Admin Minnesota
DEPARTMENT OF ADMINISTRATION

January 15, 2009

Senator Mee Moua
Chair, Senate Judiciary Committee
75 Rev. Dr. Martin Luther King Jr. Blvd., Room 120
St. Paul, MN 55155

Representative Joe Mullery
Chair, House Civil Justice Committee
100 Rev. Dr. Martin Luther King Jr. Blvd., State Office Building, Room 367
St. Paul, MN 55155

Senator Warren Limmer
Ranking Minority Member, Senate Judiciary Committee
100 Rev. Dr. Martin Luther King Jr. Blvd., State Office Building, Room 141
St. Paul, MN 55155

Representative Steve Drazkowski
Ranking Minority Member, House Civil Justice Committee
100 Rev. Dr. Martin Luther King Jr. Blvd., State Office Building, Room 247
St. Paul, MN 55155

Dear Senators Moua and Limmer and Representatives Mullery and Drazkowski:

Enclosed please find the report I am required to submit to the chairs of the House Civil Justice Committee and the Senate Judiciary Committee and the ranking minority members of those committees by January 15, 2009, pursuant to Laws 2007, chapter 148, article 2, section 74.

This report is the result of efforts by the Genetic Information Work Group I was required to convene to develop principles for public policy on the use of genetic information in Minnesota. The Work Group provided valuable insight and expertise in the development of the recommendations of this report. Please note that consensus was not possible on many of the recommendations because of disagreement about rights, responsibilities, and limitations on the use of genetic information and human biological specimens. I would also like to acknowledge that the fact that a person's participation on the Work Group implies neither agreement nor disagreement with the recommendations in the report.

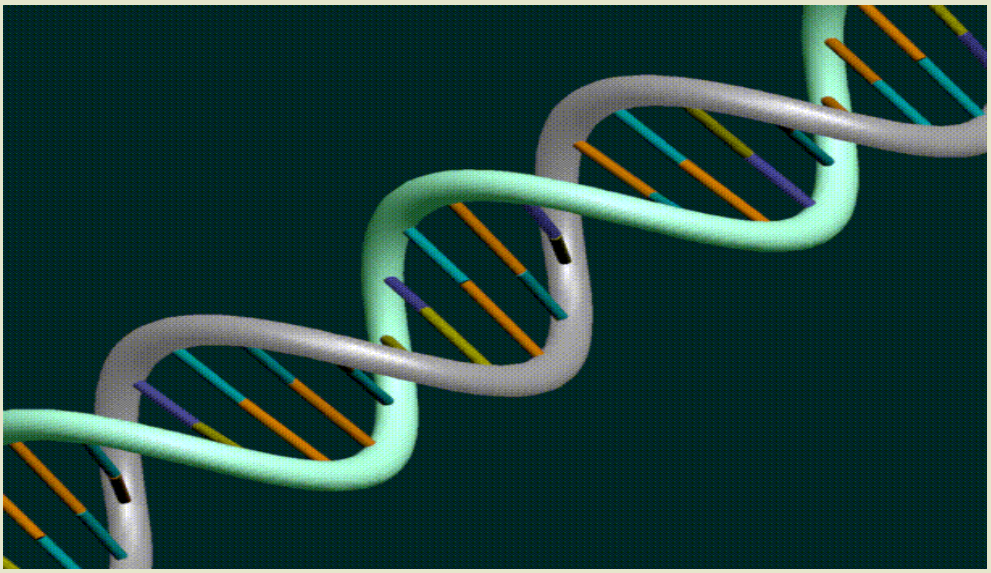
If the Department can be of further assistance, please contact Laurie Beyer-Kropuenske, Director of the Information Policy Analysis Division, at 651.201.2501.

Respectfully submitted,

Dana B. Badgerow
Commissioner

Enclosures

c: Legislative Reference Library



Genetic Information in Minnesota

A Report to the Minnesota State Legislature

January 2009

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This report is submitted to the Minnesota Legislature as required by 2007 Session Laws, Chapter 148, article 2, section 74 and addresses the State of Minnesota's handling of genetic information.

Introduction

As part of the 2007 Minnesota Session Laws, the Legislature directed the Commissioner of Administration to "develop principles for public policy on the use of genetic information." Specifically, the Legislature stated:

> Subdivision 1. **Genetic information; work group.** (a) The commissioner must create a work group to develop principles for public policy on the use of genetic information. The work group must include representatives of state government, including the judicial branch, local government, prosecutors, public defenders, the American Civil Liberties Union - Minnesota, the Citizens Council on Health Care, the University of Minnesota Center on Bioethics, the Minnesota Medical Association, the Mayo Clinic and foundation, the March of Dimes, and representatives of employers, researchers, epidemiologists, laboratories, and insurance companies.
>
> (b) The commissioner of administration and the work group must conduct reviews of the topics in paragraphs (c) to (f), in light of the issues raised in the report on treatment of genetic information under state law required by Laws 2005, chapter 163, section 87. The commissioner must report the results, 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, ~~2008~~ 2009.
>
> (c) The commissioner and the work group must determine whether changes are needed in Minnesota Statutes, section 144.69, dealing with collection of information from cancer patients and their relatives.
>
> (d) The commissioner and the work group must make recommendations whether all relatives affected by a formal three-generation pedigree created by the Department of Health should be able to access the entire data set, rather than only allowing individuals access to the data of which they are the subject.
>
> (e) The commissioner and the work group must identify, and may make recommendations among, options for resolving questions of secondary uses of genetic information.
>
> (f) The commissioner and the work group must make recommendations whether legislative changes are needed regarding access to DNA test results and the specimens used to create the test results held by the Bureau of Criminal Apprehension as part of a criminal investigation.

To begin the development of this report, the Commissioner convened a work group that included interested stakeholders, including those specifically identified by the Legislature. The Commissioner used the Secretary of State's open appointments process to recruit the members of the work group. The list of work group members and the group's regular meeting schedule is included in ***Appendix I***. Work group members, along with staff from the Minnesota Department of Administration's Information Policy Analysis Division participated in regular meetings held from September 2007 through November 2008.

In addition to the full work group meetings, four committees of the work group were created to sub-divide the discussion into the following categories:

1. Genetic Information Safeguards (pursuant to the general charge to "develop principles for public policy on the use of genetic information").
2. Access by Relatives to Three-Generation Pedigrees (pursuant to subdivision 1(d) of the legislative charge).
3. Access to Specimens Maintained by the Bureau of Criminal Apprehension (pursuant to subdivision 1(f) of the legislative charge).
4. Secondary Uses of Genetic Information (pursuant to subdivision 1(e) of the legislative charge).

The four committees consisted of both work group members and other interested parties. The four committees met during the time that the work group was convened to develop detailed recommendations for consideration by the full work group. The full work group then provided the recommendations that are detailed below.

This report continues prior work completed in the report titled, *A Report on Genetic Information and How it is Currently Treated Under Minnesota Law* submitted to the Legislature by the Commissioner of Administration on January 13, 2006.

The work group did not necessarily reach complete consensus on all of the recommendations. If applicable, work group member concerns are noted within each recommendation. Work group members were also invited to submit minority reports and/or comments in response to their review of the report version following the work group's last meeting on November 18, 2008. The minority report and comments are included in ***Appendix X***.

Current Trends in the Treatment of Genetic Information

Genetic information has received increased attention in the last decade with the completion of the Human Genome Project[1] and the passage of legislation regulating its treatment at both the state[2] and federal levels. In addition, the treatment of genetic information is of great importance because an individual's DNA can provide information about not only the individual from whom the DNA is collected, but also blood relatives of that individual. The following timely topics provide a sample of discussions taking place nationally regarding the treatment of genetic information.

GINA. The federal Genetic Information Nondiscrimination Act (GINA), passed by overwhelming majorities in the House of Representatives and the Senate, and was signed by President Bush on May 21, 2008. GINA addresses issues around the treatment of genetic information in health insurance and employment. A summary of GINA and the health insurance and employment provisions in Minnesota law is available in ***Appendix II***. The GINA provisions relating to health insurance will become effective one year after May 21, 2008 while the employment provisions become effective 18 months after enactment. To the extent that state law is more protective of genetic information, state law controls. Until the federal regulations that will implement GINA are promulgated, either by May 2008 or November 2008, it remains unclear the specific impact this federal law will have on Minnesota law.

Direct-to-consumer marketing. Direct-to-consumer (DTC) marketing of genetic tests, where genetic testing laboratories advertise their tests directly to the consumer via television, print and the internet, has caused recent national and international concern. Several companies, like 23andme, deCODEME, Navigenics and Knome, offer tests using genome-wide technology directly to consumers over the internet. One concern is that individual consumers who order these genetic tests directly from these companies may not receive adequate information to know the value and clinical utility of the tests.

The federal government has not yet taken steps to regulate DTC genetic testing. The Federal Trade Commission has jurisdiction regarding false or misleading advertising, but to date has taken no action against any genetic test advertisements. The Food and Drug Administration, despite authority to do more, currently regulates only those genetic tests that are sold as "test kits" and used by laboratories to perform testing.[3]

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[1] Information about the Human Genome Project is available from the National Human Research Institute at www.genome.gov/10001772.

[2] National Conference of State Legislatures, State Genetics Employment Laws: www.ncsl.org/programs/health/genetics/ndiscrim.htm; Genetics and Health Insurance State Anti-Discrimination Laws: www.ncsl.org/programs/health/genetics/ndishlth.htm; Genetics and Life, Disability and Long-term Care Insurance: www.ncsl.org/programs/health/genetics/ndislife.htm.

[3] The Genetics and Public Policy Center has issued a report on this topic available at www.dnapolicy.org/policy.issue.php?action=detail&issuebrief_id=32. The National Human Genome Research Institute also has a report available at www.genome.gov/12010660.

Using an offender's DNA to investigate crimes possibly committed by relatives of the offender. DNA databases, which maintain genetic information on convicted criminal offenders, are expanding across the nation. A database exists at the federal level (the National DNA Index System) as well as in a majority of the states. Authorities are permitted to search the database to match a sample from a crime scene against the genetic information on record for convicted offenders. But the question arises: should the database be searched to locate a perpetrator who may be closely related to an offender whose information is in the database?

Conducting what is known as a "familial search" is the searching of the database at a low stringency level, allowing a less-than-perfect match, with the purpose of identifying criminal suspects. If a partial match is discovered, the suspect is presumably a relative of the convicted offender. This raises questions pertaining to individual privacy rights, discrimination, racial bias, and justice.

Currently, California has adopted a policy allowing purposeful familial searches. New York and Massachusetts have promulgated regulations that provide guidance on low stringency searches. However, Maryland has passed a law specifically prohibiting these types of searches. Great Britain has been conducting familial searches for over five years, though it now encounters new questions as its database has expanded to include people who have been arrested for minor offenses.[4]

Additional Notes

Based on the increased attention and implications concerning genetic information, the Minnesota Genetic Information Work Group anticipates the recommendations in this report will provide guidance to the Legislature. However, as this area is ever evolving, the work group acknowledges the information within this report is current only as of its submission to the Legislature in January of 2009.

The following terms used within this report have meanings as defined by statute.

> **Government entity:** a state agency, statewide system, or political subdivision. (Minnesota Statutes, section 13.02, subdivision 7a)
>
> **Private health care provider:** any person who furnishes health care services and is regulated to furnish the services under chapter 147, 147A, 147B, 147C, 147D, 148, 148B, 148C, 148D, 150A, 151, 153, or 153A; a home care provider licensed under section 144A.46; a health care facility licensed under this chapter or chapter 144A; a physician

[4] See also "From DNA of Family, a Tool to Make Arrests," by Ellen Nakashima, *The Washington Post* (April 21, 2008), available at www.washingtonpost.com/wp-dyn/content/article/2008/04/20/AR2008042002388_pf.html; "State Regulations on Low Stringency/Familial Searches of DNA Databases," available at www.aslme.org/dna_04/reports/axelrad1.pdf (giving examples of statutory language in Massachusetts and New York); "Familial DNA Testing," *PBS: Religion & Ethics Newsweekly* (May 16, 2008), available at www.pbs.org/wnet/religionandethics/week1137/cover.html and "A Not So Perfect Match," *60 Minutes* (July 15, 2007), available at www.cbsnews.com/stories/2007/03/23/60minutes/main2600721_page2.shtml.

> assistant registered under chapter 147A; and an unlicensed mental health practitioner regulated under sections 148B.60 to 148B.71. (Minnesota Statutes, section 144.291, subdivision 2(h))

The terms "**genetic information**" and "**human biological specimen**" are used throughout this report. The two terms are not meant to be used interchangeably. They are used to differentiate between recommendations that relate to the data derived from a human biological specimen ("genetic information") and recommendations that relate to the actual human biological specimen.

Genetic Information Safeguards

Legislative Charge

The work group's broad charge from the Legislature was "to develop principles for public policy on the use of genetic information." To that end, the work group discussed and considered whether additional safeguards should be in place to adequately protect genetic information in Minnesota.

A committee formed to discuss genetic information safeguards met monthly from January 2008 through August 2008. The committee's recommendations were presented to the work group on September 23, 2008 and October 21, 2008. The full work group's recommendations are outlined in this section.

Background, Discussion and Recommendations

At its first meeting, the Genetic Information Safeguards Committee was asked to prioritize issues for consideration on genetic information safeguards. The committee discussed and provided recommendations to the full work group based on their prioritized issues. The information in this section provides both background and the full work group's recommendations for five prioritized issues relating to safeguarding genetic information.

1. Status of Current Minnesota Protections of Genetic Information

The committee identified the status of Minnesota Statutes, section 13.386 (treatment of genetic information held by government entities and other persons) as an important issue for the work group's consideration. In addition to the protections in section 13.386, there are genetic information safeguard provisions that apply to Minnesota health and life insurance companies in Minnesota Statutes, section 72A.139 and Minnesota employers in Minnesota Statutes, section 181.974. There are also newly enacted safeguards within federal law in the Genetic Information Non-Discrimination Act (GINA), P.L. 110-233. The committee and work group made recommendations as to the status and applicability of these current Minnesota laws.

Genetic Information Safeguards Recommendation One

The work group recommends that the health and life insurance provisions (Minnesota Statutes, section 72A.139) and the employment provisions (Minnesota Statutes, section 181.974) remain in effect at their current locations in Minnesota Statutes. The work group further recommends the need for additional guidance from the Legislature regarding genetic information held by government and other persons (Minnesota Statutes, section 13.386).

Health insurance
Section 72A.139 prohibits health insurers, in determining eligibility for coverage, establishing premiums, limiting coverage, renewing coverage, or any other underwriting decision, from:

- Requiring or requesting an individual or a blood relative to take a genetic test
- Making any inquiry to determine whether an individual or a blood relative has taken or refused a genetic test, or the results of any such test
- Taking into consideration the fact that a genetic test was taken or refused by an individual or blood relative
- Taking into consideration the results of a genetic test taken by an individual or a blood relative

Life insurance
Section 72A.139 requires life insurers must obtain an individual's written informed consent for genetic testing.

Employment
Section 181.974 prohibits an employer or employment agency from directly or indirectly:

- Administering a genetic test or requesting, requiring, or collecting protected genetic information as a condition of employment
- Affecting the terms or conditions of employment or terminating the employment of any person based on protected genetic information.

Treatment of genetic information held by government and other persons
The group recommends that the Legislature clarify the following items as they pertain to the treatment of genetic information held by government entities and other persons under section 13.386:

- The "data subject" of genetic information and human biological specimens in section 13.386 is the individual from whom the genetic information is collected (i.e. clarify subdivision 1(a)(2)).
- Whether the requirements in section 13.386 apply to both government and private sector persons. If the requirements are to apply to both government and non-government, it is recommended that the section remain in Chapter 13 and also in a chapter applicable to private sector persons.
- The scope and definition of key terms in section 13.386, including:
    - Whether the section is to apply prospectively or retrospectively to the data/specimens
    - The duration of consent in subdivision 3(4)(ii)
    - What "dissemination" means in terms of duration of consent
    - Additional requirements or limitations that section 13.386 places on current informed consent requirements

- Clarify/define "genetic condition" and "medical or biological information" in subdivision 1(b)

2. Notice of Rights and/or Informed Consent Requirements

The committee identified the adequacy of informed consent and required notices as an important issue for the work group's consideration. Currently, the Minnesota Data Practices Act (Minnesota Statutes, Chapter 13) requires a notice called a "Tennessen warning"[5] to be provided to an individual when a government entity collects private data, including genetic data, about the individual from the individual. The Data Practices Act also requires that a government entity obtain informed consent[6] from an individual for any subsequent uses or releases of genetic data that were not included in the original Tennessen warning. Minnesota has consent requirements that apply to Minnesota health care providers[7] in the Health Records Act (Minnesota Statutes, sections 144.291 to 144.298) and informed consent requirements related to the collection, storage, use, and dissemination of genetic information in Minnesota Statutes, section 13.386.

Federal law, in the regulations that implement the Health Insurance Portability and Accountability Act (HIPAA), 45 CFR Parts 160, 162, and 164, requires covered entities to provide a notice of privacy practices[8] and obtain an authorization[9] for certain uses and disclosures of protected health information. It is important to note that the current Minnesota and federal notice and consent requirements only apply to *genetic data*, not to *human biological specimens*.

The committee and work group discussed the relationship of persons who collect genetic information and human biological specimens for government programs on behalf of the government. Although there appears to be an arguable agency relationship between these parties, there was disagreement within the work group as to whether the notice and consent requirements that apply to government entities would apply to these outside persons absent a specific contractual relationship between the parties.

The committee and work group made recommendations on whether additional notice and informed consent requirements are needed to adequately safeguard both the genetic data and the human biological specimens as the requirements apply to direct-to-consumer genetic tests and private research laboratories, private health care providers, and Minnesota government entities.

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[5] The Tennessen warning requirements in Minn. Stat. § 13.04, subd. 2, include: (1) the purpose and intended use of the requested data within the collecting government entity; (2) whether the individual may refuse or is legally required to supply the requested data; (3) any known consequence arising from supplying or refusing to supply private or confidential data; and (4) the identity of other persons or entities authorized by state or federal law to receive the data.
[6] Minn. Stat. § 13.05, subd. 4 and Minn. R. 1205.1400.
[7] "Provider" is defined in Minn. Stat. § 144.291, subd. 2(h).
[8] 45 CFR 164.520.
[9] 45 CFR 164.508.

Genetic Information Safeguards Recommendation Two

In addition to the current Minnesota and federal notice of rights and informed consent requirements in the Data Practices Act, the Health Records Act, and HIPAA's regulations that apply to the collection, use, retention, and dissemination of genetic information, the work group generally agreed that some additional requirements are needed to adequately safeguard genetic information and human biological specimens that may be collected and maintained as genetic information.

The work group recommends that additional notice of rights and/or informed consent requirements are needed for the collection of genetic information, including human biological specimens, in the following topic areas.

1. Direct-to-consumer genetic tests and private sector labs

The work group recognizes that there are jurisdictional issues related to direct-to-consumer genetic tests when businesses use the internet to market the tests and conduct business across state lines. However, the work group recommends that a notice of rights should be provided by private sector labs that perform consumer initiated genetic testing in Minnesota. The notice of rights should include:

- Whether the specimen and data will be kept beyond the completion of the test
- A suggestion that the consumer consult a doctor to interpret the genetic test results
- Information about validity of the test
- A description of the risks and/or benefits of the collection, testing, retention and/or disclosure of genetic information and/or specimens
    - Why the genetic information and/or specimens will be collected
    - What the genetic information and/or specimens will be tested for beyond what the consumer is requesting to be tested
    - If applicable, how to opt out of the specimen/data retention and include the fact that a court could order the company to produce the data/specimen

The work group was somewhat divided on whether to recommend also requiring an informed consent for any use/sharing that is not included in the original notice of rights provided to consumers. Some work group members also indicated concern about how to better ensure enforcement of these requirements.

2. Private health care providers

The work group recommends extending the notice of rights and informed consent protections that currently apply to protected health information in HIPAA,[10] to health records in the Minnesota Health Records Act,[11] and medical and health data in the Data Practices Act,[12] to

[10] 45 CFR Part 164 (2008).
[11] Minn. Stat. § 144.293 (2008).
[12] Minn. Stat. § 13.04, subd. 2 (2008); Minn. Stat. § 13.05, subd. 4 (2008); Minn. Stat. § 13.386 (2008); Minn. R. 1205.1400 (2007).

human biological specimens, specifically that data subjects receive notice on how their specimens will be used. Although a majority of the work group agreed with this, some work group members strongly disagreed with it.

Work group members who disagree with this recommendation feel that it does not offer sufficient protections for genetic information and human biological specimens maintained by private health care providers.[13] Specifically, their disagreement with this recommendation includes the following issues:

- Informed consent is not always required for subsequent research[14] conducted internally within the entity that originally collected the specimen
- It lacks an opt-in to consent to subsequent research – the patient does not always know what research may potentially be conducted on his/her specimen
- Entities are not prevented from retaining data/specimens beyond a retention period
- Individuals may become involuntary research subjects

3. Collections of genetic information for government programs

Under existing law, the current notice of rights and informed consent requirements do not apply to all collections of genetic information and human biological specimens. Specifically, the following collections are exempt from the recommendation:

- Mandatory collections for law enforcement purposes pursuant to Minnesota Statutes, sections 609.117, 299C.105, 299C.11, and 390.25
- Mandatory collections pursuant to the cancer surveillance system under Minnesota Statutes, sections 144.671 – 144.69 and Minnesota Rules 4606.3303
- Mandatory collections of communicable diseases and infectious agents listed in Minnesota Rules 4605.7040, 4605.7044, and 4605.7700

The work group recommends extending current Tennessen warning requirements in the Data Practices Act (Minnesota Statutes, section 13.04) to the collection of human biological specimens by government entities. The work group also recommends that the Legislature may want to add some or all of the following to the current Tennessen warning requirements when genetic information or human biological specimens are collected:

- Known secondary uses both internally and externally
- The fact that genetic information can reveal information about a person's blood relatives
- If a Tennessen warning notice describes a use for "research,"[15] it should describe any research that is unrelated to the intent of original collection
- How long the genetic information and/or specimens will be maintained

[13] These concerns would also apply to government entities.
[14] Members were unable to agree on a definition as to what constitutes "research" as the term is used within this section.
[15] See footnote 14.

Some work group members also noted that a change in law could invalidate any limits that apply at the time of collection. However, some work group members felt it was not necessary to include this factor in the above list because it is always a possibility for any collection by the government.

The work group recommends that subsequent informed consent, as described in Minnesota Rules 1205.1400,[16] be required for any use or sharing of the specimen that is not included the original Tennessen warning. Some work group members strongly support the requirement of a consent document including the same conditions in Minnesota Rules 1205.1400 that would be collected from an individual at the same time a Tennessen warning is given.

For Tennessen warning and informed consent requirements, the work group notes that the "data subject" (the individual who must receive the notice or provide consent) is the individual from whom the genetic information is collected.

3. Use and Control of Human Biological Specimens

The committee identified human biological specimen ownership rights and responsibilities as an important issue for the work group's consideration. Currently, there is little guidance within state and federal law in determining who "owns" a human biological specimen. In other words, there is disagreement as to whether the individual that provided the specimen for testing or research owns the specimen or whether the owner is the entity that collects and maintains the specimen. Court cases from the federal 8th Circuit Court of Appeals[17] and the Supreme Court of California[18] seem to conclude that an individual providing a specimen may not always retain ownership rights in the specimen. The committee and work group were not able to provide a recommendation as to who retains ownership rights of the specimen – whether it is the individual who provided the specimen or the entity that maintains the specimen. The committee and work were able to provide recommendations as to control over the specimen.

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[16] Subp. 3. **Informed consent.** For the purposes of Minnesota Statutes, section 13.05, subdivision 4, clause (d) the following term shall have the meaning given it.
"Informed consent" means the data subject possesses and exercises sufficient mental capacity to make a decision which reflects an appreciation of the consequences of allowing the entity to initiate a new purpose or use of the data in question.
Subp. 4. **Restrictions.** For the purposes of the administration of Minnesota Statutes, section 13.05, subdivision 4, clause (d), the responsible authority shall comply with the following:
A. The responsible authority shall not take any action to coerce any data subject to give an "informed consent." The responsible authority shall explain the necessity for or consequences of the new or different purpose or use.
B. All informed consents shall be given in writing. Prior to any signature being affixed to it by the data subject, such writing shall identify the consequences of the giving of informed consent.
C. If the responsible authority makes reasonable efforts to obtain the informed consent of a data subject and if those efforts are not acknowledged in any way, the responsible authority shall interpret the silence of the data subject as the giving of an implied consent to the new or different purpose or use of the data.
[17] *Washington University v. Catalona*, 490 F.3d 667 (8th Cir. 2007).
[18] *Moore v. Regents of the U. of Cal.*, 51 Cal.3d 120, 793 P.2d 479 (Cal. 1990).

Genetic Information Safeguards Recommendation Three

The work group recommends that state law should require that both government and private sector entities with human biological specimens collected and maintained for a specific purpose have the responsibility to safeguard and manage the use of the specimens within state and federal laws and regulations.

Requirements placed on the maintaining entity to safeguard the human biological specimen should include:

- Physical security and appropriate conditions for maintaining and disposing of the specimen
- Accurate tracking and linking (if applicable) of data and specimens to each other
- Access to specimens limited to those employees whose work assignment so requires and unauthorized access to the specimen must be prevented by employees and others
- Reasonable steps for disaster recovery must be in place for *government maintained* specimens

4. Government Retention of Human Biological Specimens

The committee identified human biological specimen retention requirements as an important issue for the work group's consideration. Minnesota law, along with the laws in many other states, is silent on the issue of retention of human biological specimens maintained by government entities (see ***Appendix IV***). State laws that do address specimen retention and destruction include: Alaska, Delaware, Missouri, New Jersey, New Mexico, New York, Oregon, and Texas (see ***Appendix V***). There are some retention requirements in the federal regulations (42 CFR Part 493) applicable to laboratories that are subject to the Clinical Laboratory Improvement Amendments (CLIA). The federal regulations state that laboratories must retain cytology slide preparations for at least 5 years, retain histopathology slides for at least 10 years, retain pathology specimen blocks for at least 2 years, and preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen (42 CFR 493.1105).

