

Genetic Information Minority Report

To

Commissioner Dana Badgerow
Minnesota Department of Administration'

From

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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 Tennessee 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 Tennessean warning accurately but fails to explain two issues: First the Tennessean 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 Tennessean 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 Tennessean 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 Tennessean 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 Tennessee warning requirements does not capture the concerns of some members of the group.

As noted previously, the expansion of the Tennessee 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 Tennessee 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 be 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 possible 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 be 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.