

NO. A10-101

State of Minnesota
In Supreme Court

Alan and Keri Bearder, individually and as parents and
natural guardians of Josiah and Alexa Bearder, minors; et al.,
Appellants,

vs.

State of Minnesota, Minnesota Department of Health,
and Dr. Sanne Magnan, Commissioner
of the Minnesota Department of Health,
Respondents.

APPELLANTS' BRIEF AND ADDENDUM

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The appendix to this brief is not available for online viewing as specified in the *Minnesota Rules of Public Access to the Records of the Judicial Branch*, Rule 8, Subd. 2(e)(2).

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LEGAL ISSUES

- A. **Must Respondents obtain written, informed consent, as required by the Genetic Privacy Act, before they can store, use, and disseminate newborn blood samples and test results after newborn screening is complete?**

How Raised: Respondents raised this issue in their motion to dismiss and for summary judgment. (Def. Memo, pp. 16-27.)

Lower Courts' Holding: The district held that the Genetic Privacy Act did not apply because the newborn blood samples were not "genetic information" and the Generic Privacy Act did not supersede the Newborn Screening statute. The Court of Appeals affirmed, holding that the newborn blood samples were "genetic information" but that the Newborn Screening statute was an exception to the Genetic Privacy Act.

How Preserved: Appellants preserved this issue through timely appeal of the district court's final judgment. (Appellants' Notice of Appeal, pp. 2-3; Appellants' Statement of the Case, p. 4.) Appellants made timely petition for review of the Court of Appeals decision.

Apposite Authorities: Minn. Stat. §§ 13.386, 13.08, 144.125, 144.1255, 144.128, 645.08, 645.16, 645.17, 645.26; Minn. R. 4615.0300-.0760.

STATEMENT OF THE CASE

Under Minnesota's Newborn Screening statute ("NBS") first enacted in 1965, the Respondent Minnesota Department of Health (MDH) collects blood samples from approximately 70,000 infants born in Minnesota each year and screens them for a variety of "heritable and congenital disorders." See Minn. Stat. § 144.125 (1). Instead of destroying newborn blood samples and negative screening results when testing is complete, MDH began storing them indefinitely. As of December 31, 2008, MDH held over 1,500,000 screening records and over 800,000 newborn blood specimens of Minnesota children. Unbeknownst to the public at large, Respondents began sharing the blood samples and screening results to private institutions for general public health research, unrelated to newborn screening. As of December 31, 2008, more than 50,000 blood samples had been used for research. Respondents did not obtain consent from a single parent for these activities.

Appellants are the parents and 25 children whose blood samples were collected by MDH. They bring this action under Minnesota's Genetic Privacy Act (GPA). The GPA prohibits the collection, use, storage, or dissemination of genetic information (i.e. blood samples, and test results) without the parents' (or patient's) informed written consent. Minn. Stat. § 13.386. The parents allege that the MDH did not advise them of the right to refuse testing and did not obtain their consent to the retention, use or dissemination of the blood samples and test results. (AA, pp. 10-14). Appellants seek injunctive relief, "enjoining MDH from continuing to collect, store, use, and disseminate genetic information without informed written consent" (AA, p. 9 ¶ 3) and declaratory judgment

under Minn. Stat. § 13.08 determining that Respondents are compelled to comply with Minn. Stat. § 13.386 (AA, p. 9 ¶ 4).¹

Before the completion of discovery and before Respondents answered the original and amended complaints, the district court granted Respondents' motion for summary judgment² holding that MDH's conduct was exempt from the GPA. (AA, p. 276.) In a published decision, the court of appeals affirmed. *Bearder v. State*, 788 N.W.2d 144 (Minn. Ct. App. 2010).

¹Plaintiffs also brought damages claims for violation of the GPA, violation of the constitutional right to privacy, unconstitutional taking of genetic property without just compensation, along with various tort claims. After determining that there was no statutory violation, the district court dismissed these claims as "moot." (AA, p. 277.) The court of appeals concluded that Respondents did not violate the GPA and therefore their conduct was not open to challenge by separate tort or constitutional claims. *Bearder*, 788 N.W.2d at 151, n. 7. Pending resolution of the statutory challenges, the damages claims are not directly implicated in the present appeal as neither lower court has addressed them. Should the Court reverse the court of appeals, the damages claims would be considered by the district court on remand.

²Although MDH made an alternative motion for dismissal on the pleadings and summary judgment, the district court considered matters outside the complaint, converting the Rule 12 motion into a motion for summary judgment.

STATEMENT OF FACTS

A. Newborn Screening

In 1965, the Minnesota Department of Health (MDH) began testing all infants born in Minnesota for a single recessive genetic disorder. (AA, p. 210.) The process enlarged and today every infant is screened for more than 50 heritable and congenital disorders. (AA, p. 210.)

Newborn screening is governed by the Newborn Screening statute (NBS). Minn. Stat. §§ 144.125-128. Under the NBS, any institution caring for infants 28 days or less of age must arrange to have screening administered to every infant or child in its care. Minn. Stat. § 144.125, subd. 1. The NBS places this burden on the administrative officer or other person in charge of the facility, the person required to register the birth of the child, or the nurse midwife in attendance at the birth. Minn. Stat. § 144.125, subd. 1. The Respondent Commissioner of MDH also has a duty to “maintain a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services.” Minn. Stat. § 144.128 (3). The Commissioner must notify physicians of newborn testing results and make referrals when treatment is indicated. Minn. Stat. § 144.128 (1), (2).

Presently, a blood specimen is acquired from each Minnesota newborn child at the time of birth.³ The specimen is dried blood, which is collected on a filter paper

³If parents object to testing or elect to require that blood samples and test results be destroyed, the objection or election shall be recorded on a form that is signed by a parent and made part of the infant’s medical record. Minn. Stat. § 144.125, subd. 3. When the Commissioner receives a destruction request, she must comply with the request within 45

“specimen card.” (AA, p. 210.) The specimen card is provided to the “responsible parties” by MDH. (AA, p. 210.) The specimens are analyzed at MDH’s laboratory or on behalf of MDH at Mayo Medical Laboratories. (AA, pp. 211-212.) As part of the newborn screening, MDH and Mayo perform tests for the presence or absence of specific DNA or RNA markers. (AA, p. 212.)