Based on current Minnesota law, and within the limits of federal regulations, the following options were identified for discussion on Minnesota government entities' retention of specimens:

- Remain silent in Minnesota law (the status quo)
- Set a retention period with destruction required
- Set a retention period and allow an indefinite hold by government entities
- Retain specimens only with consent
- Retain specimens with consent, but provide exceptions
- Require destruction of specimens
- Require destruction of specimens, but allow for exceptions
- Destroy specimens upon request

Genetic Information Safeguards Recommendation Four

If a retention period for human biological specimens is not set by state or federal law, government entities must have a publicly available retention policy for the specimens. There was a strong difference of opinion among group members as to whether retention policies should include an opportunity for an individual to opt-out or to opt-in if a specimen will be used for research.[19] There was also disagreement among members as to what specifically constitutes "research" using the specimen.

There was disagreement within the work group as to which body should set the policy for retention of human biological specimens by government entities. The range of options the work group recommends presenting to the Legislature as to which entity should make the retention determination includes:

- The Minnesota Legislature
- Individual government entities that maintain human biological specimens
- A newly created body, similar to the State Records Disposition Panel,[20] to approve government entity specimen retention policies

5. Genetic Information Education

The committee identified education of employees in all three branches of government, employees in the private sector, and the public as an important issue in safeguarding genetic information. Currently, there is abundant information about genetic-related issues available on the internet. For example, an internet search on Google using the phrase "genetic information education" retrieves 4,840,000 results. Based on similar searches used on the internet, the committee was provided with samples of the currently available information related to genetic information education. The information provided to the committee is included in ***Appendix III***. The committee discussed in depth whether there is a need in Minnesota for greater dissemination of this type of information.

Genetic Information Safeguards Recommendation Five

In light of the substantial information already available on the internet, the work group generally agreed that some additional educational resources are needed to adequately safeguard genetic information in Minnesota.

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[19] An "opt-out" to a retention policy means that an individual's biological specimen is automatically retained according to the retention policy unless the individual requests the specimen to not be retained. An "opt-in" to a retention policy means that individuals must provide affirmative permission for their biological specimens to be retained.

[20] Under Minn. Stat. § 138.17, subd. 1, the records disposition panel is comprised of the "attorney general, legislative auditor in the case of state records, state auditor in the case of local records, and director of the Minnesota Historical Society."

Based on the importance of educating Minnesota's citizens in this area, and acknowledging the State's role in consumer protection, the work group recommends the development of the following resources:

- a brochure for citizens on the current protections against genetic discrimination in Minnesota and federal law;
- a consumer focused website that describes Minnesota and federal law and resources and includes links to other genetic information websites; and
- one-page fact sheets on informed consent and direct-to-consumer genetic testing that are age-appropriate (directed at both high school students and adult consumers) and readable at different levels.

The work group understands that developing any educational resources will have fiscal implications, but recommends some funding from the Legislature to accomplish these goals.

Minnesota Cancer Surveillance System

Legislative Charge

The Legislature directed the work group to consider changes to the Minnesota Cancer Surveillance System. The relevant portion of the charge is:

> (c) The commissioner and the work group must determine whether changes are needed in Minnesota Statutes, section 144.69, dealing with collection of information from cancer patients and their relatives.

The work group discussed this portion of the legislative charge at meetings on October 23, 2007 and December 6, 2007.

Background and Discussion

The Minnesota Department of Health (MDH) has been directed to establish a statewide cancer surveillance system to monitor incidence trends to detect potential public health threats, target intervention resources, inform health professionals and citizens and promote high quality research (Minnesota Statutes, section 144.671). As part of this surveillance system, Minnesota Statutes, section 144.69, allows MDH to interview patients or their relatives only with the consent of the patient's attending physician or surgeon. Under this law, the consent of the patient is not required for interviews with relatives. The interviews may include a transfer of genetic information to the patient's relatives, which is generally the type of disclosure of medical information that can only be made with the individual patient's consent under Minnesota Statutes, section 144.293.[21]

MDH provided the work group with information about the Cancer Surveillance System including the background of the program. MDH stated that the enacted statutory language was based on assumptions that relatives would not be interviewed unless the patient was deceased or was not capable of providing consent. As a part of its current practice, MDH contacts the patient (if the patient is able to provide consent) for permission to contact his/her relatives, even though this is not required under current law. MDH also noted that the physician providing the report to MDH may be a pathologist or other physician not providing direct services to the patient.

Options for change

The following options for possible change to Minnesota Statutes, section 144.69 were considered. The work group's rationale, if any, is summarized under each bulleted option.

- No change to current statute

[21] The consent required under section 144.293 would not apply to information collected for public health purposes under Minn. Stat. § 13.3805.

- MDH does not currently contact relatives without consent from the patient, even if consent is not required by law.
- The physician can act as the gatekeeper. This allows for little intrusion into patient privacy because the physician already knows about the situation.
- There are practical reasons for having the physician involved because s/he is in the best position to know about the situation.
- Some members were concerned about trusting physicians to make decisions on behalf of the patient.
- Some physicians who report to the Cancer Surveillance System do not provide continuing care to the patient.

- Consent by patient (next of kin, personal representative, or health care agent if patient is deceased or otherwise incapacitated[22]/unable to consent) and consent by physician/surgeon is needed to interview patient or relatives

- Require consultation with physician and consent by patient to interview patient or relatives
  - MDH noted that it is generally a good practice to consult with a physician and for a physician to know if a patient is asked to participate in a study or research. The physician can then provide advice to the patient about whether to participate.
  - The role of the physician should be a consultant. S/he doesn't make the decision, but becomes an advisor to the process.
  - Change statutory language from "only after ***consent*** of the attending physician or surgeon" to "only after ***consultation*** with the attending physician or surgeon."

- Provide for optional consultation with physician and consent by patient to interview patient or relatives
  - Physician consultation would be used as necessary or appropriate, but not required to request patient consent.
  - MDH would consult with a physician prior to MDH's contact with a patient, but the physician would not be required to consent for MDH to contact the patient.
  - This type of consultation may be burdensome to physicians. As explained by MDH, the role of physicians varies when they are contacted – some physicians contact individual patients, some provide broad consent, and some evaluate each situation on a case by case basis.

- Require approval of Commissioner of Health to interview patient or relatives, if necessary for public health purposes (no physician/patient consent)

Recommendation One: Consent from Patient

The work group recommends that Minnesota Statutes, section 144.69 be changed to require MDH to obtain consent from patients for all interviews conducted as part of the Cancer Surveillance System. The work group also recommends removing the requirement that MDH obtain consent from the attending physician or surgeon to conduct interviews with patients or their relatives.

[22] The term "incapacitated" as used in this section is used to describe a patient who is unable to consent. It does not include the legal definition of incapacitated.

Recommendation Two: Hierarchy of Consent

If patients are unable to provide consent because they are deceased or otherwise incapacitated, the work group recommends that the following individuals must be contacted in this specific order:

1) Legal Guardian
2) Health Care Agent
3) Spouse or Registered Domestic Partner
4) Next of Kin
5) Personal Representative

Once an individual in the above hierarchy has provided consent, or refused to provide consent, that individual's determination on consent is final. A person lower on the hierarchy cannot be approached to override a previous decision of a higher ranking decision maker, but may be approached if a future question arises and the higher ranking decision maker is no longer available. The work group agreed that by giving the patient control over contact with the patient's relatives, there is no longer a role for the physician.

Statutory Changes

Based on the work group's recommendations, Minnesota Statutes, section 144.69 should be amended as follows:

> **144.69 CLASSIFICATION OF DATA ON INDIVIDUALS.**
> (a) Notwithstanding ~~any law to the contrary, including~~ section 13.05, subdivision 9, data ~~collected~~ on individuals collected by the cancer surveillance system, including the names and personal identifiers of persons required in section 144.68 to report, shall be private as defined in section 13.02 and may only be used for the purposes set forth in this section and sections 144.671, 144.672, and 144.68. Any disclosure other than is provided for in this section and sections 144.671, 144.672, and 144.68, is ~~declared to be~~ a misdemeanor ~~and punishable as such~~.
>
> (b) ~~Except as provided by rule, and as~~ As part of an epidemiologic investigation, an ~~officer~~ agent or employee of the commissioner of health may interview patients named in any ~~such~~ report, or relatives of any ~~such~~ patient, only after ~~the~~ consent from the patient ~~of the attending physician or surgeon~~ is obtained. If the patient is deceased, or unable to provide consent, consent must be obtained from the patient's:
> (1) legal guardian or health care agent, according to the designation in the patient's health care directive;
> (2) spouse or registered domestic partner, if the patient does not have a legal guardian or health care agent;
> (3) next of kin, if the patient does not have a legal guardian, health care agent, spouse or registered domestic partner; or
> (4) personal representative, if the patient does not have a legal guardian, health care agent, spouse, registered domestic partner, or next of kin.

(c) The determination on consent is final once consent has been provided or refused.

(d) For purposes of this section, consent from the person required to report in section 144.68 is not needed before a request is made to the patient for an interview.

The work group's recommendations would also require the repeal of Minnesota Rules 4606.3306 (Physician Consent). Additional rules may also need to be repealed or modified to conform to the revised statutory language.

Access by Relatives to Three-Generation Pedigrees

Legislative Charge

The Legislature directed the work group to consider the access rights of relatives to a formal three-generation pedigree. The relevant portion of the Legislative charge is:

> (d) The commissioner and the work group must make recommendations whether all relatives affected by a formal three-generation pedigree created by the Department of Health should be able to access the entire data set, rather than only allowing individuals access to the data of which they are the subject.

A committee formed to discuss this portion of the Legislative charge met on October 9, 2007. The committee's recommendations were presented to the work group on January 29, 2008. The work group's background, discussion, and recommendations are outlined in this section.

Background and Discussion

Three-generation pedigrees

Three-generation pedigrees can be pictorial representations or narratives of family history created by medical providers based on a patient's recollection. The specific information given to a provider as recalled either by a patient, or on behalf of a patient by a family member, is the family history of disease and medical conditions. For purposes of the work group's recommendations, three-generation pedigrees do not include the actual results of genetic tests.

Sample Three-Generation Pedigree for Patient X

Sister A	Uncle B	Cousin C	Nephew D
Colon cancer	Colon cancer	Colon cancer	Colon cancer

The above chart is an illustration of a three-generation pedigree. In this sample, Patient X has provided her recollection about the incidence of colon cancer in her family. In the sample, X has identified four relatives by name (A, B, C, and D) who X recalls as having colon cancer. This information is entirely based on X's recollection and may not be accurate (e.g. the relatives may or may not have cancer, and if they do have cancer, it may or may not be colon cancer).

Current law

Under current law, access to this type of pedigree differs based on where it is maintained.

- At a ***private medical provider***, access is governed by the Minnesota Health Records Act (Minnesota Statutes, sections 144.291 to 144.298). The pedigree is kept with the patient's medical chart, making it part of the patient's medical record. The patient has

access to all the data in the pedigree and must consent before anyone else can have access to the data.

- At a ***public medical provider*** (such as Hennepin County Medical Center, local public health clinics, and other government-operated medical facilities), access is governed by Minnesota Statutes, Chapter 13. Once a patient provides data about his/her relatives, those data are about the relatives and the patient no longer has access to the entire pedigree. (e.g., Patient X has access to the data she provided about herself in the pedigree, but not to the data she provided about her sister, uncle, cousin, or nephew). By law, each relative has access to his/her own data and can consent for others to have access, but only to his/her portion of the pedigree (Minnesota Statutes, section 13.384, subdivision 3).

The Access by Relatives to Three-Generation Pedigrees Committee's recommendation to the work group was to permit the patient, for whose benefit the pedigree was created, to have access to all the data in the pedigree, regardless of where the pedigree is maintained. This means that the pedigree can be accessed only by the patient who is being treated. Any other access to the pedigree is granted only with the consent of that patient or as otherwise authorized by law.

The committee and work group provided pros and cons for the recommendation of allowing a patient access to the full three-generation pedigree without allowing access to the patient's relatives within the pedigree.

Pros of limiting access by all relatives in a three-generation pedigree

- There may be stress caused to relatives by having the knowledge of more medical information.
- Relatives should enjoy a right not to know the information in the pedigree.
- There is an invasion of privacy of the individual who supplied the data to their medical provider.
- There is an invasion of privacy of the other relatives who are detailed in the pedigree.
- Fewer people may be open and forthright with their medical providers if they fear data will be shared with other relatives.
- Greater access by relatives increases the risk that data will become more broadly known and result in insurance or employment discrimination, personal embarrassment, and damage to reputation.
- A three-generation pedigree can involve a large number of relatives and providing access would require staff time and other resources that would have a significant monetary impact.
- Access may create unintended responsibilities on the part of the physician to notify relatives of genetic illnesses in the family.
- The pedigree may not be a complete and accurate record if the pedigree does not list all relatives and the omitted relatives would not have access to the information.
- Incomplete information on relatives makes it difficult to track them.

- False information is propagated by allowing access without consent.
- False information in the pedigree could create conflict and be costly to resolve.
- Information that is included or excluded may not recognize family members who are not related by blood, whether through adoption or some other event.

Cons of limiting access by all relatives listed in a three-generation pedigree

- Access enables relatives and their medical providers to have more information that may allow for more proactive management of their health care.
- Access to more information has potential to speed care and diagnosis and save on overall medical costs.
- Sets a precedent of government denying access to the subject of data when relatives are named in the pedigree.
- Government may hold data on individuals that the individual would not be allowed to access, or even know the data exists, except from the patient who provided the data.

Recommendation One: Patient Access to Pedigree

The work group recommends that the patient providing information for a three-generation pedigree is the data subject, for purposes of Minnesota Statutes, Chapter 13. This would allow only the individual patient the access rights of a data subject to the entire pedigree. Chapter 13 currently permits parent(s) and guardian(s) of minor children and incapacitated persons to access their private data in three-generation pedigrees, unless the data may be withheld under Minnesota Statutes, section 13.02, subdivision 8 and Minnesota Rules 1205.0500. As data subjects, individuals would have the authority to consent to the release and sharing of the pedigree with anyone for any purpose.

Recommendation Two: Consistent Access at Private and Public Medical Providers

The work group also recommends that the Legislature should not provide greater access to pedigrees maintained at the Minnesota Department of Health than access the Legislature is prepared to provide to pedigrees maintained by other government entities and private medical providers. The work group recommends that medical providers subject to the Minnesota Health Records Act limit access to a completed pedigree to the patient being treated. This is consistent with current practice in releasing and protecting medical records in medical practices of all types. The group recommends that any rules of access by relatives to a pedigree should provide the same level of privacy regardless of whether an individual's medical provider is a public or private sector provider.

Statutory Changes

Based on the work group's recommendation, Minnesota Statutes, section 13.384 should be amended as follows:

> Subdivision 1. **Definition.** As used in this section:
> (a) "Directory information" means name of the patient, date admitted, and general condition.
> (b) "Medical data" means data collected because an individual was or is a patient or client of a hospital, nursing home, medical center, clinic, health or nursing agency operated by a government entity including business and financial records, data provided by private health care facilities, and data provided by or about relatives of the individual.
> (c) "Three generation pedigree" means a pictorial representation or narrative of family history for a particular disease or condition given by a patient, including the names of other family members and their relationship to the patient. A three generation pedigree does not include the results of any tests.
>
> Minnesota Statutes, section 13.384 is amended by adding a subdivision:
>
> Subd. 4. **Three generation pedigree.** A three generation pedigree is medical data about the patient and the patient has access to all of the data in the pedigree.

Access to Specimens Maintained by the Bureau of Criminal Apprehension

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Legislative Charge

The Legislature directed the work group to consider access to DNA test results and specimens maintained by the Minnesota Bureau of Criminal Apprehension (BCA). The relevant portion of the Legislative charge is:

> (f) The commissioner and the work group must make recommendations whether legislative changes are needed regarding access to DNA test results and the specimens used to create the test results held by the Bureau of Criminal Apprehension as part of a criminal investigation.

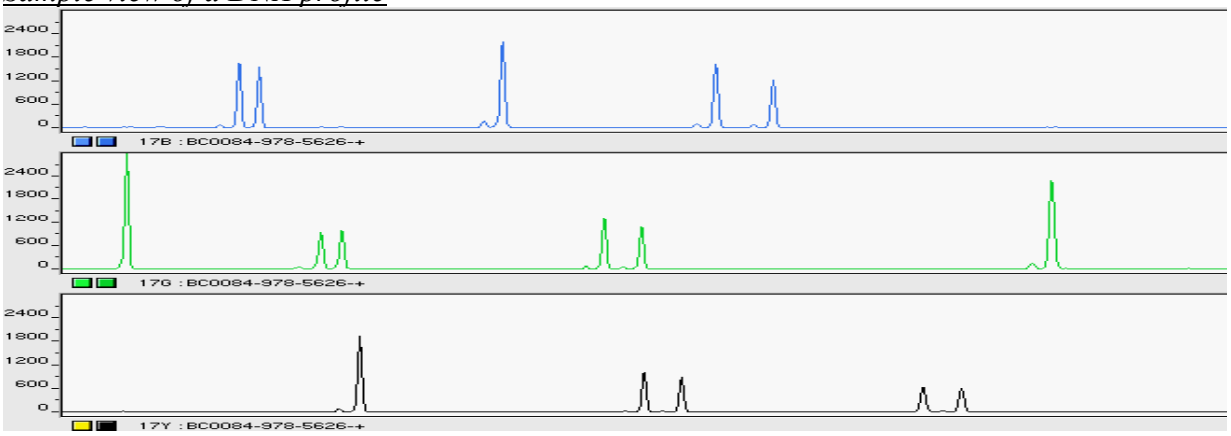
A committee formed to discuss this portion of the legislative charge met on October 18 and November 13, 2007, and January 10, 2008. The committee's recommendations were presented to the work group on February 19, 2008. The work group's background, discussion, and recommendations are outlined in this section.

Background and Discussion

At a crime scene, law enforcement collects evidence, some of which may contain human deoxyribonucleic acid or DNA. Officers may also obtain biological specimens from victims, suspects, and others for testing to help resolve the investigation. The evidence and biological specimens are sent to the BCA for testing.

The BCA tests the specimens to create a full autosomal DNA profile. Fifteen polymorphic loci and one marker to determine gender make up the DNA profile. Using the patterns of short tandem repeats (STRs), the probability of a random match between a tested specimen and a person in the general population is one in 10,000,000,000,000,000. The fifteen loci, or places in the DNA sequence that make up the DNA profile, reflect differences among humans and are not dependent on the gender of the person providing the specimen.

Sample view of a DNA profile



The DNA profile that is created for each specimen reflects numerical values that result from the testing of each of the loci and the marker for gender. The numerical values are then compared for each specimen. The BCA looks for what is known as a "high stringency match." This means that if the numerical values of the tested specimens are identical, the BCA tells law enforcement there is a match. If the values are not identical, the BCA tells law enforcement that a match does not exist.

Sample reports from the BCA to law enforcement

1. The DNA profile obtained from *Item 1* matches the DNA profile obtained from *John Doe* (and if appropriate) and does not match the DNA profile obtained from *Joe Smith*. The DNA profile obtained from *Item 1* would not be expected to occur more than once among unrelated individuals in the world population.

2. The male DNA profile obtained from the *sperm cell fraction of Item 5* did not match the DNA profile obtained from *John Doe*. (Or "An unidentified *male* DNA profile was obtained from the *sperm cell fraction of Item 5*"). A search of the Minnesota DNA databases did not detect a match with this profile. This profile will be entered in to the Minnesota DNA databases *and the National DNA Index System (NDIS)* and will be periodically searched as DNA profiles are added to these databases. Your agency will be notified if any matches are obtained.

3. A *male* DNA profile was obtained from the *sperm cell fraction of Item 5* which was searched through the Minnesota Convicted Offender DNA database and matches the DNA profile obtained from the convicted offender sample said to be from *John Doe*. Convicted offender samples are not considered evidentiary samples; therefore, additional testing can be performed following the submission of a known sample from *John Doe* to the BCA Laboratory.

Current law and BCA practice
Minnesota Statutes, section 299C.155, subdivision 4, governs the access to DNA analysis related data.

> Subd. 4. **Record.** The bureau shall perform DNA analysis and make data obtained available to law enforcement officials in connection with criminal investigations in which human biological specimens have been recovered. Upon request, the bureau shall also make the data available to the prosecutor and the subject of the data in any subsequent criminal prosecution of the subject. The results of the bureau's DNA analysis and related records are private data on individuals, as that term is defined in section 13.02, and may only be used for law enforcement identification purposes. The remedies in section 13.08 apply to a violation of this subdivision.

This subdivision classifies a DNA analysis and related records as private and allows access by law enforcement officials for criminal investigations and by the prosecutor and alleged perpetrator in any subsequent criminal prosecutions. The report sent by the BCA and maintained by the local law enforcement agency is accessible to a crime victim under Minnesota Statutes, section 13.82, subdivision 13 with limited exceptions (interference with an investigation or when the requester wants to engage in unlawful activities). Subdivision 4 does not specifically describe the BCA's current practice – as illustrated above in the sample reports – of sending the local law enforcement agency only a statement that a match does or does not exist without including the full DNA profile.

Although subdivision 4 classifies the data as private, it limits the use for law enforcement identification purposes. In other words, a crime victim who is the subject of the DNA analysis and related records would not have access to those data about him/herself. This appears to be in conflict with Minnesota Statutes, section 13.02, subdivision 12, which allows the subject of private data access to that data. At the time of this report, the BCA has never received a request from a crime victim for his/her DNA profile.

Currently, there is no statutory language that governs what the BCA may or may not do with the evidence and biological specimens that are obtained. The BCA's practice is to keep enough of the physical evidence to be able to conduct future tests, as needed. Re-testing can occur during the criminal case (upon defense request) or as part of a post-conviction appeal. In some jurisdictions, the fact that specimens are maintained has permitted re-testing that resulted in exoneration of individuals by organizations like the Innocence Project. Maintaining specimens has also meant that some cold cases have been solved following a change in testing methodology.

Recommendation One: DNA Profile

One item maintained by the BCA is the DNA profile created by testing a crime victim or perpetrator's biological specimen and the evidence. The Access to Specimens Maintained by the Bureau of Criminal Apprehension Committee recommended to the work group that current BCA practice continue. Specifically:

> There is no access to the DNA profile by a crime victim or representative. An alleged perpetrator or representative gets access only if certain conditions are met such as for use during a future criminal prosecution.

The committee further recommended that Minnesota Statutes, section 299C.155, subdivision 4, be amended to clarify that this is the access allowed to the DNA profile.

After discussion, the full work group ***did not*** agree with part of the committee's recommendation. The DNA profile is classified as private data and the work group believes that the crime victim should have access as is provided for other data classified as private. The work group's modified recommendation is:

> A crime victim or representative ***does have*** the ability to access the victim's DNA profile at the BCA. An alleged perpetrator or representative gets access only if certain conditions are met such as for use during a future criminal prosecution.

Recommendation Two: Report Comparing DNA Profiles

A second item maintained by the BCA is the report prepared from comparing DNA profiles. This report informs the local law enforcement agency whether there is a high stringency match resulting from the testing of specimens and evidence. The Access to Specimens Maintained by the Bureau of Criminal Apprehension Committee recommended that current BCA practice be followed and that the statute be amended to reflect it. Current practice is as follows:

> There is no access to the report at the BCA. A crime victim or representative may access the report from local law enforcement under Minnesota Statutes, section 13.82, subdivision 13. An alleged perpetrator or representative has access to the report as provided in the Rules of Criminal Procedure.

Again, the work group modified the committee's recommendation:

> A crime victim or representative ***does have*** access the report from the BCA, as well as from local law enforcement.

The remainder of the recommendation was not modified.

Recommendation Three: Evidence and Biological Specimens

The third items maintained by the BCA are evidence and biological specimens. The Access to Specimens Maintained by the Bureau of Criminal Apprehension Committee recommended that access to specimens be as follows:

> Crime victim access to specimens, whether his/her own or the alleged perpetrator's, is only by court order. Alleged perpetrator access to the specimens

is controlled by the Rules of Criminal Procedure during a criminal proceeding. Once the case, and any appeals, for which the specimen was collected are concluded, all other access by an alleged perpetrator requires a court order.

The work group adopted this committee recommendation.

Statutory Changes

The work group recommends that the Legislature adopt the following amendments to Minnesota Statutes, section 299C.155 to implement the recommendations.

299C.155 STANDARDIZED EVIDENCE COLLECTION; DNA ANALYSIS.
Subdivision 1. ~~**Definition**~~ **Definitions.** As used in this section, the following terms have the meanings given them.

(a) "DNA analysis" means the process through which deoxyribonucleic acid (DNA) in a human biological specimen is analyzed and compared with DNA from another human biological specimen for identification purposes.
(b) "Comparison report" means the data sent to law enforcement indicating whether there is a match following the DNA analysis.
(c) "Profile" means the data that document polymorphic loci and one gender marker that are the result of the DNA analysis.
(d) "Biological specimen" means the evidence or DNA sample provided for DNA analysis.

