment of the subject to a single committee in each body; (2) creation of a subcommittee to hear all legislative proposals that deal with genetic information; (3) creation of a joint commission to develop and hear legislative proposals in a manner similar to the Claims Committee or the Pension Committee; and (4) assignment of staff in House Research and Senate Counsel and Research to develop expertise in the science and policy of genetics to assist legislators with this work.

If the Department can be of further assistance, please contact the Information Policy Analysis Division at 651-296-6733.

Respectfully submitted,

Dana B. Badgerow
Commissioner
Department of Administration

Genetic Information Report – Appendix 1
 Participants who provided input for the report
 January 2006

| Name | Affiliation, if any |
|-------------------------|---|
| Barbara Forsland | Transportation |
| Daniel Symonik | Health |
| Dave Orren | Health |
| David Honan | Human Services |
| Deb De Bruin | University of Minnesota/Center on Bioethics |
| Dianne Ward | Office of the Ramsey County Attorney |
| Don Gemberling | Citizen |
| E. Joseph Newton | Public Safety |
| Frank Dolejsi | Public Safety/Bureau of Criminal Apprehension |
| Jim Iverson | Public Safety/Bureau of Criminal Apprehension |
| Jim Rhodes | Administration |
| John Besser | Health |
| Kathy Meyerle | Mayo Clinic, Legal Department |
| Katie Engler | Administration/Information Policy Analysis |
| Kristin Peterson Oehlke | Health |
| Laurie Beyer-Kropuenske | Administration/Information Policy Analysis |
| Mark McCann | Health |
| Mark Warner, M.D. | Mayo Clinic |
| Mary Liz Holberg | State Representative |
| Megan Fogelson | Minnesota Medical Association |
| Myron Falken | Health |
| Nancy Blume | Health |
| Patricia Segal Freeman | Health |
| Patrick Sullivan | Office of the Hennepin County Public Defender |
| Paul Doyle | Office of the Ombudsman for Mental Health and Developmental Disabilities |
| Phyllis Kahn | State Representative |
| Teresa Nelson | American Civil Liberties Union - Minnesota |
| Tom Major | Health |
| Tom Pender | House Research |
| Twila Brase | Citizens' Council on Health Care |
| Warren Limmer | State Senator |

Appendix 2
What is not covered by this report on genetic information
January 2006

1. The direction provided by the Legislature specifically named genetic information held by state agencies. Therefore, no review was done of *any other unit of government* or its practices. As a result, use of genetic information by a local public health agency, law enforcement agency or medical examiners are not included in the report.
2. No review was done of *private sector* use of genetic information. For example, the use of genetic tests to grant or deny credit is not addressed in this report.

A review of other government entities and the private sector will be of assistance in completely understanding the breadth of the impact genetic information has in today's society and should be done as the Legislature continues to work on issues related to genetic information.

3. Another issue not addressed in this report is *how long state agencies keep the genetic information* that is collected or created. The general rule is that records must be kept unless the state agency has an approved records retention schedule that authorizes disposal. *See* section 138.17. The provisions of this section apply only to records, there is no state law that addresses retention or disposal of the biological samples from which the data are generated. There is also a need for guidance when a government entity hires work done with genetic information and how the contractor must treat and hold the genetic information. Please see Item 5 for more information.
4. When law enforcement is using DNA information as part of a criminal investigation, the lack of a total match to an existing record in a data collection may provide investigators with clues about who else should be considered as a suspect. For example, if there is a less than 100% match between the current sample and an existing record in the arrestee/offender data collection, statistics predict that a family member is likely to be a better match. Providing information about a less than complete match is known as *low stringency or familial searching*.

This tool is not currently in use in Minnesota. The BCA indicates that it does not provide information about a match between a sample from a pending case and a record in the data collection unless there is a 100% match. Before the match information is provided to the other law enforcement agency, the BCA checks to make sure the individual's record should be in the offender data collection. If the individual is properly in the offender data collection, the BCA re-tests the sample from the individual in the data collection to ensure that the same results are obtained.

5. There is very little law that addresses how to handle or use the *biological sample* from which the DNA is extracted. In the criminal area, Section 590.10 was enacted in 2005 and requires that a government entity hold the biological samples used to convict someone until that individual's sentence has expired or there is a court order authorizing an earlier disposal.

The BCA holds the samples used to create the results housed in the offender data collection in perpetuity but there is no statutory provision that addresses whether or when the offender, or any other person, can access that specimen.

There is a similar situation at the Department of Health because germs and diseases also have DNA. To the extent that a biological specimen containing the germ or disease also contains the DNA of a specific human being, there is nothing in statute to address access or use of the biological specimen.

Another area for consideration is testing done on behalf of government entities when an employee is being investigated or disciplined. Contractual provisions limiting what the laboratory can or cannot do with the sample or specimen and the test results may be appropriate. As is noted in Item 6, the same issue arises for private sector employees.

Without any laws that directly address the retention, use, destruction or return of the biological sample, government entities are without definite guidance. Treatment of the biological specimen is an area that needs to be addressed by the Legislature.

6. Government is not alone in the use of biological samples. As was indicated above, use of genetic testing in insurance and employment already are the subject of statutory provisions. There is nothing, however, that regulates the practices of the *companies that do the testing of the biological samples*. Therefore, there are no controls on the storage, use, retention, return or access to the samples or results held by these companies. This is another area for study and possible legislation.
7. Another issue for future consideration is what mechanism should be in place for ensuring that genetic information that will have a major impact on the lives of an individual's relatives are *shared with those relatives*? For example, if a parent refuses to consent to the children being told of the heritable disease that has just been diagnosed, is there a process that a physician, a public health authority, or the relatives can use to ensure that the information is shared? This would be of particular importance when the heritable disease responds more when treated early and the physician wants to be able to take those important early steps with a patient's children.
8. A final major issue is the fear of *genetic discrimination*. This is certainly an area where the Legislature has already enacted some laws. However, it is another area for further study and review to determine if additional laws are necessary to provide protection to those who are otherwise required to provide biological specimens either to government or in the private sector.