In an executive decision, and without any change in statutory authority, in 1997 MDH began storing the left-over newborn blood samples. Currently, “MDH *indefinitely* stores any remaining blood spot material and test results...” (AA, p. 212, *see also* AA, pp. 179-180.) These stored samples and test results include personally identifiable information about the infants and their parents. (Def. Memo, p. 6.) MDH has blood samples dating back to 1997 and has records of test results dating back to the 1960s. (AA, p. 212.) As of December 31, 2008, MDH had stored 1,567,133 records of results of newborn genetic screening and had blood spots in storage for more than 800,000 Minnesota children. (AA, pp. 143-144.)

MDH does not seek consent from the parents to retain the blood spots and test results. MDH instead provides “opt-out” information, in brochure form, to parents. (AA, p. 210.) MDH has never sought written informed consent for the storage, use, or dissemination of blood samples or test results after newborn screening is complete. Mark McCann (MDH’s Manager of the Public Health Laboratory in the Newborn Screening Program) testified in legislative hearings: “[T]he number of parents who have given

days after receiving it and then must notify the individuals that the samples and test results have been destroyed. Minn. Stat. § 144.128 (5)-(6).

consent to store the dried, the residual dried blood spots with the Minnesota Department of Health is *zero*.” (AA, pp. 141-142.) MDH requires that parents who wish to opt-out their child from the program execute a written destruction request. (AA, p. 211.) A child who reaches the age of majority, learns of the opt-out provision, and later decides to have his or her specimen or test results destroyed can also file a destruction request. (AA, p. 211.)

Many of the stored blood samples have been used by MDH for public health studies unrelated to newborn screening, and MDH has provided samples to outside, private entities, termed “independent research organizations,” for testing beyond initial newborn screening. (AA, p. 212.) As of December 31, 2008, MDH had used more than 50,000 blood spots for studies that included “non-newborn screening efforts in the realm of emerging public health studies.” (AA, pp. 143-144.)

MDH has a contract with Mayo for the analysis of newborn blood specimens. (AA, p. 139.) This contract allows Mayo to keep dried blood samples for two years and to perform non-newborn tests on them if authorized by Mayo’s and MDH’s Institutional Review Board and the state’s authorized representative. (AA, p. 140.)⁴ MDH further admits that Mayo is allowed to keep the testing results indefinitely. (AA, p. 141.)

MDH Witness Mr. McCann also testified, in rulemaking proceedings, that while MDH believes there is a federal requirement to retain an electronic record of the test results for 2 years, federal law does not require that blood specimens be stored for any

⁴MDH asserts that Mayo destroys all blood samples in its control after two years. (AA, p. 141.) Appellants have not had the opportunity to verify this assertion through additional discovery.

length of time. (AA, p. 47.) MDH declined to answer whether it continues to conduct studies using blood spots from children that are *over* 2 years old, objecting that the request was vague and overbroad. (AA, p. 145-146.) Mr. McCann testified that during the past three years, MDH had provided three independent research organizations with access to blood samples. (AA, pp. 33-34.)

In a 2005 e-mail exchange, David Orren, then MDH's chief legal counsel, explained his belief that newborn screening was not subject to *any* data privacy laws. (AA, p. 128.) MDH's position was that the blood specimens were "property" of the MDH and not data. (AA, p. 128.) Orren stated, with regard to rules governing the privacy and handling of the newborn blood specimens: "*Basically, we could pretty much make up what we wanted to do.*" (AA, p. 128 (emphasis added).) MDH also took the position that it had property rights in the blood specimens that trumped federal rules regulating use of blood specimens in human subject research. (AA, p. 128.)

Mr. Orren recognized that "the privacy interests and implications are huge with regard to isolates and specimens because they could tell so much about the people they come from." (AA, p. 128.) He also recognized the potential for abuse:

As to releasing the blood spots for research, I can see how this would potentially lead to a lot of very good things to protect the public health. However, it doesn't take much imagination to see how misuse could do serious damage to the newborn screening program.

(AA, p. 128.)

B. 2006 Legislative Report

At the request of the Legislature, the Minnesota Department of Administration addressed the dangers of government-held DNA information in a report in January 2006 entitled, "A report on Genetic Information and How it is Currently Treated Under Minnesota Law." (AA, pp. 185-205.) The report discusses potential misuses of genetic screening information, including denial of insurance coverage or employment to applicants with a predisposition for expensive diseases. (AA, p. 190.) The report also details how genetic information's use and dissemination can affect an entire family. (AA, p. 190.) Examples included implication of a sibling in a crime or an inadvertent discovery during medical diagnostic testing that a child is not biologically related to the parent. (AA, p. 190.) The study states, "Genetic information is a powerful tool that can both assist and do harm. As a result, its collection, uses and disseminations should be controlled." (AA, p. 190.)

C. The Genetic Privacy Act (GPA)

Following this report, the legislature adopted the Genetic Privacy Act. The act prohibits the collection, use, storage, and dissemination of "genetic information" without written, informed consent. Minn. Stat. § 13.386. If the government or a responsible authority violates the GPA, they are subject to a number of civil remedies. Minn. Stat. § 13.08, subd. 1, 2, 4.

D. Proposed 2007 Rule Changes & The ALJ Report

Following enactment of the GPA, MDH proposed new rules for newborn screening that assumed that the GPA did not apply to the generic information collected

after the GPA's effective date. (AA, p. 37.) Following a hearing on the proposed rule changes, the Administrative Law Judge (ALJ) found that MDH was not fully informing Minnesota parents of MDH practices:

Based upon the information provided during this rulemaking proceedings, it appears that *parents are not informed* that the Department will maintain the test results for an indefinite period of time; that the parents may decide later to request that the blood sample and test results be destroyed; or that the blood sample may be provided to outside institutions for research purposes.