Subd. 2. **Uniform evidence collection.** The bureau shall develop uniform procedures and protocols for collecting evidence in cases of alleged or suspected criminal sexual conduct, including procedures and protocols for the collection and preservation of human biological specimens for DNA analysis. Law enforcement agencies and medical personnel who conduct evidentiary exams shall use the uniform procedures and protocols in their investigation of criminal sexual conduct offenses. The uniform procedures and protocols developed under this subdivision are not subject to the rulemaking provisions of chapter 14.

Subd. 3. **DNA analysis and data bank.** (a) The bureau shall adopt uniform procedures and protocols to maintain, preserve, and analyze human biological specimens for DNA. The bureau shall perform DNA analysis and make the comparison report available to law enforcement officials in connection with criminal investigations in which human biological specimens have been recovered. The bureau shall establish a centralized system to cross-reference data obtained from DNA analysis. ~~Data contained on the bureau's centralized system is private data on individuals, as that term is defined in section 13.02.~~ The bureau's centralized system may only be accessed by authorized law enforcement personnel and used solely for law enforcement identification purposes. ~~The remedies in section 13.08 apply to a violation of this subdivision.~~ The uniform procedures and protocols developed under this subdivision are not subject to the rulemaking provisions of chapter 14.

Subd. 4. **~~Record~~ Data classification.** ~~The bureau shall perform DNA analysis and make data obtained available to law enforcement officials in connection with criminal investigations in which human biological specimens have been recovered. (a) Data in a profile are private data on individuals as defined in section 13.02.~~

(a) Data in the comparison report are private data on individuals as defined in section 13.02. Upon request, the bureau shall ~~also~~ make the ~~data~~ comparison report available to the prosecutor and the ~~subject of the data~~ alleged perpetrator in any subsequent criminal prosecution of the ~~subject~~ alleged perpetrator. A crime victim's profile may be shared with an alleged perpetrator only as required by the Rules of Criminal Procedure. ~~The results of the bureau's DNA analysis and related records are private data on individuals, as that term is defined in section 13.02, and may only be used for law enforcement identification purposes. The remedies in section 13.08 apply to a violation of this subdivision.~~

(b) Data contained on the bureau's centralized system are private data on individuals as defined in section 13.02.

Subd. 5. **Access to the specimen.** (a) The bureau shall make the biological specimens available to the prosecutor and the alleged perpetrator during the criminal proceeding as required by the Rules of Criminal Procedure. Once the criminal proceeding is concluded, any other access by the alleged perpetrator to the biological specimens requires a court order.

(b) A crime victim may access their own biological specimens or those of an alleged perpetrator only by court order.

Subd. 6. **Remedies.** The remedies in section 13.08 and the penalties in section 13.09 apply to a violation of this section.

Secondary Uses of Genetic Information

Legislative Charge

The Legislature directed the work group to consider options for secondary uses of genetic information. The relevant portion of the Legislative charge is:

> (e) The commissioner and the work group must identify, and may make recommendations among, options for resolving questions of secondary uses of genetic information.

A committee formed to discuss secondary uses of genetic information met monthly from January 2008 through October 2008. The committee's recommendations were presented to the work group on October 21, 2008.[*] The full work group's background, discussion, and recommendations are outlined in this section.

Background and Discussion

The work group was tasked with a broad charge from the Legislature to provide options for resolving questions of secondary uses of genetic information. To help focus the discussion, the work group generally agreed to this definition of secondary use:

> A secondary use of a human biological specimen collected for the creation of genetic information is one that has a purpose that is different from the stated purpose of the original collection. When considering whether a purpose is different from the stated purpose of the original collection, the perspective of a reasonable person in the position of the individual providing the specimen/data must be taken into account.[23]

The Secondary Uses of Genetic Information Committee discussed a number of scenarios on topics related to secondary uses. The scenarios were used by the committee to frame the issues within this broad topic. The topics discussed by the committee included:

- Potential secondary uses in direct-to-consumer genetic testing
- Potential secondary uses by government programs
- Potential secondary uses by certain insurance companies
- Potential secondary uses by private health care providers
- Potential secondary uses of the convicted offender database

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[*] The full work group considered the recommendation on familial searches (Recommendation Four) at meetings on June 24, 2008 and July 22, 2008.

[23] An outstanding issue to be resolved is the secondary use of genetic information and specimens that are mandatorily collected under statute. For a list of the mandatory collections, see *Collections of genetic information for government programs* on p. 12.

The committee's feedback to the full work group on the above implications of secondary uses of genetic information provided context for the work group's recommendations.[24]

Recommendation One: Operation of Civil and Criminal Court Orders

The work group recommends that the Legislature consider the following range of options when deciding whether civil and criminal court orders may be used to gain access to a human biological specimen maintained by either government or private sector entities:

- Maintain the status quo: no change to the current operation of criminal search warrants and civil court orders because there is adequate guidance for the courts in issuing orders and warrants in statutes and case law
    - The status quo raised concerns from some group members as to the potential disruption of the expected confidentiality of the provider-patient relationship and the potential that people may forego health care knowing that a provider is required to turn over specimens in response to a search warrant or court order
- Create balancing test for non-criminal justice court orders
    - This option concern the courts because of the current guidance available in statute and precedent set by case law
- Prohibit ex parte civil court orders for data/specimens
    - This option concern the courts because of the current statutory requirements and case law precedent

Recommendation Two: Secondary Uses without Consent or Court Order

The work group recommends that the Legislature consider the following range of options when deciding who should make decisions about secondary uses of genetic information absent consent from the individual or a court order:

- The government or private sector entity collecting the specimen/data
- A neutral state agency
- A legislative committee or commission
- A body similar to the State Records Disposition Panel[25]

The work group agreed that it is important for the Legislature to be aware that secondary uses of de-identified or anonymous data or human biological specimens pose a risk of re-identification. Theoretically, re-identification of any information or specimens could take place; however, the

[24] Certain uses of genetic information and human biological specimens such as calibrating machines are not included within the scope of the secondary uses recommendations as they arguably fall within the scope of a primary use.
[25] Under Minn. Stat. § 138.17, subd. 1, the records disposition panel is comprised of the "attorney general, legislative auditor in the case of state records, state auditor in the case of local records, and director of the Minnesota Historical Society."

practical reality of re-identification is rare when it is not possible to link specimens with their original identifying information.[26]

Recommendation Three: Prohibited Secondary Uses

The work group agreed that there are some secondary uses that should never be permitted *unless* there is informed consent from the person providing the specimen or data, a court order, or a statutory mandate that does not require consent.

The prohibited secondary uses include:

- Any secondary use for specimens/data at the Bureau of Criminal Apprehension (federal law already prohibits secondary uses)
- Secondary uses of genetic information/specimens collected to screen tenants for housing, to screen employees, or to issue mandatory insurance (i.e. automobile insurance coverage in Minnesota)

Some members also believe that secondary uses of specimens or data collected or provided as part of the doctor-patient relationship should always be prohibited. In other words, every use of specimens collected as part of the doctor-patient relationship should always be limited to that patient's care.

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[26] Some work group members disagreed that it is possible to re-identify any genetic information or human biological specimens and would argue that many types of data and specimens can be de-identified irreversibly. They would also argue that for specimens containing human DNA, the practical reality of re-identification is rare when it is not possible to link the specimens with their original identifying information. The following examples were provided:

- Hospitals often submit masked data to MDH. The only data received by MDH might be a person's gender, county, the year of a hospital discharge, and medical status regarding a chronic disease. It is impossible for MDH, on its own, to re-identify the data. The ability of the hospital to re-identify the data depends on its retention and disclosure policies. Even more importantly, it depends on the hospital's design for masking the data. If >5 individuals match the description of gender, county, year of discharge, and medical status, and if the hospital never generated a "code" with personal identifiers, then the data are truly, irreversibly de-identified.
- Another data example concerns a government-run hospital, such as Hennepin County Medical Center. A hospital keeps data records of the range and distribution of genetic information, such as medical results for prostate specific antigen (PSA), the breast cancer 1 (BRCA1) genotype, and cholesterol. When collating these types of genetic information, the hospital may have irreversibly de-identified the information when it stripped off the personal identifiers. Consequently, even in theory, the information cannot be re-identified.
- The second set of examples is specimens. MDH receives stool specimens (feces) and urine specimens from people with infectious diseases. MDH analyzes those specimens for pathogens. The specimens contain no personally identifiable DNA. The patients' identifiers are removed before MDH stores the specimens; these specimens cannot be re-identified. (MDH retains the name of the pathogen and the year.)
- Another specimen example is for studies that irreversibly de-identify the blood specimen. For some studies, the investigators have dozens of tiny vials, each containing a few drops of blood. Each container has a randomly assigned study number. No "code" was generated when the drops of blood were transferred into the vials; thus, these specimens are truly de-identified.

Recommendation Four: Familial Searches of the Convicted Offender Database

One possible secondary use of genetic information is performing searches in the convicted offender database maintained by the Bureau of Criminal Apprehension (BCA) to locate an unknown perpetrator who may be related to an offender who is already in the database. Conducting what is known as a "familial search" is a search of the database at a low stringency level, allowing a less-than-perfect match, with the purpose of identifying criminal suspects. If a partial match is discovered in performing this type of search, the perpetrator is presumably a relative of a convicted offender who is already in the database.

Only a minority of other states have taken an official stand on familial searches.[27] Therefore, based on the recent developments surrounding the issue, commonly identified as a "familial search" and its secondary uses implications, the Commissioner asked the work group to include recommendations in this report.

The convicted offender database
Minnesota Statutes, section 299C.155 provides the BCA with statutory authority to collect DNA for the convicted offender registry database.

The BCA explained the mechanics of searching the convicted offender database for criminal investigation purposes. There are three levels to test for DNA matches – high, moderate, and low stringency. In order to avoid eliminating perfect matches, due to crime scene samples that include DNA from more than one person, the BCA searches for matches at the moderate stringency level. If the BCA searched at a high stringency level, many perfect matches would be missed.

For more information on these searches of the convicted offender database, see ***Appendix VI***.

Working definitions
For the purposes of discussion, the following definitions were developed:

Purposeful familial search: the intentional search in the convicted offender database at a *low stringency level*. The purpose of the search is to develop leads and identify possible relatives of the individual who left evidence at the crime scene.

Inadvertent familial search: the normal practice of searching the convicted offender registry at the *moderate stringency level* for a perfect match. The search results in a profile that is a partial match, but is close enough to gain attention of the forensic scientist. There are sufficient loci that match to suggest the offender may be a relative of the individual who left evidence at the crime scene.

[27] See ***Appendix VII*** for California's policy allowing familial searches and Maryland's law prohibiting them.

Purposeful Familial Searches
The work group developed a list of the pros and cons in whether to allow purposeful familial searches in the state of Minnesota

Pros of conducting familial searches

- Importance of using all available means and following all possible leads to find a perpetrator because forgoing use of partial matches allows violent criminals to remain at large
- Less invasion of the relative's privacy in using a specimen already stored/maintained vs. taking a new specimen
- Crime victims would not want available data/possibilities to be ignored
- Possibility of saving money in the long-run because search is narrowed
- "The apple doesn't fall far from the tree" – 46% of inmates have a family member that is/has been incarcerated

Cons of conducting familial searches

- "Suspicion by family association"
- Intrusion into the lives of innocent people
- Racial disparities in the convicted offender database
- Knowledge of previously unknown genetic relationship, or absence of previously believed genetic relationship
- Police intervention invading privacy rights of relatives
- "Lifelong genetic surveillance" of relatives
- Discriminatory (not your fault that you have a "bad" relative)
- Slippery slope – may result in a universal database in order to eliminate racial disparities
- Raises suspicion if a relative refuses to provide a specimen or may be coerced to provide a specimen; pressure on family members to reveal a relative's identity; presumption of guilt if a relative denies a request to provide DNA because s/he does not want the government to have her/his data; presumption of guilt and stigma from police visits
- Potential to create a class of suspects (e.g. people who have relatives in prison, communities of color) results in more "knocking on doors" of certain populations and increases the power of the government to disrupt families
- Statistically, as the suspect pool is broadened, the risk of false matches increases
- Potential for baseless investigations
- Potential problems in automatically assuming a relative is a suspect
- Use of the purposeful familial search automatically makes relatives the place to start an investigation
- The public will not understand the consequences; a "CSI" mentality will demand a solution where the technology is not yet completely developed
- Use of purposeful familial searches will cause an over-reliance on DNA testing
- The outcomes demonstrated by the Y-STR test are not understood. There are four different test kits for Y-STR with a different number of loci tested for each. The test

provides more information in the Caucasian population and does provide a way to eliminate leads
- It is unreasonable to rely on a newer technology that is not fully developed. It diverts attention from existing methods to solve crimes and diminishes their use
- Purposeful familial searches will require the use of lots of resources

Public safety and privacy rights. The question becomes how to balance the competing public safety and privacy interests. Some members of the work group feel that this particular secondary use of genetic information is a "slippery slope" that needs to be curtailed, arguing that this leads to a universal database which is too invasive of privacy rights. On the other hand, it was argued that using a partial match to investigate potential suspects is simply good law enforcement practice – like using a partial match on a license plate to search out possible leads. Some members of the work group feel that because this issue deals with such a rapidly changing area, the Legislature should wait to act on it.

Group members were then asked to identify their willingness to have purposeful familial searches used in Minnesota by marking a place on a continuum. The results of this exercise are noted on the continuum presented in ***Appendix VIII***. This continuum demonstrates the work group's diverse perspectives on this issue.

Inadvertent Familial Searches
Members of the work group also indicated their willingness to allow the reporting of inadvertent familial searches by marking a place on a continuum. The result of this exercise is noted on the continuum presented in ***Appendix IX*** and, again, presents diverse perspectives.

The work group discussed the possibility of safeguards in the context of inadvertent familial searches. It was generally agreed that if a BCA forensic scientist were to inadvertently discover a partial match that was so similar as to gain the scientist's attention, additional testing should be done before the partial match could be reported to local law enforcement agencies.

The work group generated a list of possible safeguards that could apply to both purposeful and inadvertent familial searching.

Possible safeguards to be applied when conducting purposeful and inadvertent familial searches

- Adopt SWGDAM* possible recommendations
  - Y-STR testing – paternal relationships
  - Mitochondrial DNA testing – maternal relationships
  - Single-source samples only
  - Search local databases first
  - Use as many of the core loci as possible

* The Scientific Working Group on DNA Analysis Methods (SWGDAM) is a group of specialists who advise the federal government on DNA policy and assist the FBI in developing new laboratory standards.

  - Compute Expected Match Ratio (EMR) and Expected Kinship Ratio (EKR)
  - Use data from all major population groups
  - Train scientists
  - Report results to FBI for compilation
- Kinship analysis – new statistical models under development
- Consider the severity of the crime in determining whether this type of search is allowed
- Destruction of biological material
- No database inclusion of relative's DNA profile
- Informed consent before obtaining specimens from relatives

Recommendation Four Conclusions. The recommendation of the work group is to highlight this secondary use of genetic information, "familial searches," as an issue the Legislature may want to address in the near future. There was no consensus reached in the work group concerning either purposeful or inadvertent familial searches. Generally, there were more concerns about purposeful familial searching when compared with inadvertent familial searching. Some members who felt that the convicted offender database should not be used to conduct familial searches at all would perhaps agree that an exception could be made to investigate severe violent crimes such as rape and murder and crimes which represent a significant threat to public safety.

Appendix I

Minnesota Genetic Information Work Group Members

Member Name	Representing
Sally Anderson (Dakota County)	Local government
Dianne Bartels	University of MN Center on Bioethics
Twila Brase	Citizens' Council on Health Care
Colin Campbell (University of MN)	Genetic researchers
Jim Iverson	MN Department of Public Safety
Marianne Keuhn	March of Dimes Foundation
Colleen Kingsbury	Public
Laurie Beyer-Kropuenske	MN Department of Administration
Jonathan Lebedoff	American Civil Liberties Union – MN
Louise Liao (MN Department of Health)	Public laboratories
Noralane Lindor (Mayo Clinic)	Private laboratories
Ruth Lynfield	MN Department of Health
Kathleen Meyerle	Mayo Clinic and Foundation
Kirsten Nielsen	Public
Mary Pohl	MN Department of Human Services
Warren Sagstuen	Judicial branch
Todd Schoffelman (Sherburne County)	County prosecutors
Susan Shogren Smith	Public
Scott Simmons (Association of MN Counties)	Local government
Karolyn Stirewalt	Minnesota Medical Association
Patrick Sullivan	Public defenders
Robert Watson (Allianz Life Insurance)	Insurance companies
Vacant	Epidemiologist
Vacant	Private employers

Minnesota Genetic Information Work Group
2007-2008 Meeting Schedule

Meetings held at:

Minnesota Department of Health's Snelling Office Park Building
Mississippi Room
1645 Energy Park Drive, St. Paul, MN 55108

Directions to Snelling Office Park: www.health.state.mn.us/about/sop.html

Meeting schedule and times:

September 24, 2007 (10:30 am to 2:30 pm)

October 23, 2007 (9:00 am to 12:00 pm)

December 6, 2007 (9:00 am to 12:00 pm)

January 29, 2008 (9:00 am to 12:00 pm)

February 19, 2008 (9:00 am to 12:00 pm)

June 24, 2008 (9:00 am to 12:00 pm)

July 22, 2008 (9:00 am to 12:00 pm)

August 19, 2008 (9:00 am to 12:00 pm) ***MEETING CANCELLED**

September 23, 2008 (9:00 am to 12:00 pm)

October 21, 2008 (9:00 am to 12:00 pm)

November 18, 2008 (9:00 am to 12:00 pm)

Appendix II

Summary of Genetic Information Nondiscrimination Act (GINA) and Minnesota Genetic Insurance and Employment Statutes

HEALTH INSURANCE			
GINA (P.L. 110-233) DEFINITIONS		MINN. STAT. § 72A.139 DEFINITIONS	
GENETIC TEST is an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. Genetic test does not mean an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved. **GENETIC INFORMATION** includes an individual's genetic test results, genetic test results of family members, and manifestation of disease or disorder in a family member (family member is a blood relative).		**GENETIC TEST** is a presymptomatic test of a person's genes, gene products, or chromosomes for the purpose of determining the presence or absence of a gene or genes that exhibit abnormalities, defects, or deficiencies, including carrier status, that are known to be the cause of a disease or disorder, or are determined to be associated with a statistically increased risk of development of a disease or disorder. Genetic test does not include a cholesterol test or other test not conducted for the purpose of determining the presence or absence of a person's gene or genes.	
GINA PROHIBITS	**GINA DOES NOT PROHIBIT**	**MN LAW PROHIBITS**	**MN LAW DOES NOT PROHIBIT**
(1) Use of an individual's genetic information in setting eligibility or premium or contribution amounts by group and individual health insurers. (2) Health insurers from requesting or requiring an individual to take a genetic test. (3) Use or disclosure of protected health information that is genetic information for underwriting purposes.	(1) Medical underwriting based on current health status. Does not mandate coverage for any particular medical tests or treatments. (2) Health care professional can *request* an individual or family member undergo a genetic test (cannot *require* a test). Health care professionals employed by or affiliated with a health plan or issuer can notify individuals about genetic tests or provide information about a genetic test as part of a wellness program. (3) Health plans from requesting a genetic test for research purposes, subject to specific conditions.	(1) Health plan companies from requiring or requesting an individual or a blood relative of the individual to take a genetic test to determine eligibility for coverage, establish premiums, limit coverage, renew coverage, or any other underwriting decision. (2) Health plan companies cannot ask, or take into consideration, whether an individual or blood relative has taken or refused a genetic test. (3) Health plan companies cannot ask about, or take into consideration, an individual or blood relative's genetic test results.	Medical underwriting based on current health status.
REMEDIES, PENALTIES & ENFORCEMENT			
GINA		MINNESOTA	
Secretaries of Labor and Health & Human Services may impose penalties.		Commissioners of Commerce and Health may investigate and enforce.	
GINA EFFECTIVE DATES			
Health insurance provisions are effective for health plan years beginning 1 year after the May 21, 2008 enactment date. The Secretary of Health & Human Services must issue final regulations to implement GINA within 1 year after May 21, 2008.			

EMPLOYMENT

GINA (P.L. 110-233) DEFINITIONS	MINN. STAT. § 181.974 DEFINITIONS
GENETIC TEST is an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes. Genetic test does not mean an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes. **GENETIC INFORMATION** includes an individual's genetic test results, genetic test results of family members, and manifestation of disease or disorder in a family member (family member is a blood relative).	**GENETIC TEST** is the analysis of human DNA, RNA, chromosomes, proteins, or certain metabolites in order to detect disease-related genotypes or mutations. Tests for metabolites fall within the definition of genetic test when an excess or deficiency of the metabolites indicates the presence of a mutation or mutations. Administration of metabolic tests by an employer or employment agency that are not intended to reveal the presence of a mutation does not violate this section, regardless of the results of the tests. Test results revealing a mutation are, however, subject to this section. **PROTECTED GENETIC INFORMATION** means information about a person's genetic test; or information about a genetic test of a blood relative.

GINA PROHIBITS	GINA DOES NOT PROHIBIT	MN LAW PROHIBITS
(1) Employers from using genetic information in hiring, firing, job assignments, promotions, compensation, or other employment decisions. (2) Employers from requesting, requiring, or purchasing genetic information about an employee or family member.	(1) Inadvertent collections of family medical history. (2) Employer offered genetic services (such as wellness programs) where employee provides voluntary authorization. (3) Requiring family medical history for FMLA purposes. (4) Obtaining family medical history from public documents. (5) Genetic monitoring of toxic substances. (6) DNA analysis on forensic lab employees for quality assurance purposes. An employer may not use/disclose genetic information acquired in above ways in violation of the law.	(1) Employers cannot directly or indirectly administer a genetic test or request, require, or collect protected genetic information as a condition of employment; or affect the terms or conditions of employment or terminate employment based on protected genetic information. (2) No person can provide or interpret protected genetic information on a current or prospective employee for an employer.

REMEDIES & PENALTIES

GINA	MINNESOTA
Employers are subject to remedies and procedures in civil rights laws such as Title VII of the Civil Rights Act and the Americans with Disabilities Act (ADA). Disparate impact on the basis of genetic information does not establish a cause of action. The Equal Employment Opportunity Commission must implement regulations to enforce the employment provisions.	Any aggrieved person may bring a civil action. The court may award: up to three times the actual damages suffered; punitive damages; reasonable costs and attorney fees; and injunctive or other equitable relief as the court may deem appropriate.

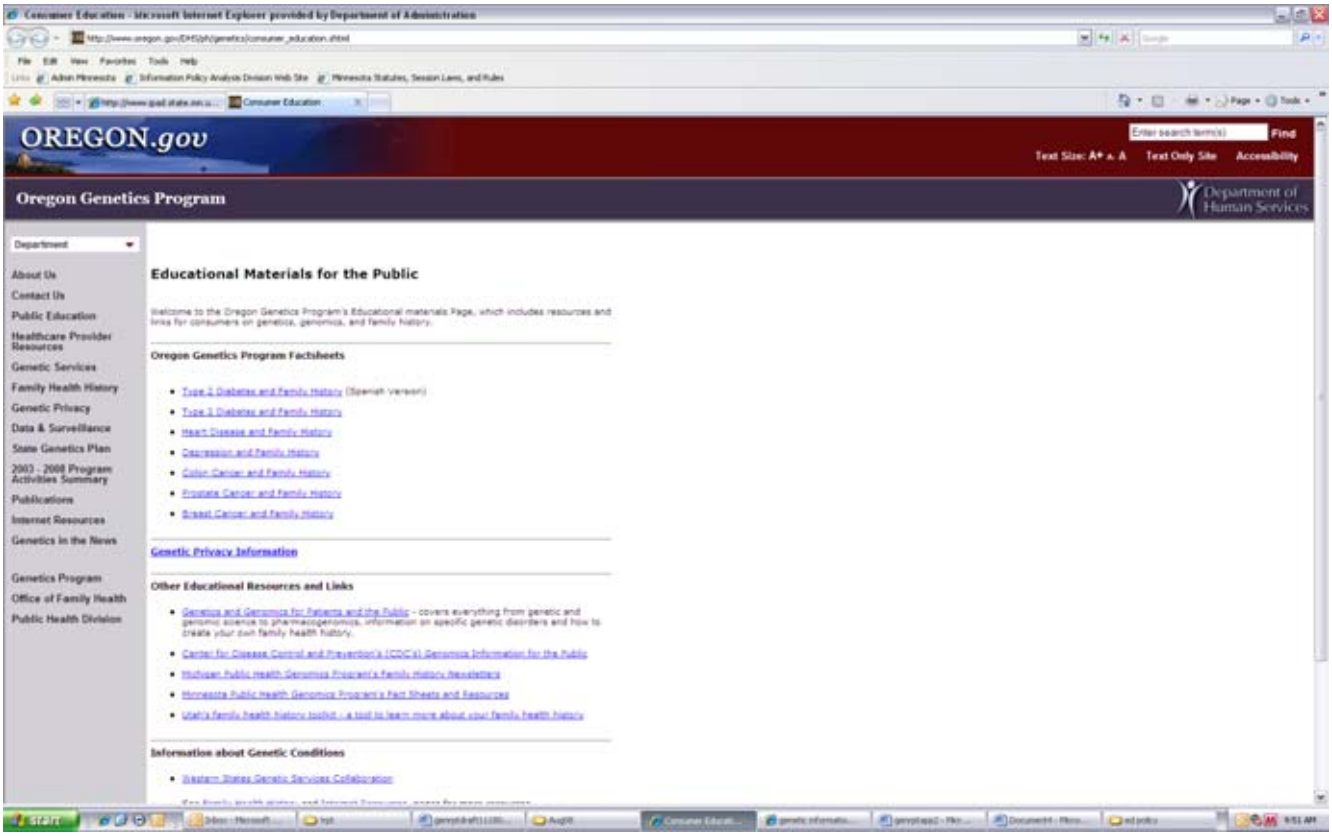
GINA EFFECTIVE DATES

All employment provisions are effective 18 months after the May 21, 2008 enactment date.

