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.
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.
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](image1)

![Gattaca: blood from newborn heel limits life choices/employment options](image2)

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.”

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:

- [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.”

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4 Robert M. Friedman, J. Craig Venter Institute, presentation at the University of Minnesota, October 8, 2008.
• “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]

Minnesota’s Newborn Genetic Screening Biobank
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 website⁶ 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
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.”

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.

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

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.
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.
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.
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.” 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.

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).”

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

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.
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.  

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

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