(AA, p. 34 (emphasis added).) The ALJ further found that the MDH opt-out information, which includes warnings about MDH's retention and storage policy, is not provided to parents until *after* they have decided to refuse to permit the child's information to be retained. (AA, p. 34.)

The ALJ concluded that the newborn screening statute *did not* authorize the indefinite retention and dissemination of genetic information without consent:

Moreover, while Minn. Stat. § 144.128 specifies that the Commissioner's duties shall include "maintain[ing] a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services," this provision does not provide any support for the Department's current practice of making information obtained from newborn screening available to third parties for research purposes. *There is no express authorization in the newborn screening statute for the Department's current practice of retaining the information indefinitely without consent and permitting the information to be used without consent for purposes other than the detection, treatment, and follow-up of heritable and congenital disorders as contemplated by the newborn screening statute.*

(AA, p. 38 (emphasis added).)

The ALJ found that the GPA "reflects a serious concern on the part of the Legislature about the collection and retention of genetic information..." (AA, p. 38.)

The ALJ further found:

[T]here is no basis for reading an implication into the statute that the Department is exempted from all of its provisions simply because a parent or guardian is given the option of opting out of the information retention system. In fact, if a parent or guardian elects not to opt out of the screening, the Department will retain the baby's genetic information for some period of time, ranging from 45 days to at least two years.

...

Therefore, after careful consideration, the Administrative Law Judge concludes that the newborn screening statute does not expressly authorize the Department to store genetic information indefinitely or disseminate that information to researchers without written informed consent provided by the parents.

(AA, p. 38 (emphasis in original).)

The ALJ concluded that the GPA does apply to the MDH's proposed rules; that the MDH's failure to incorporate the requirements of the GPA into the proposed rules was a defect; and that this defect could only be cured by adding language to the proposed rules that would require parents to "sign a form provided by [MDH] which states the purposes for which the blood and test results will be used, including provision of the child's blood or test results to outside entities for research purposes, and the period of time for which the blood and test results will be stored." (AA, pp. 38-39.)

Because the ALJ concluded the proposed rules were defective, the report was submitted to the Chief Administrative Law Judge for his approval. (AA, p. 18.) The Chief Administrative Law Judge affirmed the ALJ's Report in all respects and further denied a request for reconsideration. (AA, pp. 56-57.) He explained:

The Department is relying on the *implication* that, because the parents have the option to have the blood spots destroyed in 24 months, a parent who does not elect that option is authorizing the Department to retain the blood spots indefinitely.

While one could reasonably draw that inference, Minn. Stat. § 13.386 requires more than a logical inference or implication. It requires the exception to its coverage to be “otherwise *expressly* provided by law.”... An implication or logical inference is not an express provision. There is no express provision in law that exempts the blood spots from the coverage of Minn. Stat. § 13.386.

(AA, pp. 56-57 (emphasis in original).)

Instead of complying with the ALJ’s recommendations for revisions to the proposed rules, MDH chose not to adopt the proposed rules in their entirety. (AA, p. 184.)

E. Recent Legislative Initiatives

Despite the ALJ’s findings, MDH continued its practices. MDH still does not seek any type of consent for storing, using, or disseminating Minnesota children’s blood specimens and test results. (AA, p. 134-136.)

The Commissioner did attempt in 2007, 2008, and 2009 to obtain legislation exempting the collection, storage, use, and dissemination of newborn blood from the GPA.⁵ However, in 2008, Governor Tim Pawlenty vetoed a bill that would have provided for the opt-out system, specifically indicating to the MDH that he could not support a bill that exempted MDH from “laws which require written, informed consent for the [MDH] to store and use personally identifiable genetic information for non-screening purposes.” Gov. Pawlenty added: “I believe written informed consent should

⁵ In 2008, S.F. 3138, As Introduced (85th Legislative Session), sought to amend section 13.1386, subdiv. 3, to include a separate provision that “notwithstanding [the GPA], the Department of Health’s collection, storage, use, and dissemination of genetic information and specimens for testing infants for heritable and congenital disorders are governed by sections 144.125 to 144.128.” *See also* H.F. 1821, As Introduced (86th Legislative Session); H.F. 0901, As Introduced (86th Legislative Session).

be obtained for the long-term storage or use of the blood samples for non-screening purposes.” (AA, p. 59.)

The 2006 legislature, in addition to adopting the GPA, directed the Commissioner of Administration to create a work group to recommend public policy principles on the use of genetic information. 2006 Session Laws, C. 253, § 22. MDH participated in the work group, which issued a report in 2009 recommending, among other things, that the legislature provide “additional guidance regarding the GPA.” (AA, pp. 206-208.) The 2009 legislature did not make any amendments to the GPA. (AA, p. 183.)

F. Appellants

Appellants include 25 children and their parents/guardians. MDH collected blood specimens and performed newborn screening for each of the 25 children. (AA, p. 180.) MDH alleges that it has not yet used blood specimens from 23 of the 25 children for public health studies or research. (AA, p. 181.) MDH cannot confirm whether or not specimens from the remaining two children were used in public health studies or research, stating only that “MDH has no records indicating that their specimens were used in public health studies or research.” (AA, p. 181.)

Appellants had disturbing experiences with newborn screening. For example, Appellant Adam Bailey objected to the hospital’s taking of his newborn daughter’s blood, but the nurse ignored him and took the sample. (AA, p. 12.) Mr. Bailey again objected to a blood sample from his son, but the nurse ignored his objection and used a sample that had been taken to check his blood sugar. (AA, p. 12.) Another Appellant, Shay Rohde, heard about MDH’s conduct before the birth of her child and was prepared

to object to the taking of the blood sample. (AA, p. 10.) Rohde indicates she never received any written documents or information about the reasons for the taking of the blood test at the hospital, such as the MDH pamphlet. (AA, p. 10.) Rohde objected to the blood test but a pediatrician represented to Rohde that the blood sample was not used for a DNA test, so Rohde consented. (AA, pp. 10-11.)