Appendix III

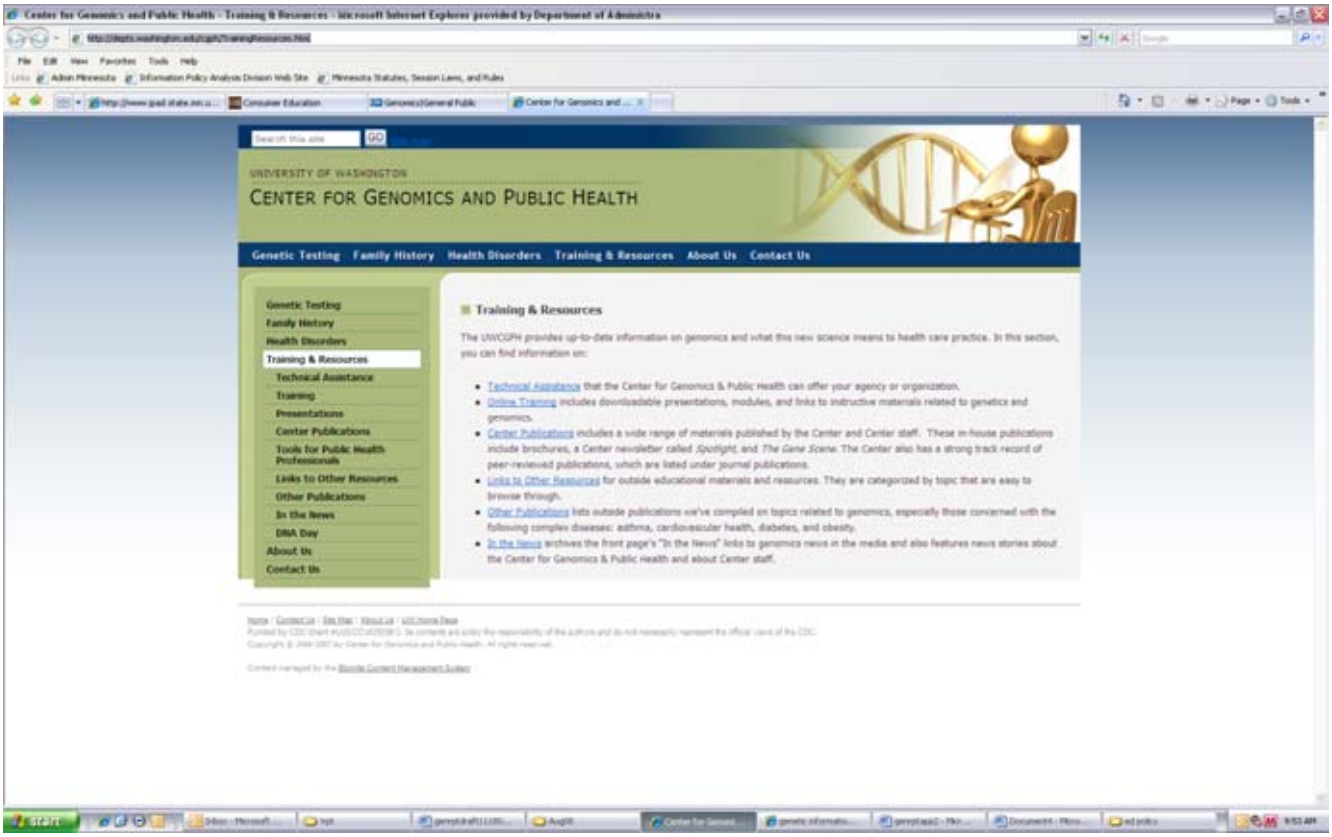
Public genetics education web resources (state & federal)

www.oregon.gov/DHS/ph/genetics/consumer_education.shtm

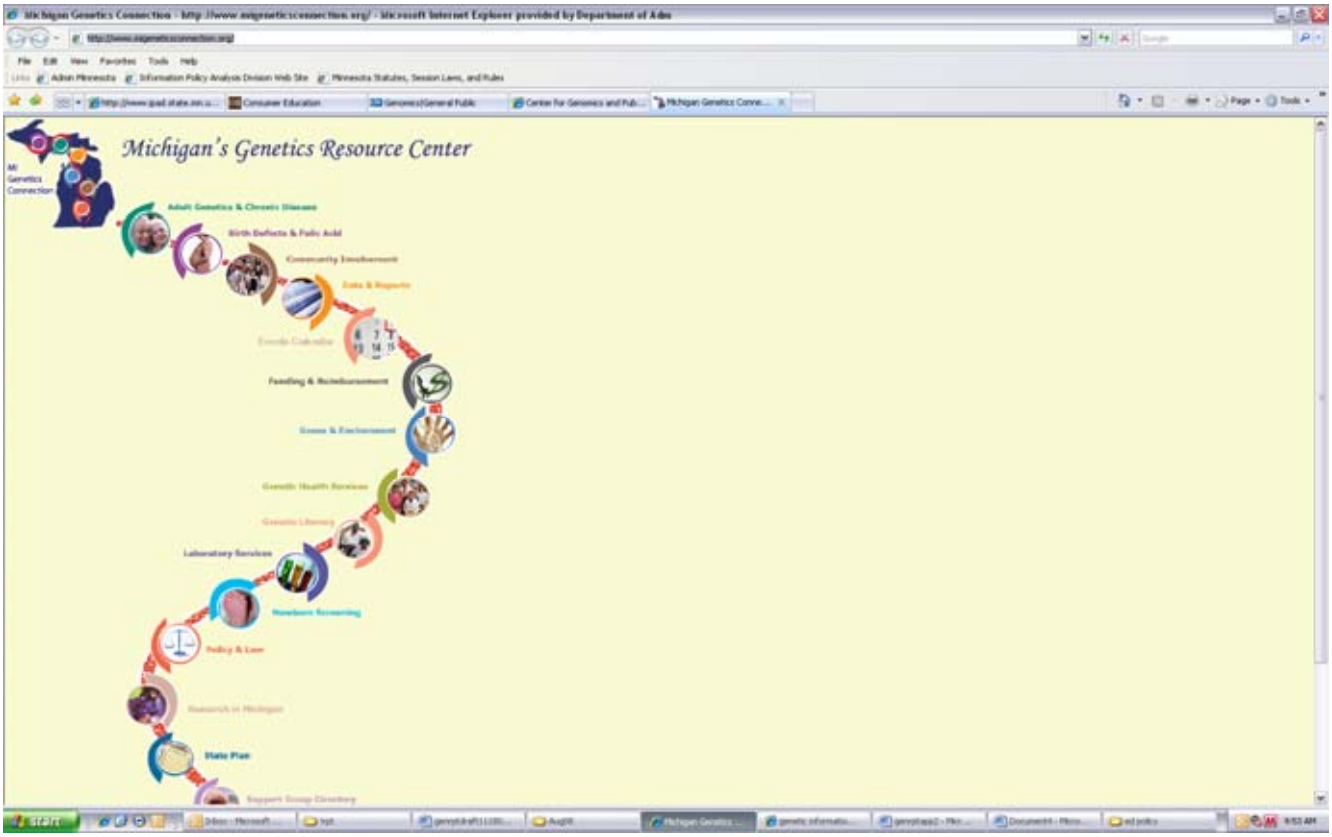


www.cdc.gov/genomics/public.htm

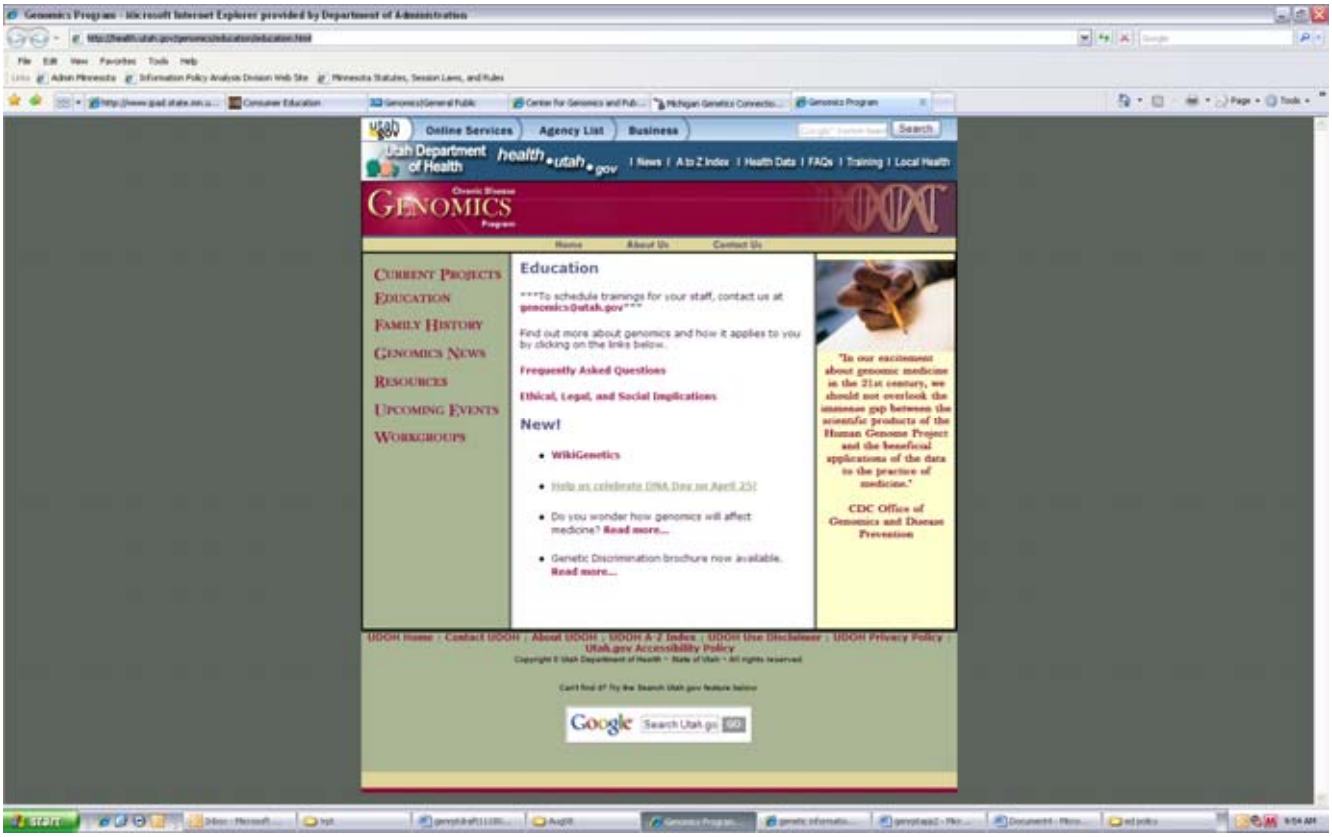
http://depts.washington.edu/cgph/TrainingResources.htm



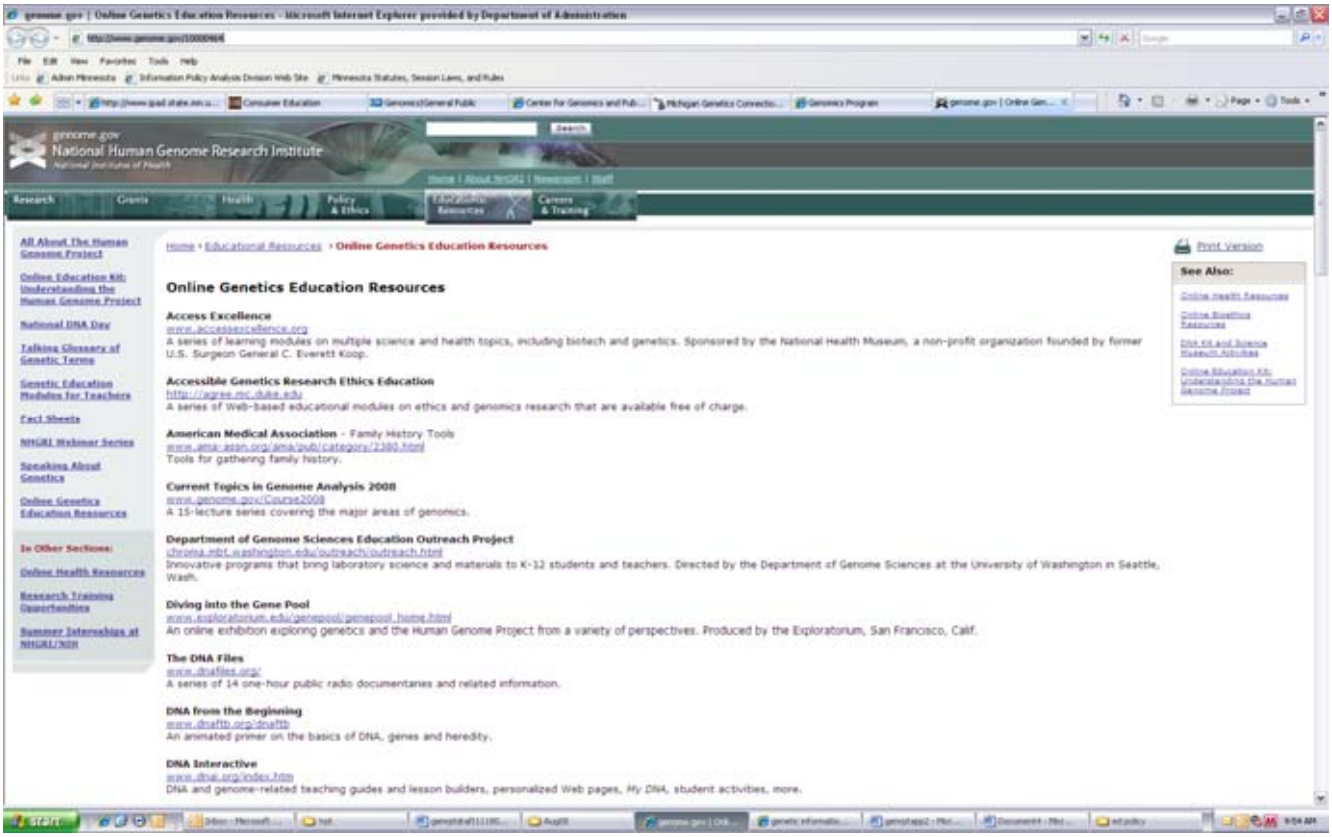
www.migeneticsconnection.org/



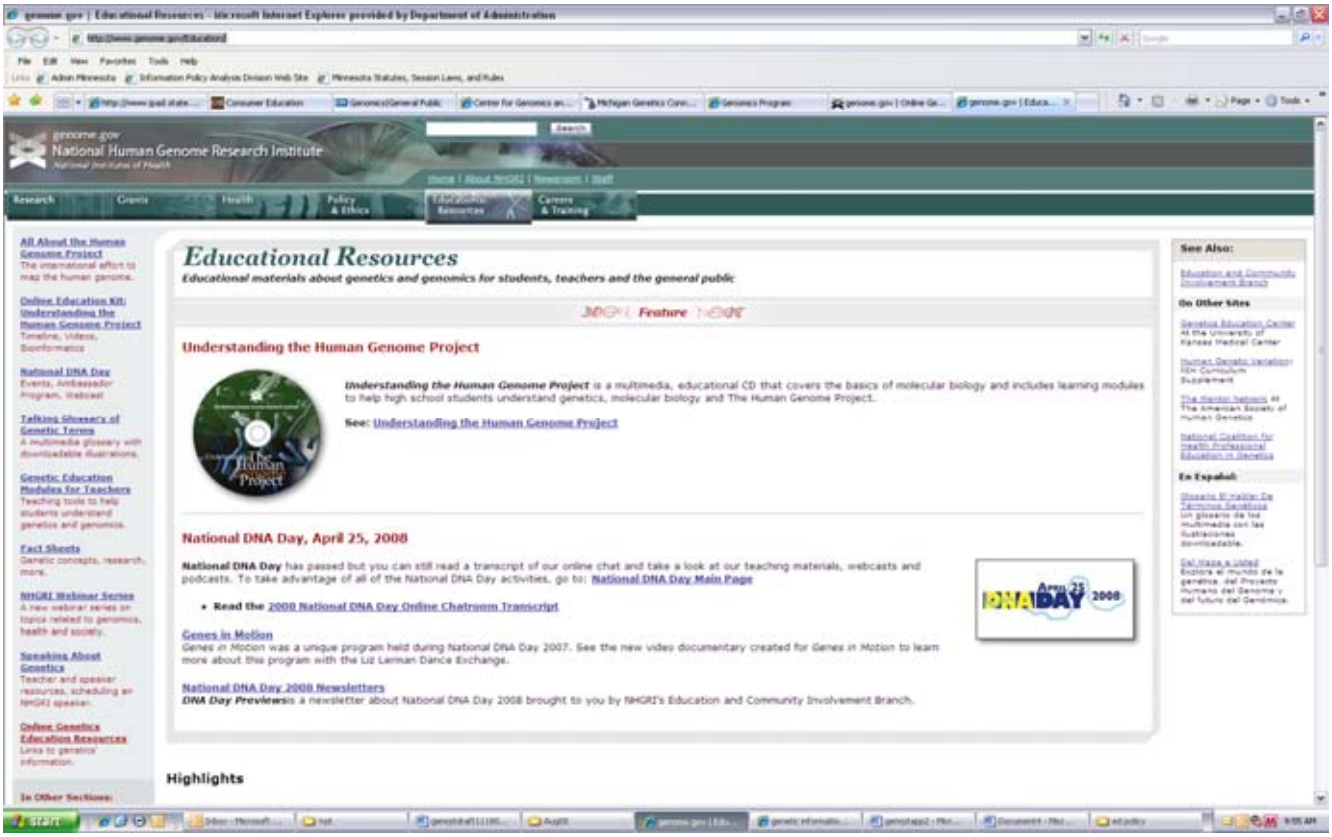
http://health.utah.gov/genomics/education/education.html



www.genome.gov/10000464

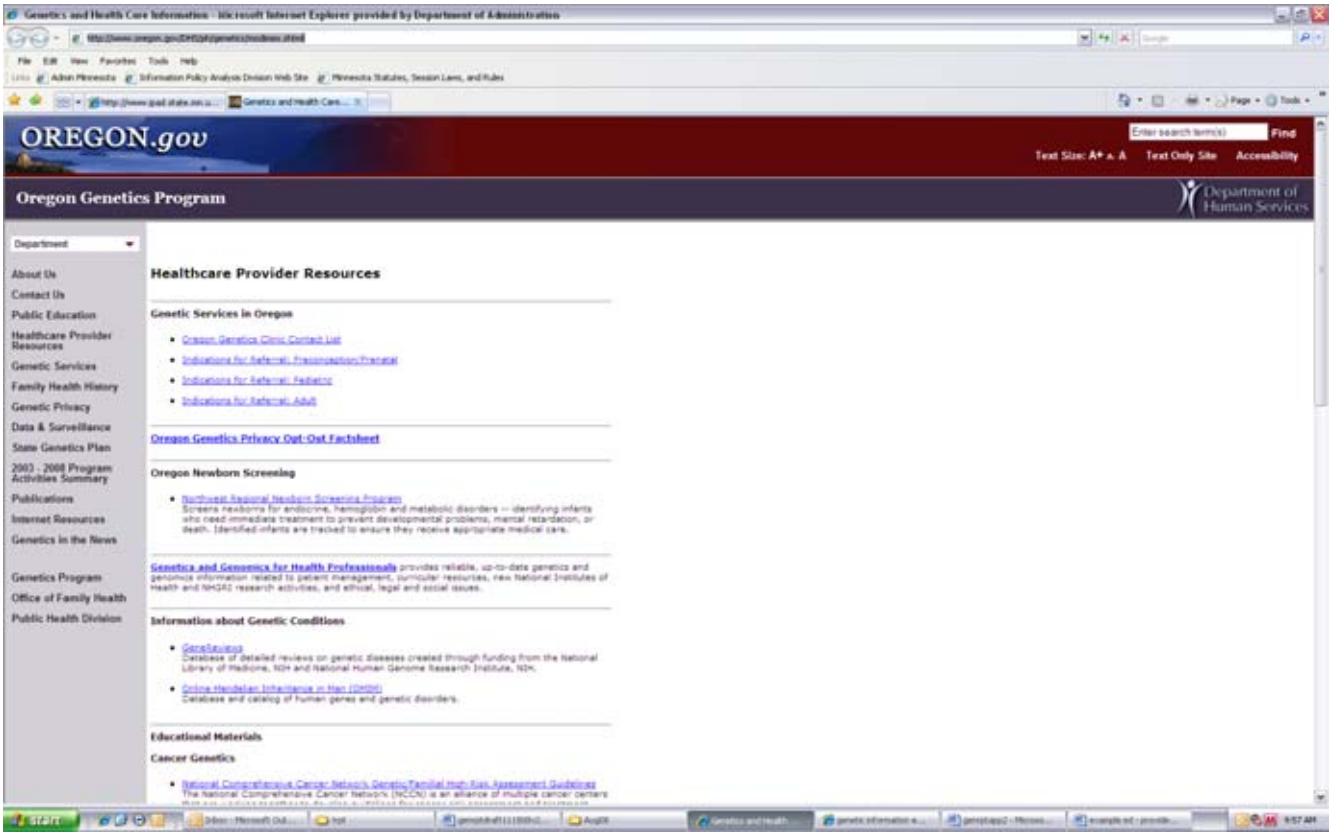


www.genome.gov/Education/

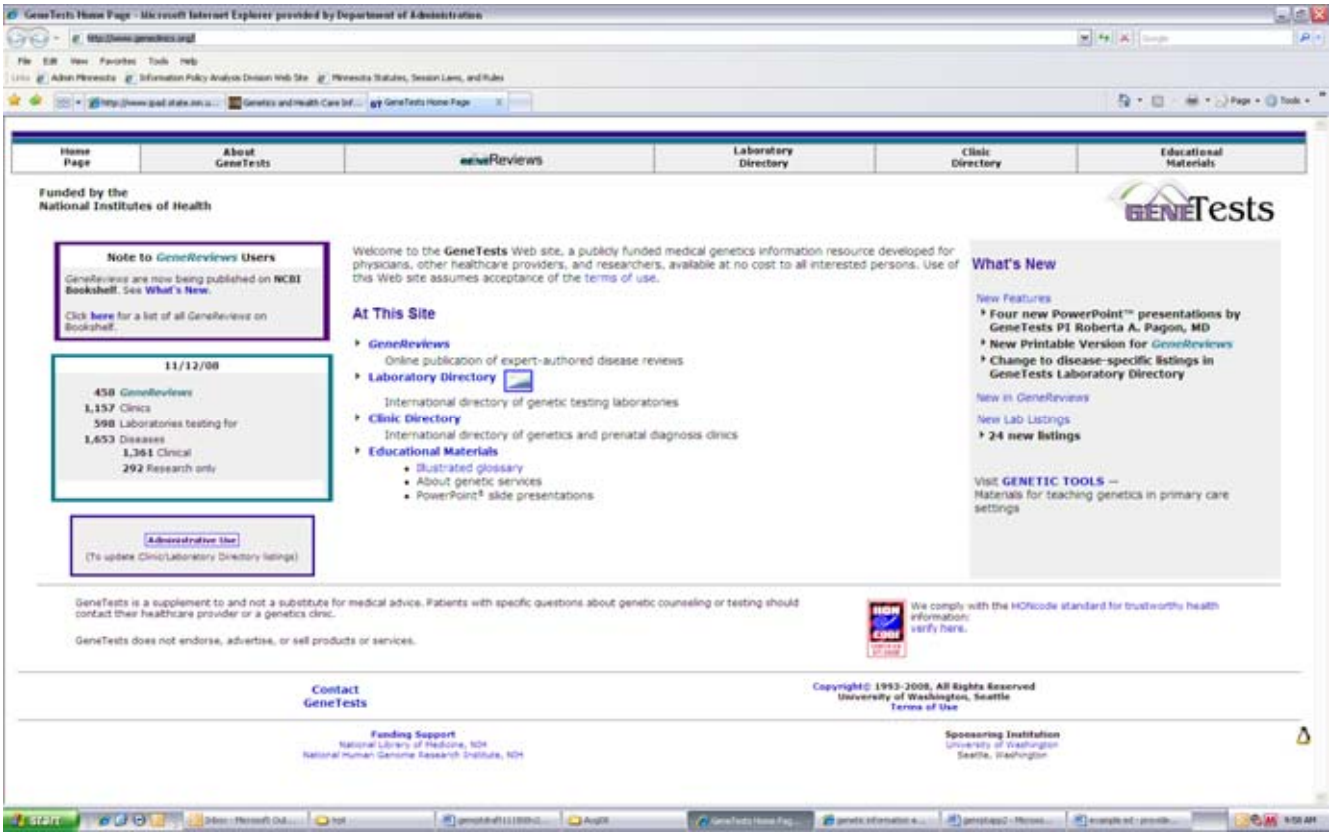


Health care provider genetics education web resources

www.oregon.gov/DHS/ph/genetics/modimes.shtml

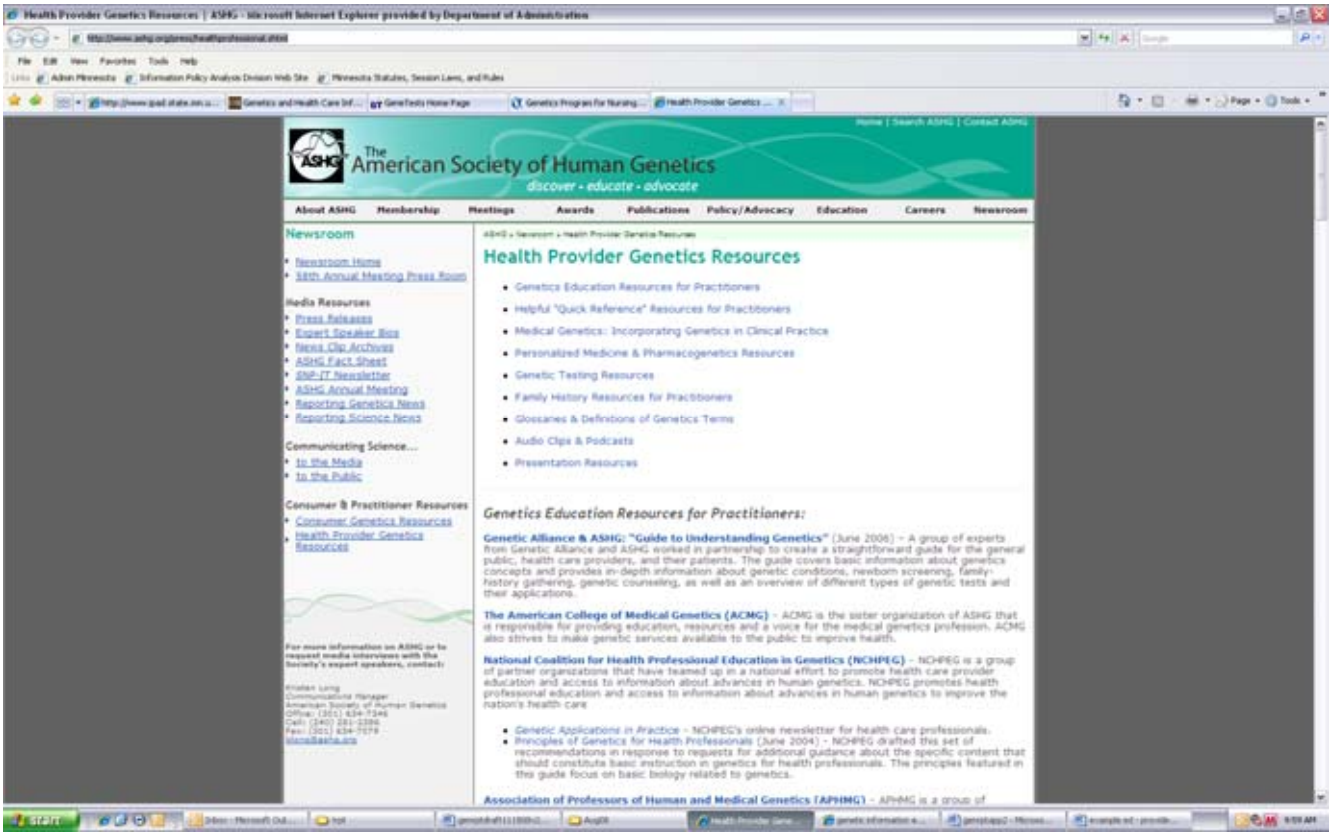


www.geneclinics.org/



www.cincinnatichildrens.org/ed/clinical/gpnf/default.htm

www.ashg.org/press/healthprofessional.shtml



Appendix IV

Summary of the Treatment of Genetic Information – State Laws

The states listed in this chart have statutes with general applicability in protecting genetic information.
The key describing the *Exceptions* follows the chart.

	Definitions	Collection	Access	Retention	Remedies
Alaska Alaska Stat., Ch. 18.13	DNA analysis; Genetic characteristic (silent on specimen)	Only with informed consent *Exceptions* [1, 2, 3, 4, 5, 9]	DNA sample & results are property of subject *Exceptions* [1, 2, 3, 4, 5, 9]	Only with informed consent *Exceptions* [1, 2, 3, 4, 5, 9]	Actual damages; Criminal penalties
Delaware Del. Code Title 16, §§ 1220-1227	Genetic characteristic; Genetic information; Genetic test (silent on specimen)	Only with informed consent *Exceptions* [1, 2, 3, 4, 5, 6]	Subject has access & correction rights; No disclosure *Exceptions* [1, 2, 3, 4, 5, 8, 9]	Only with informed consent *Exceptions* [1, 2, 4, 6, 7] Destruction required *Exceptions* [2, 6, 7, 9]	Fines; Actual damages
Florida Fla. Stat. §760.40	DNA analysis (silent on specimen)	Only with informed consent *Exceptions* [1, 2, 4]	Results are property of subject; No disclosure without informed consent	n/a	Criminal penalties
Illinois 410 ILCS 513	Genetic testing (silent on specimen)	Testing & results are private and confidential *Exceptions* [1, 2, 4]	Release only with subject's authorization *Exceptions* [1, 2, 4, 5, 9]	n/a	Liquidated or actual damages, attorney fees; Equitable relief
Nevada Nev. Rev. Stat. §§ 629.101 – 629.201	Genetic information; Genetic test (silent on specimen)	Only with informed consent *Exceptions* [3, 4, 5, 6, 7]	Subject has access rights; No disclosure without consent *Exceptions* [1, 2, 3, 4, 5, 7, 8, 9]	Only with informed consent *Exceptions* [2, 7, 9] Subject can request destruction *Exceptions* [2, 7, 9]	Criminal penalties; Actual damages, costs, attorney fees
New Jersey N.J. Stat. §§ 10:5-43 – 10:5-49	Genetic characteristic; Genetic information; Genetic test (silent on specimen)	Only with informed consent *Exceptions* [1, 2, 3, 4, 5, 6]	Subject may inspect & correct; No disclosure *Exceptions* [1, 2, 3, 4, 5, 7, 8, 9]	Only with informed consent *Exceptions* [1, 2, 4, 6, 7] Subject can request destruction *Exceptions* [2, 7]	Fines, criminal penalties; Actual damages
New Mexico N.M. Stat. §§ 24-21-1 – 24-21-7	Gene products; Genetic analysis; Genetic information; Genetic testing (silent on specimen)	Only with informed consent *Exceptions* [1, 2, 3, 4, 5, 6, 9]	No transmission without informed consent *Exceptions* [1, 2, 3, 4, 5, 6, 9]	Only with informed consent *Exceptions* [1, 2, 3, 4, 5, 6, 9] Subject can request destruction *Exceptions* [1, 2, 3, 4, 5, 6, 7, 9]	Expenses; Actual damages; Attorney fees

	Definitions	Collection	Access	Retention	Remedies
New York N.Y. Civil Rights Law § 79-L	Genetic test; Genetic pre-disposition; (specimen included)	Only with informed consent *Exceptions* [1, 5, 6, 7, 9]	Subject has access rights; No disclosure without informed consent *Exceptions* [1, 5, 7, 9]	For medical research, longer than 60 days with IRB approval & informed consent; DNA samples for 10 years with authorization & consent for indefinite retention *Exception* [9]	Fines; Criminal penalties
Oregon Or. Rev. Stat. Ch. 192	Genetic characteristic; Genetic information; Genetic test (specimen included)	Only with informed consent *Exceptions* [1, 2, 3, 4, 5, 6, 8]	Subject has protection from disclosure & misuse; Subject may request corrections & additional testing on sample; No disclosure *Exceptions* [2, 3, 4, 7, 8]	Only with informed consent – identifiable samples & information *Exceptions* [2, 3, 5, 6, 7, 8, 9]	Actual damages or fines; Attorney fees; Criminal penalties; Equitable relief
Texas Tex. Occ. Code §§ 58.001 – 58.105	Family health history; Genetic characteristic; Genetic information; Genetic test (silent on specimen)	n/a	Subject has right to results of genetic test; No disclosure without written authorization *Exceptions* [2, 3, 4, 5, 6, 7, 8, 9]	Sample must be destroyed after used for its purpose *Exceptions* [5, 7,9]	Civil penalties; Attorney fees & costs
Vermont Vt. Stat. Title 18, §§ 9331 – 9335	Genetic information; Genetic testing (specimen included)	No genetic testing without prior written authorization & informed consent *Exceptions* [1, 2, 3, 4, 5, 6]	Disclosure only with written authorization	n/a	Criminal penalties, fines; Civil & punitive damages; Equitable relief; Costs, attorney fees

Many states have separate statutes related to genetic discrimination protections in employment and insurance.

Key for exceptions notations:
[1] Convicted offender registry
[2] Law enforcement/prosecution/criminal or juvenile proceeding
[3] Identification of missing or deceased person under state or federal law
[4] Paternity determination
[5] Newborn screening
[6] Anonymous or coded research
[7] Court order
[8] Medical diagnosis of blood relatives of a decedent
[9] Other

Appendix V

Specimen Retention – State Law Samples

States included in this list specify explicit specimen retention and destruction requirements.

Alaska
No retention of DNA sample or results of a DNA analysis without informed written consent of subject. DNA sample and the results of a DNA analysis performed on the sample are the exclusive property of the person sampled or analyzed. Informed consent and property rights do not apply when retention is for:

- Convicted offender registry
- Law enforcement/prosecution/criminal or juvenile proceeding
- Identification of missing or deceased person under state or federal law
- Paternity determination
- Newborn screening
- Emergency medical treatment

Delaware
The sample from which genetic information has been obtained must be destroyed promptly. Destruction not required:

- Law enforcement/prosecution/criminal or juvenile proceeding
- Anonymous or coded research
- Court order
- Authorization by the subject

Applies only to genetic information or samples identified as belonging to an individual or family.

Missouri
Specimen must be retained for five years after initial submission to the department. After five years the specimen must be destroyed. A biological specimen may be released for anonymous scientific study unless the department is directed by the subject to:

- Return the specimen after tests are performed
- Destroy the specimen after tests have been performed.
- Store the specimen but not release it for anonymous scientific study.

"Department" means the Department of Health and Senior Services. Specimens released for anonymous study must not contain information that may be used to determine the identity of the donor.

New Jersey
The DNA sample from which genetic information has been obtained must be destroyed upon the specific request of subject. Requested destruction is not required:

- Law enforcement/prosecution/criminal or juvenile proceeding
- Court order

A DNA sample from an individual who is the subject of a research project must be destroyed upon completion of the project or withdrawal from the project, whichever occurs first, unless the subject directs otherwise by informed consent.

A DNA sample for insurance or employment purposes must be destroyed after the purpose for which the sample was obtained has been accomplished unless retention is authorized by court order.

New Mexico
A person's DNA may be retained without consent and must be destroyed upon request by the subject. Requested destruction is not required:

- Law enforcement/prosecution/criminal or juvenile proceeding
- Convicted offender registry

- Identification of missing or deceased person under state or federal law
- Paternity determination
- Newborn screening
- Not identified with the person or person's family members
- Court order
- Medical repositories or registries
- Anonymous or coded research
- Emergency medical treatment

New York
For medical research purposes, biological samples may be kept for longer than sixty days and utilized for scientific research with IRB approval and written informed consent of the subject. If consent to storage of the sample is withdrawn at any time, the entity storing the sample must destroy the sample or portions of the sample not already used for research purposes.

DNA samples may be stored for up to ten years in the absence of genetic testing, if authorized in writing by the subject and informed consent is required for testing of the sample. Retention of a DNA sample for longer than ten years requires explicit consent for longer or indefinite retention.

Oregon
A DNA sample may not be retained without the subject's authorization. Exceptions:
- Law enforcement/prosecution/criminal or juvenile proceeding
- Identification of missing or deceased person under state or federal law
- Court order
- Medical diagnosis of blood relatives of a decedent
- Newborn screening
- Anonymous or coded research conducted after notification or with consent

The DNA sample from which genetic information has been obtained must be destroyed upon the specific request of the subject. Exceptions:
- Law enforcement/prosecution/criminal or juvenile proceeding
- Identification of missing or deceased person under state or federal law
- Court order
- Anonymous research or coded research conducted after notification or with consent

A DNA sample from an individual that is the subject of a research project, other than an anonymous research project, must be destroyed promptly upon completion of the project or withdrawal of the individual from the project, whichever occurs first, unless directed otherwise by informed consent.

A DNA sample from an individual for insurance or employment purposes must be destroyed promptly after the purpose for which the sample was obtained has been accomplished unless retention is authorized by specific court order.

Texas
A sample of genetic material for a genetic test must be destroyed after the purpose for which the sample was obtained is accomplished. Destruction is not required:
- Court order
- Authorized by the subject for medical treatment or scientific research
- Research approved by IRB and retention is required by the IRB or authorized by the subject
- Newborn screening

Appendix VI

Searching the Convicted Offender Registry: Material Presented

Searching the convicted offender registry

Genetic Information Work Group
June 24, 2008

Agenda

- New issue from Secondary Uses
- Not part of legislative charge
- Familial searching – use of convicted offender registry

Issue to be resolved

What recommendations on familial searching should be included in the Commissioner's report to the Legislature?

Current law

- Current law (sections 609.117 and 299C.155)
- No prohibition or authorization
- Interpretation may permit less than perfect DNA matches
- Is this the desired result?

Minn. Stat. section 609.117

- Current law
- Convicted offenders
- Felony level offense
- DNA specimen and analysis required
- Data maintained in convicted offender registry

Minn. Stat. section 299C.155

- Current law
- Collect and test
  - Evidence from crime scene
  - Specimens from suspects, victims, others
- Data in case records, not database
- Specimens maintained at BCA

Types of DNA matches

- High stringency – all alleles match
- Moderate stringency – all alleles are represented, additional info present
- Low stringency – at least one allele in common, additional info present

Stringency comparison

Unknown	High	Moderate	Low
11,12	11,12	11,11	11,13
17,19	17,19	17,17	16,19
23, 28	23, 28	23,28	22,28
14,16	14,16	14,16	14,17
12,13	12,13	12,12	12,18
6, 9.3	6, 9.3	6, 6	6, 9

Additional tests that can be done

- Y- STR – paternal relationships
  - Testing could eliminate 99% of false leads
  - Cost factor
- Mitochondrial DNA – maternal relationships
  - Cost factor
- Kinship –new statistical models under development

Current BCA practice

- Test evidence – current number of loci is 15 and one gender marker
- Search convicted offender registry
  - moderate stringency protocol for offenders
  - 8 loci must match to continue evaluation

Familial searching

- Moderate search stringency results in “oh wow” by analyst
- Sufficient match at loci to indicate suspect may be a relative of offender in database
- Known as an “inadvertent” search

Intentional familial search

- Search convicted offender registry
- Low stringency standard
- Undetermined number of loci must match
- Possible number of allowable mismatches is 2 or 3

Why allow mismatches

Father
A,B

Mother
A,B

Possible offspring

A,A
A,B
B,B

These two siblings wouldn't match on Low Stringency

Example of partial match

Profile	Unkwn Profile	Offender
CSF1P0	***10***,11	***11***,11
D13S317	8,13	8,13
D16S539	12,12	12,12
D18S51	14,17	14,17
D21S11	***15***,17	***17***,17
D3S1358	11,***11***	11,***13***
D5S818	***10***,10	***9***,10
D7S820	13,14	13,14

60 Minutes segment

What MN law enforcement is told

Only if perfect match

Sample report format:

The DNA profile obtained from *Item 1 matches* the DNA profile obtained from *John Doe* (and if appropriate) and does not match the DNA profile obtained from *Joe Smith*. The DNA profile obtained from *Item 1* would not be expected to occur more than once among unrelated individuals in the world population.

What other states are doing

- Some states allow report of partial match
- Prior FBI requirement – only perfect match
  - Considering change; no final decision
- Now FBI allowing partials to be reported based on state practice

What should Minnesota do?

- Should Minnesota allow reporting of inadvertent partial matches? What stds?
- Should Minnesota allow intentional familial searches? What stds?
- Who should decide?
  - Minnesota Legislature
  - Department of Public Safety
  - FBI

Options

- Continue only reporting perfect matches
- Report an inadvertent partial match and allow law enforcement to investigate
- Intentionally search convicted offender registry for partial matches and report to law enforcement

Familial Searching

Conference March 17-18, 2008
Arlington, VA
Sponsored by the FBI

Dr. Thomas Callaghan-FBI Lab, CODIS Unit Chief

- Interim plan that will allow states to share information according to each state's applicable laws
  - The FBI will act as the gate keeper
- Partial Match = Searching an unknown profile looking for a perpetrator.
  - Inadvertent search
- Familial Search = Searching the database for potential relatives.
  - Purposeful search

Dr. Fred Bieber – Brigham & Women's Hospital/Harvard Medical School

- Partial data used routinely
  - "A white van was seen at the crime"
- The apple doesn't fall far from the tree
  - 46% of inmates have a family member that is/has been incarcerated
- Use an aggressive search strategy
  - Develop more/better kinship equations that will separate the "good" from the "bad".

Jeffrey Rosen-George Washington Law School

- Familial searching might be illegal under current law
- 4th amendment issues
- Secondary uses of data is wrong
- Legislative restraints are needed
- Familial searching is more constitutionally troubling than partial matching
- Testing offender samples with Y-STRs or mtDNA would bother some judges

Mitch Morrissey-Denver District Attorney

- DNA found in most violent crimes
  - Convict the guilty and exonerate the innocent
- Only finding investigative leads
  - No 4th amendment issues
- Software developed called DNA-View that is believed to eliminate 90% of non-related people
- Search the Colorado data base
  - Expect to solve 40 violent crimes
- Labs cannot withhold investigative information

Barry Scheck-Benjamin N. Cardozo School of Law/Innocence Project

- Big difference between partial matches and familial searching
- Hunt should never have been in prison (Scheck was Hunt's lawyer)
  - Not the best example of familial searching utility
- Privacy concerns outweigh public good
- Congress has never addressed this
- Troubled by rogue data bases
- Too many "hot button" issues
  - Race, privacy, constitutional issues

Rockne Harmon – Alameda County District Attorney's Office (retired)

- Victim's rights are being forgotten
  - Minorities
- Partial matches will not solve many crimes
  - Must lower the search stringencies
- Labs cannot withhold investigative information
- Policies must be developed to use the power of familial searching

Tania Simoncelli – American Civil Liberties Union; Science Advisor

- No difference between partial matches and familial searches
- Familial searching is a policy decision
  - Not a law enforcement decision
- Intrusion into the lives of innocent people
- Worry that people are coerced into providing specimens
- Familial searching will reveal "family secrets"

Stephen Mercer – Private Attorney, Rockville, MD

- Familial searching is an expansion of the data base
  - Expansion deserves public debate
- 4th amendment rights have been degraded over the last 40 years
  - Incremental changes
- Remove profiles from deceased offenders
  - Family rights vs. public rights
  - Cold cases might not be solved

Tony Lake – Chief Constable, Lincolnshire Police Department

- The UK system is different than US
- The prevention of crime is more important than the detection of crime
- Must use Intelligence Profiling as well as geographical profiling in order to develop a list of possible suspects
- Use Y-STRs and mtDNA
- DNA alone should not lead to prosecution

Hugh Whittal – Director, Nuffield Council on Bioethics, London

- A conflict between "two goods"
  - Privacy vs. Crime solving
- The Nuffield Council is an independent body that examines ethical questions raised by advances in biological and medical research
- The council concluded that familial searches can be helpful, but should only be used when necessary
- UK citizens believe government is not malevolent, it is incompetent
  - Too many accidental releases of private information

Sonia Suter – George Washington University Law School

- Previously a Genetic Counselor
- Advises a slow approach with public debate and input
- People not convicted of a crime do not have reduced expectation of privacy
- Is this the start of a "slippery slope"?
- Undocumented local databases are a major concern

Ted Staples – Georgia Bureau of Investigation – SWGDAM Chair

- SWGDAM formed a subcommittee to look at familial searching and partial matches
- Do not support unconditional release of information
- Partial matches will not find many relatives
  - Only 1 in 1000 siblings will be found

SWGDAM Recommendations

- Single-source samples only
- Search local databases first
- Use as many of the core loci as possible
- Use additional testing (Y-STRs, mtDNA)
- Compute Expected Match Ratio (EMR) and Expected Kinship Ratio (EKR)
- Use data from all major population groups
- Train scientists
- Report results to FBI for compilation

Legal Issues Summary

- Constitutional Issues—Fourth Amendment
  - Some say no violation because no seizure
  - Others say as it expands to include family members their right to be left alone is violated

Legal issues continued

- Statutory Issues
  - Some say statutes are silent as to familial searching and therefore it is allowed
  - Others say need for specific statutory authorization before it can occur
  - Some advocate that if it continues there will be a need for legislation regulating, limiting and overseeing process

Privacy Concerns and Issues

- Costs/Concerns as discussed by presenters at the conference
  - Privacy concerns of data giver
  - Privacy concerns for family member
  - Bad Ramifications-Unintended Consequences
  - Convicted felons have reduced privacy interests but family members do not
  - Slippery Slope-New and expanded uses
  - Even voluntary samples could be coercive

Privacy concerns continued

- Family Implications-Autonomy to raise family as seen fit
- Familial searching may unduly intrude on autonomy:
  - Questioned paternity
  - Incest
  - Adoption

Privacy concerns continued

- Benefits as discussed by presenters at the conference
  - Solving crimes
  - Protecting victims' interests
  - Benefit minority population as most crimes are against minority populations
  - Prevent wrongful convictions
  - Prevent crime

Recommendations discussed at conference

- Limit database to convicts
- Destroy samples of exonerated family members
- Limit use of databases
- Limit family members asked to test
- Limit false positives
- Address racial disparity
- Strong oversight

Recommendations continued

- Use only for most serious crimes
- Limit to searches that will be effective

Request for direction

What recommendations on familial searching should be included in the Commissioner's report to the Legislature?

- Secondary uses started developing positives, negatives and options

Appendix VII

(Amendment effective January 1, 2009.)

§ 2-506. Storage of DNA records and DNA samples [Amendment subject to abrogation].

(a) *DNA records.- Each DNA record of identification characteristics that results from DNA testing under this subtitle shall be stored and maintained only by the Crime Laboratory in the statewide DNA data base system, except as necessary to participate in CODIS.*

(b) *DNA samples.- Each DNA sample obtained under this subtitle shall be stored securely and maintained only by the Crime Laboratory in the statewide DNA repository.*

(c) *Typing results.- Typing results shall be stored securely in the statewide DNA data base system.*

(d) *Limitation of search of statewide DNA data base.- A person may not perform a search of the statewide DNA data base for the purpose of identification of an offender in connection with a crime for which the offender may be a biological relative of the individual from whom the DNA sample was acquired.*

[2008, ch. 337.]

Edmund G. Brown Jr., Attorney General

California Department of Justice DIVISION OF LAW ENFORCEMENT George B. Anderson, Director	INFORMATION BULLETIN	
Subject **DNA Partial Match (Crime Scene DNA Profile to Offender) Policy**	*No.* 2008-BFS-01	*Contact for information:* *Bureau of Forensic Services* Gary Sims

TO: All California Law Enforcement Agencies and District Attorneys Offices

The Department of Justice (DOJ) has developed a DNA Partial Match Reporting and Modified CODIS (Combined DNA Index System) Search Policy that may result in investigative information provided to law enforcement officials in unsolved cases where all other investigative leads have been exhausted. Because the information that is ultimately provided will be the name or names of an offender or offenders in California's DNA database who may be related to the actual perpetrator, the process developed requires special DNA testing and review of the offender's non-DNA information. The process specified in the Policy was developed keeping privacy concerns in mind while at the same time providing information that may be useful in solving a violent offense.

Background

California's DNA Data Bank, formally established in 1990, consists of a database of DNA profiles from offenders and a database of crime scene (evidence) profiles. The two DNA databases form the California CODIS. When a crime scene profile is searched against the offender database, a match is declared if the crime scene profile is "exactly" the same as the offender's DNA profile. Logic suggests that if the profiles are not exact, but close, the source of the crime scene profile may be a relative of the offender. With the recent advances of DNA technology, DNA testing beyond the standard profiling for individual identification can now be conducted to provide additional information as to whether individuals may be related.

DOJ Partial Match Reporting and Modified CODIS Search Policy

The name of an offender who is not the source of the biological material from an unsolved case may be released in an investigation under the following two situations.

I. Partial Match Obtained from CODIS Search

When a crime scene DNA profile (forensic unknown) is routinely searched by the standard method against California's Offender DNA Data Bank and a "partial match" results in which the profile shares at least 15 STR (Short Tandem Repeat) alleles with a different but potentially related offender profile, the name of the offender may be released to the investigating agency if the protocol outlined below has been followed and all of the following conditions are met:

1) The crime scene DNA profile is a single-source profile.
2) The case is unsolved and all investigative leads have been exhausted.
3) A commitment is made by the agency and the prosecutor to further investigate the case if the name of the potentially related offender is eventually released.
4) Y-STR typing of the same crime scene evidence that yielded the submitted forensic unknown profile is completed by the submitting agency and is concordant with the offender's Y-STR type obtained by DOJ.
5) If the Y-STR profiles have been determined to be consistent, DOJ will review non-forensic information in order to identify additional evidence bearing on relatedness, if available.
6) A DOJ committee will discuss the case with the local law enforcement agency, the local laboratory, and the prosecutor's office. After reviewing all of the available information, the offender's name will be released unless there is a reason not to release it.
7) If the committee cannot reach consensus, the decision to release the name to the investigating agency will be made by the Attorney General or his designee.