Appellants brought this action seeking damages and injunctive relief under statutory, constitutional, and common law grounds. (AA, p. 9.) Respondents immediately moved for dismissal under Rule 12 or in the alternative for summary judgment. Although Appellants had not been given the opportunity to complete discovery, beyond preliminary document production and admissions (AA, p. 14), the district court granted the motion. (Add., p. 63.) The Court of Appeals affirmed (Add., p. 54).

ARGUMENT

I. INTRODUCTION

At its core, this appeal concerns the extent to which the government may use private genetic information, contained in hundreds of thousands of newborn blood samples and over 1.5 million testing results, that were acquired for a narrow purpose. The case does not turn on policy considerations that either favor or disfavor such use because those policy considerations are for the legislature and the legislature has made its policy choices. The legislature enacted two statutes that partially overlap (they each address the use of blood samples and test results) and partially conflict (one prohibits any governmental use of blood samples and test results without individual consent and the other permits some limited governmental use of newborn blood samples and test results without parental consent).

The Newborn Screening statute (NBS), enacted years ago in 1965, authorizes the use of newborn blood samples by MDH, but only for the limited purpose of screening for “heritable and congenital disorders”. Minn. Stat. § 144.125, subd. 1. Viewed from a parent’s perspective, the NBS implies an “opt-out” structure – MDH can do this limited screening unless the parent objects in writing. Minn. Stat. § 144.125, subd. 3.

The Genetic Privacy Act (GPA), enacted more recently in 2006, prohibits any use, by MDH or other agents of government, of blood samples and test results (because they meet the definition of “genetic information”). Minn. Stat. § 13.386, subd. 1. Viewed again from a parent’s perspective, the GPA has an “opt-in” structure – the government

may only use the blood samples and test results for the specific purposes to which a parent has given prior written consent. Minn. Stat. § 13.386, subd. 3.

The court of appeals' attempt to reconcile these two statutes is confusing at best.

First, in analyzing whether the NBS fit the exception to the GPA for conduct "otherwise expressly permitted by law," the court gave an overbroad reading to the NBS, implying that it authorized MDH to use the blood samples of newborns and test results for any purpose, without parental consent. *Bearder*, 788 N.W.2d at 150 (stating that the NBS and other legislation "amount to an express provision of the law that authorizes collection, retention, use and dissemination of blood specimens from the newborn screening program, making the genetic privacy act inapplicable.") To the contrary, the plain language of the NBS only authorized MDH to use the blood samples for the limited purpose of newborn screening. Accordingly, the court of appeals was incorrect in concluding that the NBS "expressly provided" an exception to the broad prohibition of the GPA. In order to "expressly provide" an exception to the GPA, the NBS would need to specifically authorize MDH to make any use of the blood samples that would otherwise be prohibited by the GPA. It did not. And because the storage and use of the newborn blood samples for the public health research, that has been made or is threatened by MDH, is admittedly beyond newborn screening, MDH could only lawfully make or continue that storage and use by obtaining parental consent.

In a later section of the opinion, the court of appeals recognized that the "use of specimens for purposes not related to the newborn screening program is subject to the written informed consent requires of the Genetic Privacy Act," contradicting, but not

revising, its earlier conclusion that the GPA did not apply. *Bearder*, 788 N.W.2d at 150. Then the court of appeals erroneously concluded that the MDH assertion, that the blood samples and test results of the 25 Plaintiffs had not yet been used or disseminated, precluded Plaintiffs' claims. *Id.* In so ruling, the court overlooked Plaintiffs' claims that the continued storage of their blood samples and test reports violated the GPA, and Plaintiffs requests for an injunction to preclude further storage and any use or dissemination of their samples or test reports.

The court of appeals decision affirming dismissal of this case should be reversed. This Court should rule that the only exception to the broad prohibition of the storage and use of blood samples and test results under the GPA is for the limited purpose of newborn screening under the NBS. Because the uses made or proposed by MDH go beyond that limited purpose, this case should be remanded for trial on Plaintiffs' claims for damages and for a permanent injunction.

II. STANDARD OF REVIEW (*DE NOVO*)

This appeal presents questions of statutory interpretation that will determine whether Plaintiffs stated a claim under the GPA to enjoin and remedy MDH's unlawful storage, use, and dissemination of blood samples and genetic testing results. Construction of the GPA is a question of law that is reviewed *de novo*. *Doe v. Minnesota State Board of Medical Examiners*, 435 N.W.2d 45, 48 (Minn. 1989) *rehearing denied* April 18, 1989. No deference or weight need be given to the lower courts' construction of the GPA. *Id.*

Furthermore, this case was dismissed pursuant to Respondents' motion to dismiss or in the alternative for summary judgment. The appropriate standard of review under either theory of dismissal is de novo. *Bodah v. Lakeville Motor Express, Inc.*, 663 N.W.2d 550, 553 (Minn. 2003) (Rule 12 dismissal determining whether a complaint sets forth a legally sufficient claim for relief is reviewed de novo); *Riverview Muir Doran, LLC v. Jadt Development Group, LLC*, --- N.W.2d ---, 2010 WL 4340800,*3 (Minn. 2010) (summary judgment decisions are reviewed de novo).

III. THE DISTRICT COURT ERRED IN DISMISSING THE COMPLAINT

A. Minn. Stat. § 13.386, the Genetic Privacy Act, Requires Prior Written Consent for the Collection, Storage, Use or Dissemination of Genetic Information

MDH's collection, storage, use, and dissemination of genetic test results and blood samples following completion of newborn screening, is subject to the GPA. The GPA provides:

Unless otherwise expressly provided by law, genetic information about an individual:

- (1) may be collected by a government entity...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).

Minn. Stat. § 13.386, subdiv. 3.