II. Special Request for a Modified CODIS Search

When a law enforcement agency is investigating an unsolved case that has critical public safety implications, the agency may request that DOJ conduct a modified CODIS search with the objective of identifying any offender(s) in the database who are likely to be related to the unknown perpetrator. In these situations, the name of an offender may be released to the investigating agency if the protocol outlined below has been followed and all of the following conditions are met:

1) A written request is sent to the Chief of the Bureau of Forensic Services that describes the case, and attests that all other investigative leads have been exhausted, and that the investigating agency and the prosecutor's office are committed to further investigate the case if the name of an offender is eventually released.
2) The crime scene profile is a single-source profile.
3) Y-STR typing of the same crime scene evidence that yielded the submitted forensic unknown profile has been completed by the submitting agency prior to the search.
4) The modified CODIS search conducted by DOJ must result in a manageable number of candidates.
5) The candidate matches resulting from the modified CODIS search will be prioritized by DOJ using appropriate statistical calculations for relatedness.
6) Based on this prioritization, DOJ will conduct Y-STR analysis of the offender sample(s).
7) If the Y-STR profiles of the evidence and offender sample(s) are consistent, DOJ will review non-forensic information in order to identify additional evidence bearing on relatedness, if available.
8) A DOJ committee will discuss the case with the local law enforcement agency, the local laboratory, and the prosecutor's office. After reviewing all of the available information, the offender's name will be released unless there is a reason not to release it.
9) If the committee cannot reach consensus, the decision to release the name to the investigating agency will be made by the Attorney General or his designee.

Initiating the Partial Match Investigation

When a partial match occurs that has at least 15 shared STR alleles with an offender, DOJ will contact the local laboratory's CODIS administrator to confirm that the case is not yet solved. If the case is still active, the case investigator should be notified of the partial match by the local CODIS laboratory and the process defined in the policy will be followed upon request.

Partial matches that occurred prior to the date of this bulletin will be addressed on a case-by-case basis by DOJ.

Initiating A Modified CODIS Search

If an investigator has a case where no search of the crime scene DNA profile has produced an offender hit or a partial match as described above, and the case otherwise meets the criteria specified, a modified CODIS search request can be made to DOJ. These special requests should be on agency letterhead and sent to:

Chief
Bureau of Forensic Services
1102 Q Street, 6th Floor
Sacramento, CA 95811

In either of the two instances described above, a memorandum of understanding will be formally established between the investigative agency and DOJ, as any costs associated with the special DNA testing of the crime scene evidence must be paid for by the investigative agency, unless the crime scene evidence testing was performed by DOJ.

Sincerely,

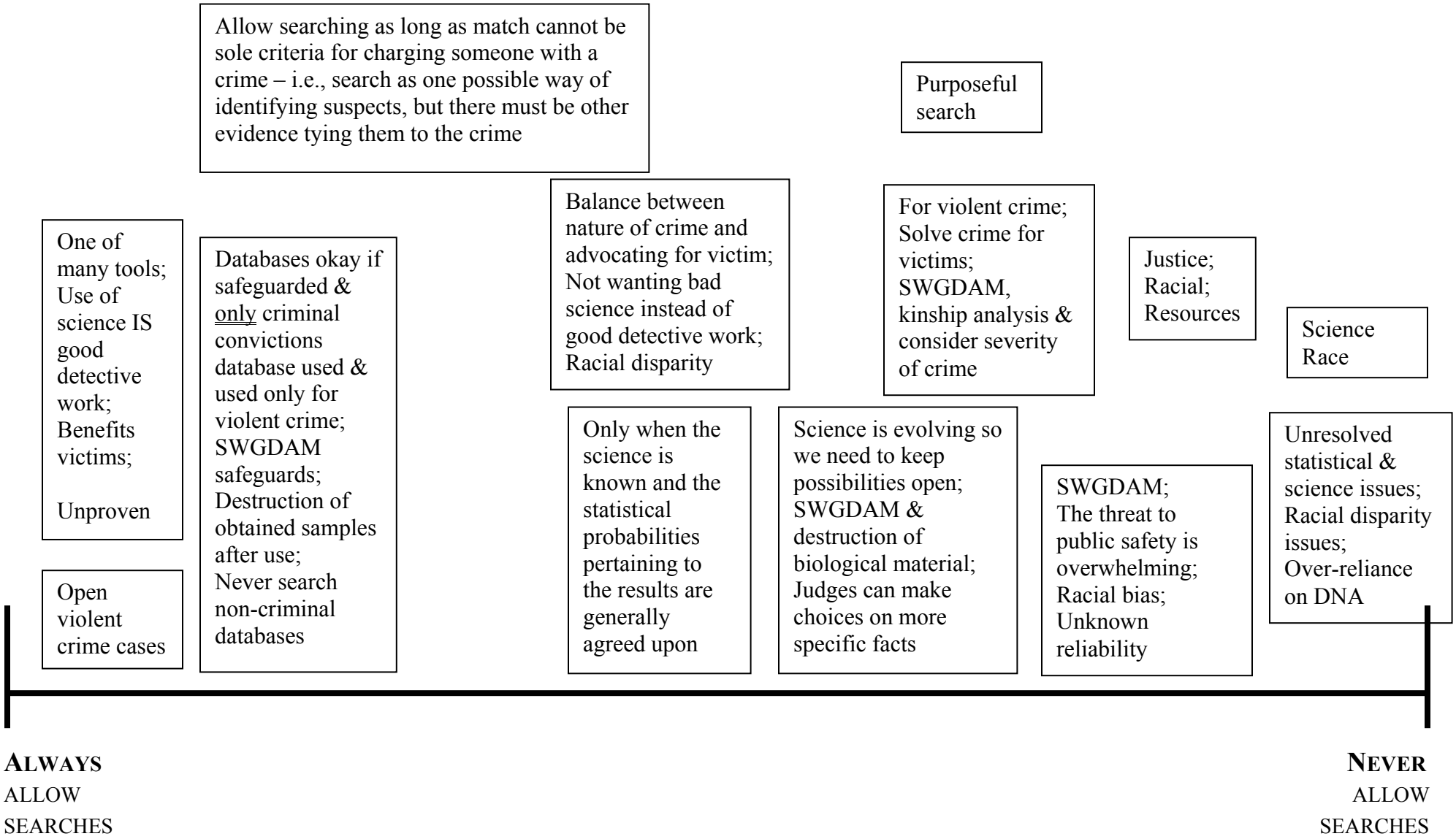
LANCE GIMA, Chief
Bureau of Forensic Services

For EDMUND G. BROWN JR.
Attorney General

Appendix VIII

Continuum for Purposeful Familial Searches

July 22, 2008



Appendix IX

Continuum for Inadvertent Searches

July 22, 2008

SWGDAM;
Use all available means;
Set specific & higher standard;
Use only criminal database

With excellent match;
Never outside criminal database

Violent crimes;
Open case

Effort made to ensure highest level of care possible to allow mixed specimen analysis w/o excluding actual perpetrator;
Only convicted offender database

Use for all crimes;
Do more testing;
SWGDAM safeguards before releasing;
Crime database only;
Can't ignore data
Need some threshold for "oh, wow"

Discretion ok;
Gather data;
Report;
Violent crimes;
Y-STRs ok;
Criminal database

For victims- need to consider utility
But concerns re: tech & use

SWGDAM;
Violent crimes limitation;
Concerns: racial bias, reliability

Unresolved statistical & science issues;
Racial disparity issues;
Over-reliance on DNA;
No research

Science is not to this point

ALWAYS ALLOW SEARCHES

Same as intentional searches – Pursue as an investigative lead, but it is not the sole criteria for prosecution

NEVER ALLOW SEARCHES

Appendix X

Minority Reports and Comments

December 13, 2008

Commissioner Dana Badgerow
Minnesota Department of Administration
200 Administration Building
50 Sherburne Ave
Saint Paul, MN 55155

Re: **GENETIC INFORMATION MINORITY REPORTS**

Dear Commissioner Badgerow,

Thank you for inviting us to participate as members of the Minnesota Genetic Information Work Group. The group's charge included addressing the ever increasing issues related to the privacy and security of genetic data, the use and control of DNA and the rights of citizens to control the use of their own genetic information and material.

The work group struggled with many issues and could not reach consensus on several key issues which remain very important to the privacy and autonomy rights of individuals. Throughout the work group process it became clear that the final draft report would not necessarily express a clear sense of the debate or the disagreements. During the final meeting, your staff informed work group members that minority reports were expected, could be written, and would be sent to you along with the draft of the majority report.

From the beginning of the work group process, we had hoped that a minority report would be unnecessary. However, we have now concluded that a response to the majority report is critical to ensuring that the voice of people who believe in privacy rights and self-determination be heard.

To that end, we have combined our individual concerns and our written efforts to provide you with two separate, yet equally concerned, Minority Reports in response to the '2009 Genetic Information Report – DRAFT Version Two.'"

You will find critical overviews of the issues and concerns that we believe are not sufficiently covered in the final draft of the majority report, a list of specific concerns regarding the report's recommendations, and several legislative recommendations.

Please feel free to contact us at any time regarding these critical issues. And thank you in advance for your interest in our reflections of the work group process and our recommendations to the legislature. We were honored to be a part of this very important process.

Sincerely,

Twila Brase, R.N., P.H.N.
President
Citizens' Council on Health Care
651-646-8935

Susan Shogren Smith
Attorney
612-812-8160

Citizens' Council on Health Care

Genetic Information
Minority Report

to

Commissioner Dana Badgerow
Minnesota Department of Administration

from

Twila Brase, RN, PHN
Member, Minnesota Genetic Information Work Group
President, Citizens' Council on Health Care

In response to the "2009 Genetic Information Report – DRAFT Version Two," the following Genetic Information MINORITY REPORT with Recommendations, Background, and Specific Concerns is hereby submitted:

RECOMMENDATIONS

I. The Minnesota Genetic Privacy Law (Minn. Statutes 13.386) must remain intact for all public and private sectors, retrospectively and prospectively, requiring fully informed written consent for the collection, storage, use (including secondary use) and dissemination of genetic information including written data, DNA, and biological specimens.

II. Biological specimens must not be defined or treated as medical records under the Minnesota Health Records Act.

III. Individual ownership rights to DNA should be acknowledged in law.

IV. Government should not impose regulations on the Direct-to-Consumer genetic testing market and their contractual arrangements.

V. The Minnesota Department of Health should be prohibited from creating genetic pedigrees (profiles) on individuals and families.

VI. The Minnesota Department of Health should be required to provide information to all subjects of government-held data upon request of the subject.

VII. Newborn genetic testing (collection, storage, use, and dissemination) must not be exempted from the genetic privacy law and its informed written consent requirements.

VIII. The Minnesota Department of Health's newborn genetic testing program should face sanctions if it continues to refuse to comply with the consent requirements of the Minnesota Genetic Privacy Law, and constitutional prohibitions against "unwarranted search and seizure" of persons, houses papers and effects.

IX. Newborn blood and DNA retained by the Minnesota Department of Health without parent consent (since July 1, 1997) should be destroyed.

X. Informed written consent requirements for government collection, retention, use and dissemination of genetic information should not be replaced by Tennessen warning requirements.

XI. Third parties that collect data and biological specimens on behalf of the government should be held accountable for complying with notice and informed written consent requirements of the state genetic privacy law.

XII. Cancer patients should not be placed into government cancer surveillance without their informed written consent.

XIII. Minnesota Department of Health research using medical records, genetic test results, and biological specimens should not be exempt from the definition of research or informed written consent requirements.

XIV. Medical ethics, human dignity, voluntary participation requirements of the Nuremberg Code, and individual rights under the Constitution of the United States must not be superceded by corporate research plans, overreaching scientific agendas, or sweeping claims of "public health" authority over all facets of private life, including the human genome.

CCHC, 1954 University Ave. W., Suite 8, St. Paul, MN 55104 **PHONE:** (651)646-8935 **FAX:** (651)646-0100 **WEB:** www.cchconline.org

BACKGROUND

Genetics, Public Health, and Human Rights

The ability to unlock and assess an individual's genetic blueprint has now stretched far beyond science fiction. As genetic science rapidly advances, the calls for genetic privacy and the protection of an individual's genetic information and DNA have become increasingly urgent.

Public Concerned about Privacy

Public opinions polls have demonstrated the public's concerns about genetic privacy. One study found that 86 percent of American adults think doctors should get their permission before conducting genetic testing, while 93 percent think researchers should get their permission.[1] Dr. William W. Lowrance, Ph.D. similarly cautioned at an international privacy conference,

> "But with the coming of electronic medical records, increased linking of databases, and so on − and given the vague foreboding that many people feel about anything "genomic" − public concerns are intensifying. As was mentioned at the outset of this document, the abuses that can be imagined range from embarrassment, blackmail, fraud, and group stigmatization, to negative discrimination for health or life insurance, employment, promotion, mortgages, or loans. Another possible abuse, depending on point of view, is unconsented parentage testing."[2]

Genetic Research

Every cell in the human body contains human genes and DNA. Unbeknownst to patients and citizens, private entities and government agencies are now retaining blood, tissue and body parts left behind in the course of patient's treatment—often viewing them as genetic gold mines and opportunities for obtaining research grants and building research credentials. Ellen Wright Clayton, M.D., J.D., director of the Vanderbilt Center for Genetics and Health Policy, says:

> "People may not understand…that tissue samples they provide may be used for genetic research…They may believe that samples will be discarded after testing, although the law often requires that samples be retained. When samples are obtained as part of medical care, patients may not be told about the possibility that these samples will be stored and used for research… [O]ne investigator has found that documents used to obtain informed consent in genetic research usually do not inform subjects that the samples they provide may be retained and used for research well into the future, including research on disorders unrelated to those for which the subjects originally provided their samples and by investigators at other institutions."[3]

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[1] "Public Attitudes Toward Medical Privacy," conducted by the Gallup Poll for the Institute for Health Freedom, September 2000.

[2] William W. Lowrance, Ph.D. "Privacy, Confidentiality, and Identifiability in Genomic Research." "'Law Meets Technology' Dragon: Protecting Privacy Through Deidentification: Reality or Fallacy?" 29th International Conference of Data Protection and Privacy Commissioners. October 2006. http://www.privacyconference2007.gc.ca/workbooks/Terra_Incognita_workbook7_E.html. Accessed 12/12/08.

[3] Ellen Wright Clayton, MD, JD, et. al. "Informed Consent for Genetic Research on Stored Tissue Samples." JAMA. 12/13/1995.

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Genomic Technologies

On the genetic horizon is the potential for widespread **genetic sequencing** of the public as portrayed in the rather ominous, yet inspiring, 1997 movie, Gattaca. Of particular note, the letters in the title—G, A, T and C—are the four nucleotides that make up DNA:

Gattaca: the movie

Gattaca: blood from newborn heel limits life choices/employment options

Serious concerns about genetic discrimination, genetic engineering, chimeras (mixing cells from two different organisms) and beyond have also emerged. For instance, **genetic manipulation** has scientists and others both excited and very worried, as noted by Robert M. Friedman, recent speaker at a University of Minnesota forum on synthetic genomics:

- "[We hope to] get beyond engineering…and get to the stage of designing an organism with useful properties. This is the dream. **To others, it's their worst nightmare."** *[emphasis added]*

- "DNA Synthesis makes 'Impossible' Genetic Manipulations Doable in Real Time."[4]

Genetic Biobanks (Warehouses)

On the subject of genetic biobanks, warehoused collections of biological samples and DNA, Henry T. Greely, a genetic expert from Stanford University and an invited speaker at a University of Minnesota genomics forum, cautions that genetic biobanks and related genetic research hold special concerns for individuals who have been poorly informed or from whom consent has not been obtained:[5]

- [Under the federal Common Rule for research] "the creation of a genomic biobank by collecting information from subjects will be human subjects research."

- "The biobanks' intensive genotyping, and possibly **ultimately sequencing**, will be likely to turn up information about many different diseases or disease risks." *[emphasis added]*

- "Neither…'confidentiality' nor…'anonymity' means what most research subjects expect, because neither can be guaranteed to be effective. The problems with each are magnified in genomic biobanks."

[4] Robert M. Friedman, J. Craig Venter Institute, presentation at the University of Minnesota, October 8, 2008.
[5] Henry T. Greely. "The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks." Annual Review of Genomics and Human Genetics. 2007. 8:343-64.

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- "The increase in genomic data, as well as the increase of computerization of other records about individuals, will only make identifying 'anonymous' biobank files easier and easier."

- "Coded identifiers…cannot be made definitely secure. Those who are authorized to use the links might use them for improper purposes…or as a rogue action by a biobank official. Third parties might steal the links by hacking into a computer file where they are contained, finding a notebook in which they are recorded, or watching an authorized person enter, say, a password that gives access to the links. Finally, one could determine a particular subject's file by submitting new information on that person and then searching the coded database for someone with that information."

- "Consent forms need to stress that confidentiality cannot be guaranteed, even with anonymous samples…Second, **anonymizing samples, far from being a simple way to protect subjects, is itself both undesirable and unethical**…Anonymity also effectively takes away the right of a research subject to withdraw from research, and anonymity makes it easier for researchers, biobank managers, IRBs [institutional review boards], and others to overlook the problems of protecting information." *[emphasis added]*

- "[C]oded or anonymized data cannot be guaranteed to be nonidentifiable and, thus, those affected are subject to possible harms from disclosure of personal information…"

- "The growth of genomic biobanks aggravates…gaps in the [federal research] Common Rule as it enables biobanks to provide more samples with more associated information to a greater number of researchers for purposes of less interest to the subjects."

- "[A] person may be willing to have her samples or information used in some research, but not in some other research that she finds **objectionable**…One person might be understandably outraged to learn that her DNA and personal data were used, without his (sic) knowledge or consent, in research on race, genetics, and violence. Another might be offended to learn that his DNA was used in research on the evolution of humans…" *[emphasis added]*

<u>Minnesota's Newborn Genetic Screening Biobank</u>
The issue of the state health department's newborn (genetic) screening biobank was regularly brought up and discussed by members of the work group, and its subcommittees. There was significant disagreement on the issues of retention, use, and research—and the issue of informed written consent. The concerns as well-documented on the CCHC website[6] are as follows:

- There is no authority in statute for creating a biobank of newborn blood.
- The biobank, which began storing newborn blood on July 1, 1997 without parent consent, holds the blood and DNA of more than 780,000 children.
- Researchers have accessed and used the DNA of at least 42,210 children without the knowledge or consent of parents.

[6] http://www.itsmydna.org

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- The 2006 state genetic privacy law requires written informed consent for collection, storage, use and dissemination of genetic information.
- Administrative Law Judge Barbara Neilsen ruled on March 23, 2007 that the state health department is in violation of the genetic privacy law regarding storage, use and dissemination.
- Governor Tim Pawlenty vetoed the Minnesota Department of Health's 2008 attempt to exempt collection, storage, use, and dissemination of newborn blood from the genetic privacy law's consent requirements (SF 3138)
- The Minnesota Department of Health has confirmed that it continues to store, use and disseminate newborn blood and DNA without parent consent—and in violation of the state genetic privacy law.

Legal Challenges to DNA Retention Begin

Legal challenges to retention and use of genetic information and DNA have begun. For instance, on December 4, 2008, the European Court of Human Rights announced in a ruling that made international news that the estimated 800,000 fingerprints and 800,000 DNA samples of innocent people in British police databases must be destroyed. The court ruled that retaining the information "could not be regarded as necessary in a democratic society."[7] This is just the beginning of the legal challenges to retained DNA and claims of government and corporate ownership of the unique identities, genetic codes and genetic details of individual lives.

DNA Ownership

Finally, the issue of DNA ownership is key to the protection of medical privacy and personal autonomy. As Sue Blevins, president of the Institute for Health Freedom, testified to the Pennsylvania Senate:

> The Pennsylvania legislature could prevent serious privacy invasions in the coming years by writing a law that defines clearly who owns one's DNA. Without this basic clarification, the line between genetic privacy and genetic ownership will remain fuzzy. For example, without a DNA ownership law, researchers theoretically could maintain one's genetic privacy but inappropriately use someone's DNA for cloning. In other words, a state law that addresses genetic privacy but ignores genetic ownership will not necessarily prevent individuals' genetic information from being used inappropriately.[8]

Ownership has become pressingly important. **Michael Crichton**, the author of Jurassic Park, told a group of legislative staffers in Washington, D.C.:[9]

> Under present law, if somebody takes my picture, I have rights forever in the use of that picture. Thirty years later, somebody publishes it or puts it in an ad, I still have rights. But if somebody takes my tissue, part of my body, I have no rights. I have more rights over my image than I have over the physical tissues of my body. That's just plain absurd.

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[7] Richard Ford. "Police are ordered to destroy all DNA samples taken from innocent people." The Times. December 5, 2008.
[8] Sue A. Blevins. "Testimony Before the Pennsylvania Senate Communications and High Technology Committee: Hearing on Privacy and Security in the Information and Technology Age." June 4, 2001. http://forhealthfreedom.org/Publications/privacy/PennTestimony.html
[9] Michael Crichton. "Genetic Research and Legislative Needs: A Talk to Legislative Staffers." Washington, DC. September 14, 2006. http://www.michaelcrichton.com/speech-legislativestaffers.html

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Universities are being very foolish. Patients will figure this one out. Let me give you a futuristic scenario. I have to go to the hospital for a blood test. Right now, I pay for the test. But I will soon go to priceline.com to get a bid for which hospital will pay me the most for the privilege of doing my test, and keeping my blood. So if you think that current rulings about tissues protect medical research, think again. If my tissues are valuable but you give me no rights once they leave my body, then my whole focus will be to control the point of departure. Fleets of lawyers will converge on this point. What happens next will be brutal, and expensive.

So: how can we really assist medical research? By giving patients appropriate control. I donate my tissues for a purpose, and that purpose only. You want to use them for something else, you need my permission again. You can't get my permission, you can't use the tissues. Simple. Two reasons for this: first, it gives me that emotional sense so important to me because it makes explicit the tie to the tissue even if it has left my body. Second, it acknowledges there may be significant legal and religious reasons why I do not want the tissue used for another purpose.

In light of these and other concerns about genetic information, here are a list of specific concerns related to the Minnesota Genetic Information Work Group's *2009 Genetic Information Report - DRAFT Version Two*."

SPECIFIC CONCERNS

1. **Executive Summary Gives Incomplete Picture of the Debate** – The final draft report's Executive Summary, likely the only part of the report to receive attention from a majority of policymakers and the public, fails to note the significance of the policy divisions between members of the work group. While the final draft of the Executive Summary was not received for purpose of drafting this Minority Report, the draft summary reviewed on the final meeting on November 18, 2008 gave only a single statement about the lack of consensus—at the bottom of the third and final page.

2. **Statement Regarding Consensus Minimizes Serious Disagreements** – In the Executive Summary, the statement that the work group "did not necessarily reach complete consensus" seems to signify minimal disagreement when in fact there was and remains significant disagreement over many of the report's final recommendations, as noted in the following 18 concerns.

3. **Attempt to Undo the Minnesota Genetic Privacy Law** (p. 7) – As opposed to Safeguards Recommendation One, the state genetic privacy law does not need "additional guidance." Comments by many group members representing researchers, the health care industry and government agencies made it clear that the purpose of such guidance would be to limit the reach of the genetic privacy law—essentially to undo it.

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This attempt to undo the law represents a clear sign of how effective the 2006 genetic research law has been for the protection of human subjects and the consent rights of individuals whose genetic test results and biological specimens (blood, human tissue, hair, organs, etc.) reside in public and private databases and genomic biobanks.

The statute's power to protect citizen genetic privacy rights was made clear during the 2008 state legislative session. In hopes of continuing their illegal collection, storage, use, and dissemination of newborn blood and baby DNA and retaining the state's newborn DNA warehouse, the Minnesota Department of Health attempted to exempt the newborn screening program from the genetic privacy law's written informed consent requirements. Since there is no statutory authority today to retain, use or disseminate newborn blood, the proposed language was also an attempt to establish such authority. However, after hearing from concerned citizens and policymakers, Governor Tim Pawlenty vetoed the bill (SF 3138).

The Health Department's continuing disregard for the rule of law does not invalidate the genetic privacy law's clear authority to protect babies and families from the Department's ongoing illegal retention and research activities. The Department's attempt to undo the law last session represents their acknowledgement of its legal authority to protect individual and family privacy rights.

4. **Recommendation Would Enable Undoing of Genetic Privacy Law** (p. 8)

   - Attempt to Limit Application of Informed Consent– There is no need to clarify that the genetic privacy law applies to both government and private entities. That is clear by the fact that the law is in Chapter 13 and it addresses "other persons." Rather, there may be a need to simply *copy* the language of the current statute from Chapter 13 into another section of Minnesota statutes regarding the private sector.

   - Attempt to Minimize Covered Entities and Protected Genetic Information – Currently the law provides comprehensive protection of genetic information. Questioning whether the law should be applied to data and specimens dated before the law's August 1, 2006 effective date is potentially an attempt to negate privacy protections for every person born before the law went into effect. In addition, attempts to limit consent requirements or define the terms "dissemination," "genetic condition," and "medical or biological information" will likely serve as opportunities for proponents of unconsented research to create legal loopholes that undo the strong genetic privacy protections now in effect.

5. **Direct-to-Consumer Genetic Testing Recommendation Hinges on Hypocrisy** – The final draft report's recommendation is an example of a double standard that exists in the minds of many regarding government and industry. As noted previously, the Minnesota Department of Health has gone out of its way to keep the public in the dark about its collection, storage and use of data and biological specimens, yet this recommendation suggests that government regulation is necessary to force corporate entities to provide citizens with a full accounting of their use of data and specimens.

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In addition, the recommendation that government regulate the private market of genetic testing should concern the Minnesota public. Recommending government oversight of the private affairs and contractual decisions of individuals and private parties invites intrusive government monitoring, expensive government regulation, and unnecessary government meddling in the private decisions of individual consumers.

Finally, while the report makes a point by anticipating secondary uses of consumer genetic information and/or specimens, it does not actually recommend informed consent for such secondary uses. (p. 10)

6. **Attempt to Equate Biological Specimens with Medical Records** – Recommendation number 2 on page 10 ("Private health care providers") is *dangerously misleading and insufficiently explains the basis for the strong disagreement mentioned*. The report recommends that human biological specimens be treated in the same fashion as medical records under the Minnesota Health Records Act. This is a particularly disturbing recommendation.