Genetic information includes genetic test results as well as the blood samples themselves. Under the GPA, genetic information has two definitions. Under the first, genetic information means “information about an identifiable individual derived from the presence, absence, alteration, or mutation of a gene, or the presence or absence of a specific DNA or RNA marker, which has been obtained from an analysis of (1) the individual’s biological information or specimen; or (2) the biological information or specimen of a person to whom the individual is related.” Minn. Stat. § 13.386, subdiv. (1) (a). Under the second definition, genetic information means “medical or biological information collected from an individual about a particular genetic condition that is or might be used to provide medical care to that individual or the individual’s family members.” Minn. Stat. § 13.386, subdiv. (1) (b).

Respondents never challenged the notion that the genetic test results of Newborn Screening fit within the definition of genetic information. In the lower courts they challenged whether the blood specimen itself fit within this definition. The court of appeals, however, held that blood samples constitute genetic information under the GPA’s definitions. *Bearder*, 788 N.W.2d at 150, n. 6. Respondents did not seek further review of this holding and it is now the law of the case. Thus, the plain language of the GPA prohibits MDH from continued storage, use or dissemination of Plaintiffs’ genetic test results and newborn screening blood samples, beyond the initial newborn screening, without written informed consent - unless that conduct, is “expressly” authorized by the NBS.

The NBS has a narrow purpose – to identify positive cases of heritable and congenital disorders in newborns. Under that statute, the MDH may only use genetic information for initial testing for heritable and congenital disorders and for specific follow-up where the initial screening shows positive results for those disorders. As to follow up, the NBS states:

The Commissioner shall:

- (1) notify the physicians of newborns tested of the results of the tests performed;
- (2) make referrals for the necessary treatment of diagnosed cases of heritable and congenital disorders when treatment is indicated;
- (3) maintain a registry of the cases of heritable and congenital disorders detected by the screening program for the purposes of follow-up services;
- (4) prepare a separate form for use by parents or by adults who were tested as minors to direct that blood samples and test results be destroyed;
- (5) comply with a destruction request within 45 days of receiving it;
- (6) notify individuals who request destruction of samples and test results that the samples and test results have been destroyed; and
- (7) adopt rules to carry out sections 144.125 to 144.128.

Minn. Stat. § 144.128. Although the NBS allows the commissioner to periodically revise the list of tests to be administered, that authority is likewise limited to tests “for determining the presence of a heritable or congenital disorder.” Minn. Stat. § 144.125, subd. 2.

Nowhere does the NBS expressly authorize MDH to collect, store, use, or disseminate blood samples or test results for any purposes other than newborn screening. As to storage, the Commissioner is only authorized to “maintain a registry” of positive test results. Minn. Stat. § 144.128 (3). And, in conjunction with that registry, the Commissioner may allow for a process of destroying any information retained by MDH concerning the positive results. Minn. Stat. § 144.128 (4).

Despite the omission of any explicit authority to do anything other than following up from and maintaining a registry of positive test results, the court of appeals concluded that the NBS and “other governing legislation granting the commissioner broad authority to manage the newborn screening program amount to an ‘express’ provision of law that authorizes the collection, retention, use and dissemination of blood specimens for the newborn screening program, making the genetic privacy act inapplicable.” *Bearder*, 788 N.W.2d at 150. This conclusion, which implies that the NBS authorizes MDH’s use for any purpose, not just the limited purpose of newborn screening,⁶ violates basic rules of statutory construction.

“The object of all interpretation and construction of laws is to ascertain and effectuate the intention of the legislature.” Minn. Stat. § 645.16. “Statutory words and phrases must be construed according to the rules of grammar and common usage.” *Larson v. State*, --- N.W.2d ---, 2010 WL 4643074, *2 (Minn. 2010). *Accord* Minn. Stat. § 645.08 (1). “A statute is to be construed, where reasonably possible, so as to avoid irreconcilable difference and conflict with another statute.” *Erickson v. Sunset Memorial Park Association*, 108 N.W.2d 434, 441 (Minn. 1961). *See also Beaulieu v. Independent School District No. 642*, 533 N.W.2d 393, 396 (Minn. 1995) (“[A]pparently conflicting laws are to be construed together, if possible, to give effect to both provisions.”). “[C]ourts should construe a statute to avoid absurd results and unjust consequences.” *Swanson v. Brewster*, 784 N.W.2d 264, 274 (Minn. 2010). *See also* Minn. Stat. § 645.17

⁶As noted, the court later contradicted this conclusion by recognizing the limitation, but did not use that recognition to reanalyze the applicability of the GPA.

(1) (the courts may presume that “the legislature does not intend a result that is absurd, impossible of execution, or unreasonable...”).

“The first step in statutory interpretation is to determine whether the statute’s language, on its face, is ambiguous. If a statute is unambiguous, then [this Court applies] the statute’s plain meaning.” *Larson*, 2010 WL 4643074, *2 (internal quotations and citations omitted). *See also* Minn. Stat. § 645.16. Where a statute is ambiguous, this court may guide its interpretation by considering, among other things: the occasion and necessity for the law, the circumstances under which it was enacted, the mischief to be remedied, the object to be attained, the legislative and administrative interpretations of the statute, and the consequences of a particular interpretation. Minn. Stat. § 645.16. Above all else, “[i]t is the duty of this court to apply the law as written by the legislature.” *International Brotherhood of Electrical Workers, Local No. 292, v. City of St. Cloud*, 765 N.W.2d 64, 68 (Minn. 2009).

1. The plain meaning of “expressly provided by law” does not include implied authorization or authorization putatively acquired through an amalgam of general statutes.

The meaning of “expressly provided by law” is unambiguous. When the legislature used the word “express” it did not mean “implied” or “assumed.” This is consistent with the common meaning of express. For example, the Merriam Webster on-line dictionary defines “express” as “directly, firmly, and explicitly stated” or as “exact” or “precise.” “Express.” Merriam-Webster Online Dictionary. 2010 Merriam-Webster Online. 12 December 2010. <<http://www.merriam-webster.com/dictionary/express>>.The

court of appeals cited *Black's Law Dictionary*, 661 (9th ed. 2009) as “defining express as clearly and unmistakably communicated; directly stated and contrasting that definition with implied.” *Bearder*, 788 N.W.2d at 150 (internal quotations omitted). The NBS does not directly, firmly, and explicitly authorize MDH’s collection, storage, use or dissemination of newborn blood samples and test results beyond the initial newborn screening for heritable or congenital disorders.