   First, a medical record and a biological specimen cannot be compared. A medical record is a limited set of data that is or can be fully known and reviewed by the patient. A human biological specimen, on the other hand, contains information about the patient that is unknown to the patient or the doctor; information that can be interpreted incorrectly, can reveal hidden secrets (paternity comes to mind), and can be used for purposes objectionable to the subject. Furthermore, the tissue and cells of a biological specimen can be combined with other biological specimens and synthetic material to create new entities. They can also be used experimentally to create new living being, including organs and potentially new humans (e.g. clones).

   Second, to treat biological specimens as medical records for the purpose of research is to remove almost all patient notification and consent requirements for research. In 1997, the Minnesota's health records law was changed to allow researchers *internal* to an organization to conduct medical and other research using private medical records without patient consent. Only *external* researchers are now required to request patient consent…however, consent is *implied* if the prospective subject does not respond to the researcher's request**.** We strongly opposed the legislation because it allows patients to become involuntary research subjects. The Mayo Clinic was instrumental in the passage of this legislation.

   The Mayo Clinic has untold numbers of human biological specimens. In 2003, the *Saint Paul Pioneer Press* reported that a "nondescript warehouse" in Rochester, MN is packed with "pieces of Mayo Clinic patients going back to 1906."[10] Members of the work group clashed repeatedly over this recommendation, which was put forth by a member representing the Mayo Clinic. Although the draft report lists some of the concerns, it does not accurately reflect the statutory basis for the strong disagreement.

[10] "Genetic Gold Mine." Saint Paul Pioneer Press. August 24, 2003.

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Permitting genetic research on human biological specimens retained by hospitals, clinics and laboratories without informed patient consent would undo the genetic privacy law, create millions of involuntary research subjects, and be a significant violation of individual genetic privacy rights.

7. **Continued Disregard for ALJ Ruling on Tennessen Warning & Third Parties** – As noted on page 9 of the draft final report, work group members disagreed about "whether the notice and consent requirements that apply to government entities would apply" to [third parties] "who collect genetic information and human biological specimens for government programs on behalf of the government." Despite a contrary ALJ ruling, representatives from the health department continued to maintain their claim that third parties are not responsible for providing the Tennessen warning—and work group members representing hospitals agreed. However, as noted in Administrative Law Judge Barbara Neilsen's March 23, 2007 ruling on the Department's proposed revision of the newborn screening rule:

> "The Department maintains that the Tennessen warning does not apply to the newborn screening situation because the blood is collected by private or non-profit hospitals, not by government entities. The Department further contends that, even if the Tennessen warning does apply, the requirements of the Tennessen warning are essentially contained in its current newborn screening brochure given to parents."
>
> "After careful consideration, the Administrative Law Judge finds that the Department's contention that the Tennessen warning statute does not apply to the newborn screening program to be flawed. The proposed rules demonstrate that hospitals are merely acting, for a very brief period of time, as agents of the Department in carrying out the newborn screening program…It is the Department that collects and retains both the blood samples and the test results; the Department merely relies upon the responsible parties to implement the necessary communications and the actual drawing of the blood."
>
> The Administrative Law Judge concludes that the requirements of the Tennessen warning do apply to this situation and that a parent or guardian must receive all of the information required by Minn. Stat. § 13.04, subd. 2 before the screening test is done and before the parent or guardian decide whether to 'opt out' of the information retention scheme. Furthermore, the Administrative Law Judge concludes that the newborn screening brochure currently used by the Department does not satisfy the requirements of Minn. Stat. § 13.04, subd. 2(c) or (d)."[11]

8. **Tennessen Warning Limits are Insufficiently Described** – The report also does not sufficiently address the fact that the Tennessen warning is not informed consent as required by the genetic privacy law today. In fact, the document does not even require a signature. In addition, as an example of how poorly the warning can be written —as

[11] Barbara Neilsen. Report of the Administrative Law Judge. Office of Administrative Hearings. March 23, 2007. http://www.oah.state.mn.us/aljBase/090017586.rr.htm

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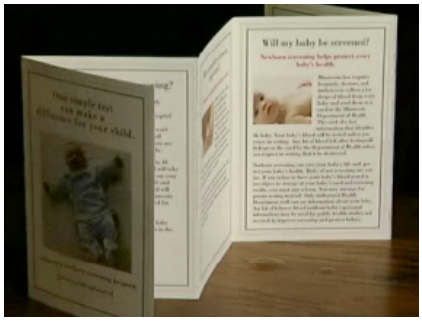
underscored by Judge Neilsen's statements above—the four-color accordion-folded brochure that essentially serves as a marketing piece for the newborn genetic testing program has the Tennessen warning "strewn" throughout *(MDH agreed to this characterization of the brochure's inclusion of the warning, during testimony in a Senate Committee, 2008)*. Parents will not look at this brochure and see the stern warning that a Tennessen Warning is meant to be. Nor would it in any way qualify as informed written consent. (pp. 9, 11)



MN Department of Health's Newborn Screening Brochure

9. **Recommendation to use Tennessen Warning is Place of Informed Consent Violates Privacy Rights; Would Void Genetic Privacy Law** – CCHC strongly disagrees with the report's recommendation of "extending current Tennessen warning requirements in the Data Practices Act…to the collection of human biological specimens by government entities." Rather, we support *informed written consent* as is now required by the Minnesota Genetic Privacy Law (M.S. 13.386). Given the contentiousness of this issue, the disagreement over this recommendation is not sufficiently noted in the final report. (p. 11)

10. **Ownership of DNA Insufficiently Discussed** – There was insufficient dynamic discussion of this issue to warrant the report's statement: "The committee and work group were not able to provide a recommendation as to who retains ownership rights in the specimen." In fact, DNA ownership was given relatively little time and attention. The issue seemed to be the unwanted elephant in the living room. Attempts to have a thorough and thoughtful discussion of the issue were regularly diverted to discussions about assuring physical security and facility access and control procedures for biological specimens. (p. 11)

11. **No Individual Control over Use of Human Biological Specimens** – Although physical security and access controls for retained biological specimens by public and private entities recommended in Safeguards Recommendation Three is important, this recommendation does not go far enough. The recommendation should, but does not, provide the subject of the biological specimen with any control over the storage, dissemination or use of their specimen or its DNA. (p. 12)

12. **State Genetic Privacy Law Should Not Be Held Hostage** – Genetic Information Safeguards Recommendation Four offers options on government retention of specimens as limited by the federal Clinical Laboratory Improvement Amendments regulation.

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However, the federal regulation is not statutory law, underscored by the fact that not all facilities comply with the regulation. To recommend that Minnesota genetic privacy law be held captive by federal regulations is to disempower the elected representatives of the Minnesota public. (p. 12)

13. **Retention Policies are Insufficient for Protecting Citizens** – Genetic Information Safeguards Recommendation Four is insufficient. While government retention policies should be publicly available for human biological specimens, opt-in informed written consent for the retention of specimens must also be required because the purpose for retention of specimens, particularly newborn blood specimens, is research.

    However, the Minnesota Department of Health stated at several work group meetings that the public health and genetic studies conducted by MDH are not and should not be defined as "research." This assertion by MDH is patently untrue. MDH has a particularly troubling history regarding retention and research. As noted previously, MDH has retained newborn blood and baby DNA and used it for genetic research since July 1, 1997 without statutory authority or parent consent. MDH has also collected, stored, used, and disseminated it without informed written consent, a violation of the 2006 state genetic privacy law as ruled by ALJ Barbara Neilsen. Furthermore, the Department has refused to provide the public with access to public documents regarding use and dissemination of newborn blood for research.[12] (p. 13)

14. **Claim that Federal Notice and Consent Laws Protect Genetic Privacy is False** – The report does not clearly state that the federal "privacy rule" established by the Health Insurance Portability and Accountability Act (HIPAA) does **not** provide protections for biological specimens. Furthermore, the report does not explain that this "privacy rule" does **not** protect privacy. Instead, as discussed in *The Wall Street Journal, Consumer Reports, Modern Healthcare*, and other major publications including the regulation itself, the privacy rule **permits broad access** to private medical record data, allowing at least 600,000 entities access without patient consent. Finally, the draft final report does not note that the Genetic Information Nondiscrimination Act puts genetic information (exclusive of biological specimens) under the privacy protections of the HIPAA "privacy rule," eliminating most privacy protections for genetic information. (pp. 5, 9, 10)

15. **Government Genetic Information Campaign Needs More** – It is unclear that a new government education campaign is necessary. However, if such an information campaign is initiated, it essential that the campaign include specific information on *how* genetic information and DNA are accessed and used in Minnesota's public and private sectors. In addition, specific contact information should be published allowing individuals to receive an accounting of such disclosures and uses. (p. 14)

    That said, past experience, particularly with the Minnesota Department of Health, has shown that government agencies intent on expanding government access to private data on individuals may present information in a way that provides incomplete information and discourages questions about government practice. As an example, the following is

[12] "MDH Refuses to Disclose DNA research documents." http://www.youtube.com/watch?v=kL8igqDVA6c

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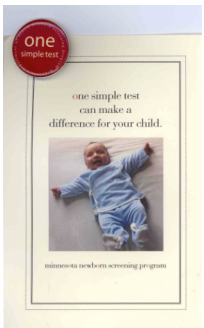
the "One Simple Test" newborn screening brochure and the *attached* red button handed out at the 2008 Minnesota State Fair:



First and foremost, this brochure fails to acknowledge the written informed consent requirements of the Minnesota Genetic Privacy Law (M.S. 13.386). Instead, the back of the single-page brochure mentions the right to "object" as found in the newborn screening law (M.S. 144.125). The brochure says parents have a right to "opt out" of "newborn screening, dried blood spot storage, or participation in public health studies and research for their baby."

Important facts missing from the brochure which might be of significant interest and concern to parents—beyond the failure to inform parents about their consent rights—include the following:

- The newborn screening test is a genetic test.
- There are risks associated with genetic testing.
- The baby's blood and DNA become state government property.
- If parents do not opt-out the blood will be kept indefinitely.
- The legislature may opt to decide to use the blood for purposes beyond research
- Impact of positive diagnosis or "genetic trait" on future insurance/employment
- Lack of treatment for many of the conditions tested.
- Government retains testing results data on child and parents in a database.
- Parents have no right over the types of genetic research conducted.
- The hospital will not necessarily remind them they have the right to opt out.
- It is not a "simple test," (anxiety over false positives, pain to the baby, etc.).
- Their baby's blood may be shared with corporate and other researchers.
- Certain research could be objectionable to parents.
- Research conducted by the department may not be specifically "for their baby" as stated or even to the benefit of their baby.

16. **Minnesota Cancer Surveillance System** – The work group was not asked to discuss the merits of the MN Cancer Surveillance system, how this surveillance system provides another example of covert and unconsented government surveillance of individuals. Most cancer patients do not know that they have been placed in the Minnesota cancer surveillance system. Most patients do not know it exists. Minnesota law should require informed written consent for including patients in the state's cancer surveillance system.

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A lifetime of patient privacy rights should not be stripped from those unfortunate enough to receive a diagnosis of cancer.

17. **Government-Created Pedigrees (Genetic/Family Profiles) Are Not Expressly Authorized in Minnesota Statutes** – This is a particularly troubling section of the draft work group's report, leaving most work group members with more questions than answers, a fact not made clear in the draft report.

    The legislature charged, "The commissioner and work group must make recommendations whether all relatives affected by a formal three-generation pedigree created by the Department of Health should be able to access the entire data set, rather than only allowing individual access to the data of which they are the subject." However, the authority to create pedigrees remains unclear. During discussions of MDH pedigrees, the department's answers to questions were obtuse and incomplete. Nor is was is made clear how the Minnesota Department of Health creates pedigrees (where the data comes from) or why the Department is in the business of family profiling through pedigrees. The draft report does not clarify the issue of authority, or the basis or extent of pedigree creation. Unresolved concerns include the following:

    First, this recommendation may be more than it appears. There appears to be no statutory authority for the Minnesota Department of Health to create three-generation family pedigrees. Could the Department be creating pedigrees without statutory authority in the same way it began retaining newborn blood and DNA in 1997 without statutory authority? It appears that adding this language to law may authorize an activity taking place today that is not actually permitted by law today.

    Second, Is it possible that MDH is using Minnesota Statutes 62J.301 and 62J.321 to build health, medical, and genetic profiles (pedigrees) on individuals and families without the knowledge or consent of these individuals and families?

    In 2002, when MDH proposed a rule to implement these sections of Minnesota Statutes 62J, the public's outrage became front-page news more than once. The proposed rule required every hospital and every health plan to electronically transmit at least 105 data elements on every patient and medical encounter, including identifiers, diagnoses, physician information, treatment codes, medications, etc.

    After several legislative committee hearings, and in response to the public's outrage, the health department withdrew the proposed rule in March 2003. Do these family pedigrees indicate that MDH has found another manner of implementing Minnesota Statutes 62J despite the public's anger over their first attempt? Would not family profiling through pedigrees also outrage the public if the public were informed of the activity?

    Third, as opposed to the recommendation of the draft report, the legislature should provide citizens with full access to pedigrees held by government. A government with secret and unavailable data collections on its citizens is a danger to the public. As noted on page 21 of the draft report, we find that the shielding of data from data subjects in the

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pedigree "Sets a precedent of government denying access to the subject of data" and leads to a government that is less open and less accountable to the public. For this reason, MDH should be working to limit or eliminate collections of data on individuals, not expanding data collection or using the excuse of privacy to keep the public in the dark about its data collection and profiling activities. (p. 19-21)

18. **Definition of "Secondary Use" is Problematic** – if passed into law, this parsing of the definition of "genetic information" will limit privacy protections for the specimen in which the individual's DNA resides (see Concern #6). In addition, the phrase "reasonable person" related to determining the definition of "secondary use" portends the creation of an impossibly broad legal loophole with plenty of room for abuse and misuse—and potentially litigation. (p. 29)

19. **Secondary Uses Without Consent or Court Order Infringes on Privacy Rights** – Secondary uses should always require written informed consent or a specific limited court order. Furthermore, the legislature should make the decision, not the entities listed in the report. Legislators are the elected representatives of the people, and fully accountable to the public. Finally, it should be noted that state agencies are not "neutral," elected or sufficiently accountable to the public. (p. 30)

20. **List of Prohibited Secondary Uses is Incomplete** – All research, including MDH "public health studies," should be listed as a prohibited secondary use. Such medical and genetic research must be prohibited unless there is informed written consent. (p. 30-31)

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Genetic Information
Minority Report

To

Commissioner Dana Badgerow
Minnesota Department of Administration'

From

Susan Shogren Smith, Attorney
Member, Minnesota Genetic Information Work Group

As a response to the "2009 Genetic Information Report-DRAFT Version Two" the following recommendations, observations and concerns are respectfully submitted as a Minority Report:

Recommendations

I. Any entities that gather genetic specimens or data on behalf of the government to offer a Tennessen warning prior to their gathering of the specimen or information and also to receive informed written consent as required by the Minnesota Genetic Privacy Law. (M.S.13.386)

II. There should be no interference in the individual's right to contract with private providers of services related to genetic testing.

III. Individual privacy rights in relationship to genetic information and material must not be infringed upon.

IV. Any government agency or any entity acting on behalf of the government to collect genetic information or specimens must identify the primary intended use of the

information or material at the time of collection. EVERY other use of genetic information or specimens will be considered a secondary use and would require a specific written consent by the patient or identified patient representative. The collecting entity must receive informed written consent prior to the collection if the collection is voluntary.

V. Government agencies, and all persons or entities assisting the government in its collection of genetic information or specimens, must be required to secure informed written consent prior to the collection and storage of genetic information or specimens. This informed written consent must include an explanation of all known and planned uses as well as clear timelines for the destruction of the specimens or information. Unless mandated by law, participation in all government programs that collect and store genetic information or specimens should be "opt-in" or voluntary.

VI. An individual should always retain ownership rights in regards to his own DNA unless that individual specifically waives the ownership, in writing.

VII. Retention policies for genetic information and specimens collected by or on behalf of government agencies must be in writing and provided directly to the individual from whom the genetic information and/or material is collected. Additionally, an individual must be informed about the reason for the retention of the information or specimen and whether or not the retention is obligatory or voluntary.

VIII. Clear limits must be established that prevent the ability of one government agency to access genetic information or specimens held by another government agency unless informed written consent of the individual is received.

IX. Familial searches of genetic information retained by law enforcement or any other government agency should be prohibited.

X. No genetic information or material shall be retained about any person by any government agency without that person's knowledge and informed written consent unless otherwise required by statute.

Overview of Issues

As noted in the majority report, the Legislature directed the Commissioner of Administration to convene the Genetic Information Work Group. This group's charge included making recommendations to the legislature that address the evolving technology related to the collection, identification and storage of genetic specimens and the rapidly improving technology related to the data management, including security, of increasingly specific genetic information.

This group discussed, debated and sometimes argued about the many issues before us. The Department of Administration has compiled a report that describes many of the issues addressed by the group but fails to capture the concerns of some of the members in a manner that identifies the root of our disagreement: a concern about the growing ease with which some government agencies and entities in the private sector can access, utilize and share an individual's private genetic material and /or information without that individual's knowledge or informed consent.

This minority report offers explanations as to why it is imperative the Legislature seek to strengthen the individual's right to control his or her genetic information, whether it be a physical specimen or a piece of data. The following minority report includes a summary of the issues of most concern and the philosophical concerns relevant to them.

I. Public Health and the Public Good

As an introduction to the issues, it seems necessary to discuss the role of "Public Health" in today's society. As researchers unlock the human genome and identify more genes that may predispose people to a host of illnesses or behaviors there is a greater risk of the government and other entities using this information to the detriment of the individual. When the government involves itself in the storage of information or genetic material about specific and identifiable individuals, those individuals may have their privacy violated.

At the outset, the group was confronted with differing views about what "Public Health" and the "public good" really mean. When a concern was raised at the very first meeting of the group about the government storage of individual's DNA, one of the participants commented that this concern was unwarranted because:

> "Once we have universal health care the government will have all of your information, anyway."

This comment provides a clear example of the differing perspectives held by members of the Work Group.

Some members of this group recognized the creeping expansion of the use of the words "Public Health" to push an agenda that leads to expanded government involvement in and control over people's private lives and personal information.

Does "Public Health" refer to policy issues that protect the general population? Most people would accept that there is a role for the Health Department to intervene in instances when a person has an illness that is potentially fatal or contagious and therefore puts the general population at risk. People who are infected with illnesses like Tuberculosis, HIV and other Sexually Transmitted Diseases, Hepatitis, Measles, etc. pose a risk to other unsuspecting people. Also, there are situations in which a cluster of similar health conditions arise that result in a Public Health threat from an environmental concern. (However, even in this circumstance we should thoroughly question the extent that the government intervenes or maintains data on individuals.)

Increasingly, Public Health seems to take an interest in health concerns that do not pose a risk to people generally but rather represent isolated risks to unique individuals. This increasing level of involvement requires answers to a variety of questions. For example:

- Is it either the responsibility or the prerogative of the government to insert itself into the private health matters of individuals?
- Is it the government's right to access and store information about a person's Body Mass Index?
- Whether or not a person carries a gene for Breast Cancer?
- Or how about if the person has a mental illness like depression?

Should the Health Department intervene in issues that relate only to a specific person? Maybe some people are risk takers who might make choices that lead to negative consequences. Maybe skydiving is a public health risk. What should the Health Department do people who like to ski

fast or play football? What if researchers discover a gene that predisposes people to such risk-taking behavior? Should the government have the authority to intervene in the lives of individuals and usurp their privacy rights to protect those individuals from themselves? Do Americans and, for the purposes of this issue, Minnesotans have the right to make choices (even careless or dangerous choices) and practice self-determination?

Any time the government attempts to create policy or practice to limit personal autonomy and freedom, citizens should question and challenge the reasons and the validity of those efforts. This is especially true as relates to genetic information or material.

Often our discussions in the Work Group would implicate public health concerns and refocus the group on the gulf between those who believe in expansive public health policy and practice and those who believe in the need to protect personal freedom and privacy. For example there were members of the group who vehemently believe that researchers must have unfettered access to genetic information to increase the possibility that those researchers will develop tests for genetic disorders or discover the cure for diseases. In the view of some this must be allowed in the name of "Public Health" and the public good.

Some of us believe just as strongly that individuals do not exist to provide research opportunities for scientists. We may even specifically choose to avoid researchers and/or doctors who do not want to ask our permission to include us in their studies. Some of us may not want to participate in research that may result in practices that we find abhorrent. For example, scientists have developed tests that can screen for Down Syndrome in the first trimester of a pregnancy. Certainly these tests are the result of extensive research using an untold number of women and people with Down Syndrome. A consequence of this early screening is that now many sources report that upwards of 80% of babies determined to have Down Syndrome prenatally are aborted. Perhaps people should have the right not to participate in research that they believe will lead to immoral consequences.

An additional example to consider relates to Newborn Screening for more than 50 disorders. Newborn Screening is performed on all babies born in Minnesota unless a parent submits a special form indicating their objection and desire to "opt-out" of the screening. The test costs just over $100.00 and identifies fewer than 200 children per year who have or are at risk of developing a disorder that is non-contagious and therefore limited to that specific child. The vast majority of parents would choose to have their child's heel pricked to ensure the child does not have one of the

conditions. There is no dispute that making this test available to parents offers a wonderful opportunity to protect the few children who might be harmed if there were no early testing.

It is after the heel prick and the initial testing when Public Health ventures down a more questionable path. After the initial screening, the Department stores the blood spots for future use. While it is possible that some parents may choose to access the blood spot at a later date, the truth seems to be the main reason for keeping the spots is to allow researchers to utilize the samples for their own purposes- purposes totally unrelated to the specific child from whom the blood was taken. Parental consent is not required and is not sought prior to allowing the research to proceed.

When people concerned with privacy rights raise concerns about the policy and practice surrounding Newborn Screening there is often a knee-jerk attempt to paint that dissenter as a person who wants little babies to suffer a horrible fate. This contention is wrong. Believing that government agencies should be required to secure consent from the parents of newborns is not some extremist position. It is reasonable to assert the position that parents should control their child's DNA, not the government.

It is also interesting to note that there are only two groups of people who routinely have their DNA or genetic material collected and stored by the government: convicted criminals and newborn babies...

While it is true that the Minnesota Department of Health does contribute to the improvement of some aspects of the health of our society, it is also true that this Department must be kept in check. Not all ends are necessary and the ends do not always justify the means.

As technology improves, as information can be shared more and more quickly, as more of our medical records and personal information is stored on networks accessible to hackers and voyeurs from around the world, we must be cautious about how trusting we are of any government agency to secure our freedom and our privacy. The reports of security breaches, lost laptops, unnecessary employee access, etc. provide ample evidence that security is complicated and difficult to achieve.

To conclude, people have a right to be free from unreasonable government searches and seizures. People have the right to be free of the Department of Health unless their health or conduct poses a threat to the general public health.

II. Notice of Rights and/or Informed Consent Requirements

The majority report describes the Tennessen warning accurately but fails to explain two issues: First the Tennessen warning is inadequate to protect the rights of people from whom genetic information or specimens are taken. Additionally, the state of Minnesota seems to regularly utilize private entities to gather medical samples that contain genetic data. The employees of these private entities act on behalf of the government but are not required to offer a Tennessen warning to individuals on the government's behalf.

The Work Group engaged in an extremely heated discussion about whether the government could require private entities to give a Tennessen warning. Representatives from various private entities made their position extremely clear: The private entities would not accept the responsibility to advise individuals about their rights in relation to the government. Based on current law, there is no requirement these collectors offer information regarding the primary or secondary uses of the data or specimens they collect on behalf of the government.

The lack of regulation and the gap in delineated responsibility between the government and those who contractually walk in the government's shoes creates a privacy risk for individuals. The legislature should draft legislation that would require those entities that gather genetic specimens or data on behalf of the government to offer a Tennessen warning prior to their gathering of the specimen or information and also to receive informed written consent as required by the Minnesota Genetic Privacy Law. (M.S.13.386)

III. Direct-to-consumer genetic tests and private sector labs

When a consumer enters into a contract with a private entity, contract law should govern the terms to which the parties agree. In the area of genetic testing and private sector labs there may be a discrepancy between the knowledge of the buyer and of the seller. This unlevel playing field may pose a risk to consumers but this difference occurs between consumers and sellers of many sorts of goods and services.

The majority report suggests the legislature require a notice of rights that would include a wide variety of issues. When ***must*** the legislature intervene in contractual relationships to protect the buyer from himself?

Interestingly, some who argue the most vigorously on behalf of requiring private entities to fully disclose all possible present and future intended uses of genetic information and specimens also argue against placing those same requirements and responsibilities upon the government or the entities that gather data or specimens on behalf of the government.

This irony should not be lost on the legislature: this polarized approach highlights an issue that recurred throughout our meetings. The intent of some on the Work Group was to expand the ability of the government to collect and store genetic information and specimens so as to facilitate the government's use of that information at ***its*** will, without the consent, or even knowledge of, the individual from whom the information or material was taken. At the same time, regulation would be used to interfere with an individual's ability to contract with private entities.

Consumers may, and routinely do, utilize the civil courts to seek redress for contractual violations by private entities. Citizens have little ability to seek redress when the government imposes upon their rights. **Any expansion of the government's ability to limit either the right to contract or the privacy rights of the people should be looked at with a healthy dose of skepticism.**

IV. Private Health Care Providers

The report to the legislature notes some of the issues identified by those who have concerns related to informed consent. This minority report would like to stress the extent of the disagreement.

The group engaged in ***extensive*** discussions about primary vs. secondary uses of genetic information or specimens by private health care providers. While it might seem obvious that the primary use of information or specimens gathered from a patient would be determined based upon the purpose as understood by the patient, a surprising number of members took the position that the purpose as understood by the collector of the information or of researchers might be different. Some member of the Work Group actually asserted the perspective of the COLLECTOR should be determinative.

There seemed to be a clear intent of some on the committee to undermine the privacy rights of those who receive care at private hospitals by reclassifying genetic data as simply a part of the medical record. Such a classification would enable researchers to routinely access any genetic information within a patient's chart and use that information for their own

purpose. This information could be used without patient knowledge or consent.

In other words, *currently* the collector or researcher may know there is another intended purpose but choose not to disclose this to the patient. **During the Work Group discussion, the reason medical researches do not want to seek consent became obvious: A large number of patients would refuse to share their personal genetic information.**

It became clear that there are private health care providers that believe that research ***"would come to a grinding halt"*** if researchers were required to get informed consent for research or other secondary uses of genetic information or specimens. If no additional protections are put in place by the legislature, every patient's genetic information and specimens will continue to be at risk of being used for research purposes without the patient's informed consent or knowledge.

Please note, this minority report stipulates that any legislation that would limit secondary uses should include a provision allowing for secondary uses necessary to ensure that all equipment is functioning properly, is calibrated, etc.

This report urges the legislature to define the primary use of genetic information or specimens as the specific use or uses identified at the time of collection and those to which the patient has consented, in writing, at the time of collection. EVERY other use of genetic information or specimens will be considered a secondary use and would require a specific written consent by the patient or identified patient representative.

IV. Collections of genetic information for government programs

As noted in the report to the legislature, there are several laws that mandate and control the collection and storage of genetic information and specimens by the government. Many of these laws and regulations noted by the majority report were not generally in dispute, however the proposed language to extend Tennessen warning requirements does not capture the concerns of some members of the group.

As noted previously, the expansion of the Tennessen warning to include human biological specimens collected by government entities will not protect citizens privacy when the government contracts with a third party to secure the specimen. The information provided to the task force indicated that the government generally relies on third parties to gather

information and specimens. These third parties are not bound by the requirements of a Tennessen warning.

Additionally, there are ever-increasing issues related to the potential of government entities or private facilities linking individuals using DNA. Every cell in the human body contains the unique genetic markers of the individual from whom those cells originated. These genetic markers link us to our parents and children, our grandparents and aunts and uncles, our cousins and to relatives so distantly removed that a family tree could not possibly include the connections. The DNA of every person holds the unique key to innumerable traits that merge into a distinct individual. While the individual is unique, there can be no denying the genetic links between relatives.

When the government stores genetic information about one person, by default it stores information about others. Researches have yet to discover a means to uncouple genetically linked individuals. In fact, the more scientists learn about DNA the more likely they become to connect people to each other.

Individuals have a right to privacy in regards to their DNA but they also should have the absolute right to control what the government does with personal genetic information and specimens. Regardless of whether or not the collection is mandatory or voluntary, the government (or any person, agency or entity acting on behalf of the government) should be required to inform an individual about the reasons for gathering genetic information and/or specimens, all known and expected secondary uses, including research possibilities, and also to disclose how long the specimen or information will be maintained.

This report recommends the legislature establish laws that require government agencies, and all persons or entities assisting the government in its collection of genetic information or specimens, to secure informed written consent prior to the collection and storage of genetic information or specimens. This informed written consent must include an explanation of all known and planned uses as well as clear timelines for the destruction of the specimens or information. Unless mandated by law, participation in all government programs that collect and store genetic information or specimens should be "opt-in" or voluntary.

V. Use and Control of Human Biological Specimens

The committee had limited, yet heated, discussions about ownership of DNA. While the issue came up, the discussions were directed away from ownership towards control. There was no articulated reason for the avoidance of the issue but the implications of transferring ownership of an individual's genetic information or material to a third party is a serious issue and deserved more attention that was possible in this forum. Efforts to discuss ownership were not successful.

Clearly genetic information and material, specifically DNA, is uniquely associated with the individual from whom it originates. Why shouldn't an individual retain ownership of his or her own DNA? What property could be more closely connected to an individual than his own DNA? By definition, unless a person has an identical twin, his DNA can only "belong" to him. The only possible reason to sever ownership is to allow some other entity to profit or benefit from the information or specimen.

This report recommends the legislature clearly establish a person's ownership rights in regards to his own DNA. Additionally, this legislation should establish statutory guidance requiring government agencies to collect and retain specimens only after receiving informed written consent as to the purpose of and the retention period for the specimen. The legislation should also require the destruction of all genetic specimens and information at the culmination of the retention period unless written consent to retain is received.

VI. Retention Periods for Human Biological Specimens

The work group discussion regarding setting retention periods for human biological specimens raised several issues. There was fundamental disagreement within the group as to who could and should determine reasonable retention periods. Some on the work group contended that researchers and others more familiar with the collection of specimens would be better able to determine the length of time the government should be able to keep and utilize information and/or specimens.

Clearly, some members of the group believe that unfettered access to and control of other people's genetic information is justifiable if there can be some public good identified by the government agency. How much "public good" would be necessary to justify retention of an individual's genetic information or material was indeterminable. In fact, it seemed that a quantifiable measure of "public good" didn't need to be identifiable: if a researcher believes there is *any* potential for a public good to result from a research project then that belief would be enough to extend retention.

The most interesting point occurred when a proposal was made to establish a new body, similar to the State Records Disposition Panel, to approve government entity retention policies. Of course, the degree of public good necessary to strip a person of his right to control his own genetic information would be determined by this board or by the individual government entities involved in the collection and storage of data or specimens. ***This idea was suggested because some on the work group indicated the legislature was not competent to determine what retention periods would be appropriate for different government agencies.***

This minority report would like to clearly assert that the legislature should establish retention periods because it is the ONLY body accountable to the public for the decisions made.

This is not a complicated issue. This minority report suggests that those who think only "experts" can understand this issue have, themselves, created the dust cloud that inhibits their own understanding of this issue. The only purpose for such a board would be to usurp the right of the individual to control his own genetic information and material.

This report recommends the legislature establish retention policies for genetic information and specimens. These retention periods must be provided to all individuals whose genetic information or specimens will be collected and retained by a government agency. Additionally, an individual must be informed about the reason for the retention of the information or specimen and whether or not the retention is obligatory or voluntary.

VII. Secondary Uses of Genetic Information

As noted previously, there was extensive disagreement as to what constituted a "secondary use" of genetic information and specimens. There was also disagreement as to when and why the public might demand one government entity share genetic information or material with another government entity.

A primary area of concern at this time centers on the potential use of familial searches of the Convicted Offender Database to narrow down a search for perpetrators of crime. Currently, few states utilize familial searches as a tool to solve crimes however as technology improves the ease with which such searches can occur will increase. Familial searches may have many consequences. Uninvolved, innocent people may be drawn into law enforcement investigations. People may pressured to turn over

lists of known relatives to law enforcement so as to narrow down possible suspects who may have engaged in criminal conduct.

It is possible that without protections put in place there could come a time when the newborn blood spots retained by the Department of Health are converted into a DNA database that could be used for law enforcement purposes, paternity claims and any other purpose evolving technology may allow.

Additionally, the group engaged in extensive discussions about secondary uses of information or specimens that had been de-identified or anonymized. There was a great deal of disagreement as to the legitimacy of claims that data can truly be anonymized. While some members of the group argued vigorously that data can be anonymized, others noted that emerging technology makes it increasingly possibly to match samples and then link them back to individuals.

The Ontario Genomics Institute notes on its website:

> *"Whether anonymization is ever really possible is debatable. Technology allows anonymous samples to be matched with other samples that link to an individual. Anonymization has also been criticized because it prevents updating as well as rights of withdrawal. An important difficulty with anonymized data is that it may be used to avoid obtaining consent for secondary uses. Some commentators suggest that there may a continuing privacy interest in anonymous information."*

Based on the information received over the course of the Work Group meetings, this minority report makes the following recommendations:

The legislature should establish clear limits to the ability of one government agency to access genetic information or specimens held by another government agency unless informed written consent of the individual is received.

The legislature should ban familial searches of genetic information retained by law enforcement or any other government agency.

VIII. Potential for Data Collection and Retention About Individuals Without Their Knowledge or Consent

It seems necessary to note a potential issue raised during the small work group meetings related to Access by Relatives to Three-Generation Pedigrees.

As noted previously, it is virtually impossible to separate an individual from other genetically linked individuals. When a person provides a medical history to a health care provider or other individual or entity, that person often includes information about family members that may or may not be totally accurate. Additionally, that individual may share information about another person who may not want their information discussed.

During the small group meetings noted previously, it seemed possible from the discussion that the Department of Health could create files about a third party based on information collected from the original patient or subject. This third party would be unaware of any retained information if it existed because it would have been gathered via a relative.

When questioned as to how a person could find out if the Department of Health had a file about that person, the response was that a person could contact the Department of Health in regards to the issue to learn if the Department had in fact created a file.

In the final meeting of the Work Group, a representative from the Department indicated that there would not be a file created about a person based on information received from a family member.

To ensure that government agencies do not create files about individuals based on interviews or information gathered by government employees or agencies from a third party, the legislature should prohibit the retention of identifiable information about any individual without informed written consent unless otherwise required by statute.

Conclusion

The United States and Minnesota both have a long and outstanding tradition of celebrating individual freedom and autonomy. The advances in technology put the privacy rights and autonomy of more and more Americans and Minnesotans in jeopardy every day.

The federal government and the states will be faced with the increasingly difficult challenge of securing all individuals' private information, including genetic information and characteristics.

The ability of scientists and doctors to use genetic information to determine an expanding array of personality traits and health issues is increasing at an amazing rate. At the same time, technology makes it more and more possible for those with ulterior motives to access information stored on the networks of agencies, businesses and even home computers. Genetic privacy is at risk and the consequences of the diminishing security of genetic information continue to grow more serious.

On December 4, 2008 the European Court of Human Rights declared that the storage of DNA samples taken from innocent people by the criminal court constituted a breach of the Human Rights Convention. This European Court determined it is wrong for the court in the UK to store DNA taken from people believed to have committed a crime once they have been determined to be not guilty. The courts have placed the matter back into the hands of legislature with a clear mandate to ensure the privacy rights of the citizens of the UK are protected.

The Minnesota legislature should take note of this recent decision as it attempts to develop laws to protect the people of our state. Any government maintenance of individual genetic information or material must be undertaken with great care and concern for the privacy rights of that individual. If it is true that the storage of the DNA of innocent adults violates the human rights of those adults then it must logically follow that it is also a violation of human rights to store the DNA of innocent children.

In short, the question of whether genetic information is different than other medical information has a clear answer: Yes.

This report encourages the Department of Administration and the Minnesota Legislature to seek to strengthen the protections surrounding genetic information and material.

Minnesota Department of Health Comments to the
2009 Genetic Information Report

Introduction. The Minnesota Department of Health (MDH) thanks Commissioner of Administration, Dana Badgerow, and her staff and the members of the Genetic Information Work Group for their hard work, dedication, and thoughtful insights that went into the preparation of the 2009 Genetic Information Report. The topic of genetic information is extremely complex and nuanced and is rapidly evolving in response to rapid scientific progress.

MDH's mission is to protect, maintain, and improve the health of all Minnesotans. In order to carry out its mission, MDH collects a great deal of health information and many human biological specimens. MDH has always carefully protected privacy of this information and these specimens. MDH has always been an advocate of strong legal privacy protections.

MDH collects many types of health information:

- MDH collects health information so we can detect outbreaks at their earliest stages and so we can respond quickly and effectively to control the outbreaks and to learn how to prevent or minimize future outbreaks.
- MDH conducts inspections and surveys of nursing homes to ensure that vulnerable patients are protected.
- MDH responds to complaints about health care facilities and conducts investigations, as necessary.
- MDH collects data on birth defects so we can better understand and prevent the 70% of birth defects where the cause is unknown.
- MDH collects information on every case of cancer in Minnesota in order to continue the improvement in cancer prevention, diagnosis, and treatment, which will continue the impressive gains in the battle against cancer. Note that the information collected on all cancers was instrumental in MDH determining that there was an unusually high occurrence of mesothelioma in northeastern Minnesota. This has led to an in-depth study to determine the cause.
- MDH uses information and specimens to continuously improve the newborn screening program, which currently finds approximately 140 babies a year with serious, but treatable, conditions, thereby saving lives or preventing serious disability.
- MDH collects and uses health information and specimens for many other specific programs, all directed at protecting, maintaining, and improving the health of all Minnesotans.

MDH protects health information in many ways:

- MDH has a culture of respect for and protection of the confidentiality of health records.
- In addition, when MDH has to use or disclose health information to protect the public's health, we disclose only as permitted by law and then only the minimum necessary and only to those with a need to know.
- MDH provides data practices training to staff, along with continuing education on a monthly basis to all staff about data privacy and data security.
- MDH has a Data Practices Coordinator available to all staff for consultation on data privacy issues.
- In summary, MDH uses health information legally and respectfully and only on a need to know basis and we carefully protect the information from disclosure outside of MDH.

Almost all health information has a genetic component, whether it is a specific genetic condition or a genetic host factor that affects how a person is susceptible to or able to recover from an infection or how a person's body is able to process toxins or chemicals found in the environment.

MDH needs continued access to all types of health information, including genetic information and human biological specimens, in order to continue to fulfill its mission to protect, maintain, and improve the health of all Minnesotans.

Executive Summary. The main points of MDH's response to the draft 2009 Genetic Information Report are:

=> MDH supports privacy protections for human biological specimens, but encourages more study into what the protections should be and how to avoid unintended consequences when putting protections into place.

=> MDH needs exceptions to the genetic privacy statute (Minnesota Statutes, section 13.386) in order to carry out its responsibilities to protect public health and for health oversight activities related to health care providers licensed or otherwise regulated by MDH. These exceptions would be similar to the exceptions for MDH that exist to health information privacy statutes.

=> MDH agrees with the draft report recommendation to amend the Minnesota Cancer Surveillance System (MCSS) statutes to give the patient (as opposed to the patient's physician) the right to decide if relatives can be interviewed by MCSS for an epidemiologic investigation.

=> MDH agrees with the draft report recommendation that the data subject of a third generation pedigree is the individual who provided the information.

=> MDH supports clarifying that the data subject is the individual from whom the genetic information is collected. MDH also supports the other clarifications recommended in the draft report. These clarifications would make the genetic privacy statute more workable.

=> MDH has many concerns about expanded Tennessen Warning requirements related to the collection of genetic information and human biological specimens.

Privacy Protections for Specimens.

The draft report recommended that the protections for health data be extended to human biological specimens. The draft report noted specifically that these health privacy protections included those in the HIPAA Privacy Rule, the MN Health Records Act, and medical and health data under the Data Practices Act.

MDH agrees in concept with this recommendation. Protections for the privacy of specimens are important, but significantly more study has to be done before extending data privacy protections to specimens. More harm than good can come from acting without sufficient forethought to avoid unintended consequences.

Things to consider in any privacy protections for specimens are the important differences between data and specimens. Data can be copied and redacted; specimens generally cannot be copied or redacted. Specimens are physical property; media that data are stored on are physical property, but the data themselves are generally not physical property. These important differences were not addressed in the draft report and need to be considered before passing any legislation.

Public Health Exceptions to the Genetic Privacy Statute.

All three systems of privacy protection for health related data mentioned in the draft report are extensive in their detail. For each of these systems of data privacy protections, there are many necessary exceptions that are thoughtfully and carefully crafted to protect the public. For example:

- The Minnesota Health Records Act includes seven pages to define the protections for health records held by Minnesota health care providers and patient rights to those records.
    - For the Minnesota Health Records Act, MDH is required to develop a notice of disclosures of health records that may be made without the written consent of the patient. MDH has developed a one-page document that can be used by providers to give patients this notice. MDH has also prepared a list with a one or two sentence summary of the disclosures and the conditions necessary for a provider to make the disclosures, along with the statutory citation. This list is nine pages long.
- The Minnesota Government Data Practices Act includes 120 pages to define privacy protections for government data in Minnesota. This is in addition to many other privacy references distributed throughout other chapters of Minnesota Statutes.
    - Exceptions or special conditions are found in many places in the Data Practices Act.
- The federal HIPAA Privacy Rule includes at least 40 pages to define the core of the federal privacy protections for protected health information (PHI), along with references to many other pages of text that create definitions, describe federal preemption, and set out penalties for violations.
    - Specific exceptions to these privacy protections are the public responsibility exceptions to the HIPAA Privacy Rule. In 45 Code of Federal Regulations, section 164.512, there are 12 public responsibility exceptions that allow the disclosure of PHI without patient authorization. Among these 12 exceptions are three that permit health care providers and health plans to disclose PHI to MDH and to other public health authorities and health oversight agencies. These include:
        - Uses and disclosures required by law.
        - Uses and disclosures for public health activities.
        - Uses and disclosures for health oversight activities.
        - Note that the text of the applicable portions of the HIPAA Privacy Rule is included at the end of these comments.

The bottom line is that privacy is very important, but for society to operate, it is necessary to have many thoughtfully crafted exceptions.

These exceptions to patient consent or authorization are essential for MDH to gather and use the data necessary to protect public health and conduct health oversight activities.

Similarly, it is essential that there be exceptions to genetic privacy protections in order to allow

MDH to gather and use the genetic information necessary to protect public health and conduct health oversight activities.

To accomplish this, MDH suggests that the Minnesota Genetic Privacy Statute be amended in subdivision 3 as follows:

"Subd. 3. **Collection, storage, use, and dissemination of genetic information.** (a) Unless otherwise expressly provided by law, genetic information about an individual:

(1) may be collected by a government entity, as defined in section 13.02, subdivision 7a, or any other person only with the written informed consent of the individual;

(2) may be used only for purposes to which the individual has given written informed consent;

(3) may be stored only for a period of time to which the individual has given written informed consent; and

(4) may be disseminated only:

(i) with the individual's written informed consent; or

(ii) if necessary in order to accomplish purposes described by clause (2). A consent to disseminate genetic information under item (i) must be signed and dated. Unless otherwise provided by law, such a consent is valid for one year or for a lesser period specified in the consent.

(b) Unless otherwise expressly provided by law, the Department of Health is exempt from paragraph (a) as follows:

(1) for collecting, using, storing and disseminating genetic information as required by law;

(2) for public health activities that include collecting, using, storing, and disseminating genetic information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions;

(3) for collecting, using, storing, and disseminating genetic information for health oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of the health care system and entities subject to governmental regulatory programs for which genetic information is necessary for determining compliance with program standards."

Minnesota Cancer Surveillance System (MCSS)

In response to a legislative directive, the draft report made the recommendation to amend the MCSS statute to require MDH to obtain consent from patients for all interviews. The draft report also recommended removing the requirement that MDH obtain consent from the attending physician to conduct interviews with patients or their relatives.

MDH agrees with this recommendation. It has been MDH's practice to seek the consent of the patient, unless the patient is incapacitated, so this recommendation would be consistent with MDH's current practice.

The draft report made a second recommendation on who could give consent on behalf of the patient when the patient is incapacitated. The draft report recommended a hierarchy of individuals who would be authorized to give consent in this situation. The hierarchy is:

1) Legal Guardian
2) Health Care Agent

3) Spouse or Registered Domestic Partner
4) Next of Kin
5) Personal Representative

MDH agrees with this recommendation to determine which person can give consent on behalf of the patient for interviews.

MDH has several other concerns:
1) MDH may need to contact relatives to find out if there is a legal guardian or health care agent.
2) It may be important for MDH to consult with the patient's physician for several reasons:
    a) to see if the patient is well enough to be interviewed;
    b) to help explain the interview and its purpose to the patient; and
    c) to see if the patient is an appropriate subject for the interview.
3) The term "incapacity" is not defined. The patient's privacy is protected by the hierarchy of consent proposed in the draft report, so MDH urges the Commissioner of Administration to recommend that MDH determine when a patient is incapacitated.

MDH recommends further amendments to Minnesota Statutes, section 144.69, as follows:

=> The last sentence of paragraph (b) should have language added to the recommendation of the draft report to say: "If the patient is deceased, or <u>if the commissioner determines that the patient is</u> unable to provide consent, consent must be obtained from the patient's:"

=> Renumber paragraph (d) as paragraph (f).

=> Add a new paragraph (d) that says: "<u>With the approval of the commissioner, the department may contact the spouse, registered domestic partner, next of kin, or physician of the patient to learn if the patient has a legal guardian or health care agent.</u>"

=> Add a paragraph (e) that says: "<u>The department may consult with the patient's physician to learn if the patient is well enough to be interviewed, to ask for the physician's help in explaining the interview and its purpose to the patient, and to see if the patient is an appropriate subject for the epidemiologic investigation.</u>"

Third generation pedigree.

The draft report recommends that the patient providing information for a three-generation pedigree is the data subject. The draft report also recommends that there not be greater access to pedigrees maintained at MDH than to pedigrees maintained by other government entities and private medical providers.

MDH agrees with these recommendations. Clarifying that the patient who provides information is the data subject will make this public health tool and health care tool workable.

The draft report suggests language to amend Minnesota Statutes, section 13.384, to make this the law for public sector medical providers. The department suggests adding language to section 13.3805 to make this the law for health data held by the department.

=> Add a new subdivision 5 that says: ""Three generation pedigree" means a pictorial representation or narrative of family health history given by an individual, including the names of other family members and their relationship to the individual. A three generation pedigree does not include the results of any tests from the family member's medical record. A three generation pedigree is health data about the individual. The individual is the data subject of the pedigree and has access to all of the data in the pedigree."

Clarification of the genetic privacy statute.

The draft report makes several recommendations for clarifying the genetic privacy statute, Minnesota Statutes, section 13.386. These include defining the data subject of genetic information and human biological specimens to be the individual from whom the information or specimens are collected. These also include six other clarifications.

MDH supports these clarifications. It has been over two years since section 13.386 was passed. Based on experience in working with the law, it has become apparent that these clarifications are needed.

Tennessen Warning for collection of genetic information and human biological specimens.

The draft report recommended extending Tennessen Warning requirements in the Data Practices Act to the collection of human biological specimens by government entities. The draft report recommended that a Tennessen Warning have additional requirements when genetic information and human biological specimens are collected:

- known secondary uses both internally and externally;
- the fact that any genetic information can share information about a person's blood relatives;
- if a Tennessen Warning notice describes a use for "research," it should describe any research that is in addition to a particular genetic condition; and
- how long the genetic information and / or specimens will be maintained.

The draft report also discussed the possibility of adding Tennessen Warning requirements when other persons collect genetic information and biological specimens and then submit these to a government entity.

MDH has many concerns about the recommendation for expanded Tennessen Warning requirements and the additional discussion of requiring a Tennessen Warning when someone other than the government entity collects the information or specimen.

Almost all health related information is also genetic information.

- Some health information is about a specific condition caused by a single gene. This type of health information is clearly genetic information.
- Advances in science have increased our understanding of genetic components in many health conditions. Heart disease and diabetes are two health conditions with strong genetic components. These types of health information are also genetic information.
- There is evidence that there are host genetic factors in how people are susceptible and respond to some infectious diseases. We believe that this may be true for all or most infectious diseases.

There are also host genetic factors in how people are affected by toxins and other substances in the environment. So, even health information about infectious diseases and environmental pollutants might be considered genetic information.

What this means is that any expanded Tennessen Warning requirements for genetic information would apply to almost everything collected by MDH.

The Tennessen Warning is only a workable requirement when the government entity is asking an individual to supply private or confidential data about that individual. For example, when MDH interviews a person with a reportable communicable disease to determine how the disease was spread and whether the treatment has been effective, we give a Tennessen Warning and use the data consistent with the Tennessen Warning.

The Tennessen Warning is not workable when the government entity is collecting data about an individual from someone who is not the individual. For example, when a lab tests a specimen referred by a doctor for diagnosis and the lab determines an individual has a reportable communicable disease, the lab is required to report to MDH and in some cases send a specimen. Because MDH does not have direct contact with the individual, MDH cannot give the individual a Tennessen Warning. Further, the consequences of not giving a required Tennessen Warning are that MDH would not be able to use the information or specimen. MDH would be unable to protect public health if MDH was prohibited from using disease information or specimens.

Likewise for genetic information and human biological specimens, the Tennessen Warning would only be a workable requirement when the government entity asks an individual to supply information or specimens from that individual.

Specifically, a Tennessen Warning requirement would not be workable for the reporting of communicable diseases or related specimens or for the collection of many other types of public health data or specimens. There may be other privacy protections or some sort of modified Tennessen Warning, but they would have to be tailored to balance MDH's responsibility to protect public health with the individual's privacy. The goal would be to maximize public health protections while minimizing any intrusion on personal privacy.

When MDH directly collects an individual's specimen from that individual, MDH supports a Tennessen Warning. However, MDH does not support a Tennessen Warning under other circumstances that would inhibit our ability to protect public health.

=-=-=-= Public Responsibility Exceptions to HIPAA that Affect MDH =-=-=-=

"§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required. A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law.*

(1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

. . .

(b) *Standard: uses and disclosures for public health activities.*

(1) *Permitted disclosures.* A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

. . .

(d) *Standard: Uses and disclosures for health oversight activities.*

(1) *Permitted disclosures.* A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:

(i) The health care system;

(ii) Government benefit programs for which health information is relevant to beneficiary eligibility;

(iii) Entities subject to government regulatory programs for which health information is

necessary for determining compliance with program standards; or

(iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.

(2) *Exception to health oversight activities.* For the purpose of the disclosures permitted by paragraph (d)(1) of this section, a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:

(i) The receipt of health care;

(ii) A claim for public benefits related to health; or

(iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.

(3) *Joint activities or investigations.* Notwithstanding paragraph (d)(2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of paragraph (d) of this section.

. . . ."