MDH and the court of appeals cited Minn. Stat. § 144.125, subd. 3, as expressly providing that genetic information may be stored and used by MDH indefinitely. *Bearder*, 788 N.W.2d at 149. But that provision grants no express authority to MDH. It provides:

Persons with a duty to perform testing under subdivision 1 shall advise parents of infants (1) that the blood or tissue samples used to perform testing thereunder as well as the results of such testing may be retained by the Department of Health, (2) the benefit of retaining the blood or tissue sample, and (3) that the following options are available to them with respect to the testing: (i) decline to have the tests or (ii) to elect to have the tests but to require that all blood samples and records of test results be destroyed within 24 months of the testing.

Subdivision 3 does not expressly authorize MDH to either conduct the testing or to retain the blood samples and test results after the initial newborn screening. First, the provision only applies to “persons with the duty to perform testing.” Under subdivision 1, these are administrators, nurses, or other individuals at the birthing facility, and not MDH. Second, the provision does not grant any authority to MDH but, instead, only imposes duties on other persons to “advise” parents that the tissues or samples used to

perform the initial screening tests may be retained by MDH.⁷ The only argument that Subdivision 3 authorizes the MDH to retain blood samples is that such authority is implied from Subdivision 3. Whether or not that argument has merit is irrelevant to the GPA because that statute only exempts conduct that is “expressly” provided by law. The court of appeals decision, in effect, rewrote Subdivision 3 to exempt conduct that is “otherwise ~~expressly~~ impliedly provided by law.”

The court of appeals also cited Minn. R. 4615.0600 and .0760 for the proposition that the department was required to maintain a record of “all cases.” *Bearder*, 788 N.W.2d at 149. Yet, Rule 4615.0600 only states that MDH shall maintain a “record of all cases of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia reported to it...” and Rule 4615.0760 similarly limits the registry to only “diagnosed cases” of specific diseases. The rules say *nothing* about indefinite retention and use of other genetic test results or of any blood samples.

The court of appeals went on to derive “express” authority from other “general powers” provided MDH by law. The court cited Minn. Stat. § 114.05, subd. 1(a), which provides the Commissioner authority to “[c]onduct studies and investigations, collect and analyze health and vital data, and identify and describe health problems.” This subdivision says nothing about blood samples or other genetic information.

The court also cited Minn. Stat. § 144.1255, which establishes a commission to “provide advice and recommendations to the commissioner concerning tests and

⁷ In fact, the narrow limits of subdivision 3 make perfect sense when read in conjunction with section 144.128, providing that the only post-newborn testing authority given to the Commissioner of MDH is to retain a registry of positive test results.

treatments for heritable and congenital disorders found in newborn children.” The committee’s “activities” include collection of information on the efficacy and reliability of various tests, treatments, and severity of medical conditions for heritable and congenital disorders. Minn. Stat. § 144.1255, subdiv. 2. But this statute does not authorize MDH to collect, store, use or disseminate genetic information.

The court of appeals’ reliance on these general authority statutes is misplaced because the GPA, which was enacted later and is more specific as to the handling of genetic information, overrides the general authority statutes. *See* Minn. Stat. § 645.26 (specific provisions of law control the general; law latest in date of final enactment prevails over earlier law). More importantly, these general authority statutes do not provide any express power to collect, use, store, or disseminate genetic information obtained from newborns after initial newborn screening is complete. The only argument for finding such power in the general statutes would again be that it is *implied*.

The court of appeals attempted to make this implied authority “express.” To do as the court of appeals, one would have to amend the NPS to precisely state that “MDH may use, store, and disseminate all blood samples and test results acquired through newborn screening for any purpose without written informed consent.” But a central tenant of statutory interpretation is that a court may not read into a statute language which the legislature intentionally omitted. *See Larson*, 2010 WL 4643074, at *5. This additional language cannot be considered when examining the interplay between the GPA and NBS.

Instead, in order to harmonize the GPA and NBS, one should read the plain language of the NBS to mean that the only post-screening use and dissemination

“expressly provided by law” is to keep a registry and provide follow-up for diagnosed cases of disease. *Miller v. Colortyme, Inc.*, 518 N.W.2d 544, 551 (Minn. 1994) *petition for clarification denied* Aug. 2, 1994 (“A statute is to be construed, whenever reasonably possible, in such a way as to avoid irreconcilable differences and conflict with another statute.”); Minn. Stat. § 645.16 (“Every law shall be construed, if possible, to give effect to all its provisions.”). Reading the NBS harmoniously with the GPA means that MDH may continue to collect blood samples and perform initial screening, but otherwise must comply with the requirements of the GPA. In this way, effect is given to both statutes. *Beaulieu v. independent School District No. 624*, 533 N.W.2d 393, 396 (“conflicting laws are to be construed together, if possible, to give effect to both provisions”). The NBS accomplishes the goal of screening newborns for potentially life threatening disorders while the GPA protects the privacy interests of Minnesota newborns once newborn screening is complete.

2. If the phrase “expressly provided by law” is ambiguous, further statutory construction establishes that the GPA controls MDH’s conduct beyond initial newborn screening.

If this Court concludes that “expressly provided by law” is ambiguous, further interpretation still establishes that the GPA controls all conduct occurring beyond initial screening. In addition to the canons of construction addressed above, the Court’s examination of legislative intent extends to examining among other things: the occasion and necessity for the law, the circumstances under which it was enacted, the mischief to be remedied, the object to be attained, the legislative and administrative interpretations of

the statute, and the consequences of a particular interpretation. Minn. Stat. § 645.16. Each consideration compels the conclusion that the GPA prohibits the collection, storage, use and dissemination of genetic information beyond initial newborn screening.

Occasion, Necessity, Circumstances, and Purpose. As noted above, the two statutes have different purposes and should be read in harmony to give effect to each. Importantly, the legislature adopted the GPA following a 2006 legislative report detailing the potential misuses of genetic screening information in the context of insurance coverage, employment, and criminal, and family law. (AA, p. 190.) The report specifically called for “control” over the collection, use, and dissemination of genetic material. (AA, p. 190.) The GPA was enacted to satisfy the concerns posed to the legislature.

Legislative Interpretations. Legislative interpretations also suggest that the GPA is meant to control Respondents collection, storage, use, and dissemination of genetic information after initial newborn screening is complete.

As noted earlier, after the ALJ made findings that the NBS does not expressly authorize the MDH “to store genetic information indefinitely or disseminate that information to researchers without written informed consent provided by the parents,” MDH sought express legislative authority by bills proposed in 2007, 2008 and 2009. The 2007 bill did not pass. The 2008 bill passed but was vetoed by Governor Pawlenty, for the specific reason that it would exempt the MDH from “laws which require written, informed consent.” (AA, pp. 58-59.) The 2009 bill, which attempted to address Governor Pawlenty’s concerns, still did not pass.

During the legislative debate on the 2009 bill, key legislators made clear their view that the GPA controlled the collection, storage, use and dissemination of newborn blood samples after initial screening. For example, the following statements were made to MDH employee McCann in a March 16, 2009 hearing considering amendments to the NBS:

Senator Hann:

And, Mr. Chairman and Mr. McCann, I guess I thought that was a requirement, that any collection or storage or use of genetic material had to – it was required that informed consent be a part of that process to do that, so I'm not sure if I understand why you say there's no law that governs that. I thought we did have a general law that said you can't store this without consent.

Mr. McCann:

Mr. Chair, Senator Hann, I don't think my response indicated that there wasn't a law, just not a current practice for us to have written, informed consent to operate a newborn screening program.

Within the boundaries of program operations – our interpretation of current law – it's well within the boundaries to operate a program and use those dried blood spots to test and also for quality assurance, quality control, and quality improvement outcomes.

Senator Hann:

Well, Mr. Chairman and Mr. McCann, I really object to that. I – my understanding is the law on informed consent is pretty clear. It sounds like what you're saying is that you just have not been abiding the law and collecting and storing the material anyway.

I've also been told and have reason to believe that there was an administrative law court ruling that pertained to this issue, and the response to that was that the Department changed the rule and kept up with the practice.

And I find this disturbing that the Department has been acting in this fashion, when it seems to me to be pretty clear that you need to have informed consent if you're going to collect this kind of material from people and use it for any purpose, and I'm concerned that the Department has been ignoring that law or those provisions and now you have brought a

law that is, in effect, giving you that statutory authority to do what you have been doing without authority.

(AA, pp. 73-74.)

Similarly, in a March 17, 2009 committee session concerning the same bill to amend the NBS, Representative Emmer explained that “the law already requires [MDH] to destroy [the blood samples].” (AA, p. 163.) In response, Representative Thissen, one of the sponsors, agreed, “I think that the way the bill was originally drafted called on this to happen actually...” (AA, pp. 163-164.)

It is clear that by adopting the GPA, the legislature was attempting to prevent government misuse of an individual’s genetic identity. If the GPA did not control Respondents’ conduct following initial newborn screening, the legislature’s intent in enacting the GPA would be completely undermined.

Administrative Interpretations. Although the MDH has followed the practice of ignoring the GPA for purposes of newborn screening, that practice has not been codified into a rule and thus should be given no deference. To the contrary, when MDH attempted to codify its practice in a proposed rule, that rule was rejected by the administrative law judge as violative of the GPA, and, to come full circle, the ALJ’s findings regarding the proposed rule were relied on by the legislature in connection with the MDH’s attempts to amend the NBS in 2008 and 2009. As a result, the relevant administrative interpretation of the interplay between the GPA and the NBS is that of the ALJ.

When MDH proposed rules that would reflect the interpretation that its conduct under the NBS was not subject to the GPA, the ALJ presiding over the rule making

analyzed the interplay between the proposed rules and the GPA. The ALJ concluded that the NBS expressly authorized the initial collection of genetic information by MDH from the newborns for the initial screening, but the ALJ found that that the newborn screening statute *did not* authorize the indefinite retention and dissemination of the genetic information for other purposes:

Moreover, while Minn. Stat. § 144.128 specifies that the Commissioner's duties shall including "maintain[ing] a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services," this provision does not provide any support for the Department's current practice of making information obtained from newborn screening available to third parties for research purposes. *There is no express authorization in the newborn screening statute for the Department's current practice of retaining the information indefinitely without consent and permitting the information to be used without consent* for purposes other than the detection, treatment, and follow-up of heritable and congenital disorders as contemplated by the newborn screening statute.

(AA, p. 38.)

The ALJ found that the GPA "reflects a serious concern on the part of the Legislature about the collection and retention of genetic information..." (AA, p. 38.)

The ALJ stated:

[T]here is no basis for reading an implication into the statute that the Department is exempted from all of its provisions simply because a parent or guardian is given the option of opting out of the information retention system. In fact, if a parent or guardian elects not to opt out of the screening, the Department will retain the baby's genetic information for some period of time, ranging from 45 days to at least two years.

...

Therefore, after careful consideration, the Administrative Law Judge concludes that the newborn screening statute does not expressly authorize the Department to store genetic information indefinitely or disseminate that

information to researchers without written informed consent provided by the parents.

(AA, p. 38 (emphasis in original).)

In denying MDH's request for reconsideration of the ALJ's decision, the Chief

ALJ explained:

The Department is relying on the *implication* that, because the parents have the option to have the blood spots destroyed in 24 months, a parent who does not elect that option is authorizing the Department to retain the blood spots indefinitely.

While one could reasonably draw that inference, Minn. Stat. § 13.386 requires more than a logical inference or implication. It requires the exception to its coverage to be "otherwise *expressly* provided by law."... An implication or logical inference is not an express provision. There is no express provision in law that exempts the blood spots from the coverage of Minn. Stat. § 13.386.

(AA, pp. 56-57 (emphasis in original).)

After the ALJ's decision became final, the MDH could only adopt the proposed rules with the ALJ's amendments to make clear that MDH was required to obtain prior written consent to store, use and disseminate the blood samples and test results. The MDH dropped the proposed rules.

Consequences of Interpretation. Lastly, the Court should consider the consequences to the public of adopting MDH's interpretations. Minn. Stat. § 645.16. If the Court adopts MDH's position, it would conclude that the government's indefinite collection, storage, use, and dissemination of the unique genetic makeup of every child born in this state is permitted unless the parents affirmatively object. This would render

the GPA meaningless. To give the GPA any meaningful effect, the use and dissemination by MDH must be limited to initial newborn screening.

This Court may presume that “the legislature does not intend a result that is absurd, impossible of execution, or unreasonable...” Minn. Stat. § 645.17. It is unreasonable to construe the general grant of authority to MDH to promote public health to be an “express” exception to the GPA. It would also be unreasonable to conclude that the legislature intended to infringe upon fundamental rights to privacy by such general and broad grants of authority. *See Erickson v. Sunset Memorial Park Association*, 108 N.W.2d 434, 441 (Minn. 1961) (“The general terms of a statute are subject to implied exceptions founded on rules of public policy and the maxims of natural justice so as to avoid absurd and unjust consequences.”) The legislature made the policy choice to prefer the rights of privacy in genetic information over the general public interest in health. MDH chose to ignore the legislature’s choice. The conduct of MDH should be enjoined.

B. Plaintiffs are entitled to relief.

To ensure protection of genetic privacy, the GPA may be enforced through a number of civil remedies, including an action for damages and an injunction to prevent a state agency from engaging in a practice that violates the Government Data Practices Act, including the GPA. *See* Minn. Stat. § 13.08.⁸ But the court of appeals concluded that

⁸ The GPA applies to genetic information collected on or after August 1, 2006. 2006 Session Laws, Ch. 253 § 4. The government is liable to any person who is damaged by a violation of the GPA. Minn. Stat. § 13.08, subd. 1. “A responsible authority or government entity which violates or proposes to violate this chapter may be enjoined by the district court. Minn. Stat. § 13.08, subd. 2. Furthermore, “any aggrieved person... may bring an action in district court to compel compliance with [the GPA]...” Minn.

Plaintiffs were not entitled to relief for two reasons: (1) the GPA did not apply to 16 of the 25 plaintiff children because it was enacted after their birth and only applied to genetic information collected after enactment; and (2) there was no evidence that the screening results of the 25 children were used in public health studies or research. *Bearder*, 788 N.W.2d at 151. Those conclusions are without merit. At a minimum, Plaintiffs stated claims for injunctive relief.

Plaintiffs are all proper parties to an action for an injunction and to compel compliance with the GPA. Nine plaintiff children were born after the GPA's effective date. (AA, p. 180.) Blood specimens were collected from each of these children. (AA, p. 180.) Initial newborn screening has been completed for all of these children. (AA, p. 180.) Clearly, these nine have standing to assert claims under the GPA.

Blood specimens were also collected from each of the 16 children born before the GPA's effective date. (AA, p. 180.) The initial screening for these 16 has long ago been completed. (AA, p. 180.) MDH continues to store blood specimens and test results for these children.⁹ (See AA, p. 180.) Although the original collection of these blood samples was not subject to the GPA, the NBS did not authorize MDH to use them for any purpose except newborn screening. Thus, these Plaintiffs have standing to seek an injunction preventing MDH from using their blood samples and test results for any

Stat. § 13.08, subdiv. 3. There is no immunity from an action seeking to remedy violations of the GPA. Minn. Stat. § 13.08, subd. 1.

⁹The record indicates that MDH received a destruction request for one child to destroy both the child's blood specimen and test results and another simply to destroy the child's test results. For the other 26 children from the original 28 children, MDH has not destroyed the specimens or test results. (See AA, p. 180.)

purpose not authorized by the NBS. Moreover, any additional testing of the blood samples from these 16 children, after August 1, 2006, would create new genetic information that would be subject to the GPA. Thus, these 16 children also have standing to seek to enjoin any such testing under the GPA. Even if the 16 children's samples were collected before August 1, 2006, they also have standing to enjoin unlawful dissemination after August 1, 2006.

Pursuant to section 13.08, Plaintiffs sought an "injunction against Defendants enjoining Defendants from continuing to collect, store, use, and disseminate genetic information without informed written consent." (AA, p. 9.) Plaintiffs also sought an order "compelling defendants to comply with [the GPA]."¹⁰ (AA, p. 9.) Standing for such relief merely requires that there be uncertainties concerning the rights, status, or legal relations between the parties requiring clarification. As this Court explained:

Clearly, in order to constitute a justiciable controversy, there need not be such an actual right of action in one party against the other as would justify a granting of consequential relief but only a right on the part of the complainant to be relieved of an uncertainty and insecurity arising out of an actual controversy with respect to his rights, status, and other legal relations with an adversary party. Jurisdiction exists to declare the rights, status, and other legal relations of the parties if the complainant is possessed of a judicially protectable right or status which is placed in jeopardy by the ripe or ripening seeds of an actual controversy with an adversary party, and such jurisdiction exists although the Status quo between the parties has not yet been destroyed or impaired and even though no relief is or can be claimed or afforded beyond that of merely declaring the complainant's rights so as to relieve him from a present uncertainty and insecurity.

¹⁰Plaintiffs' Amended Complaint also seeks damages pursuant to section 13.08. (AA, p. 9.) Resolving the damages claim requires further discovery, including how Respondents have used the stored blood samples and test results and why Respondents cannot account for what happened to two of the plaintiff children's blood samples. In district court, Plaintiffs asked for additional time to complete discovery. Both the district court and court of appeals refused to address this plea for additional discovery.

Minneapolis Federation of Men Teachers, Local 238, A.F.L., v. Board of Education of City of Minneapolis, 56 N.W.2d 203, 205-206 (Minn. 1952).

MDH's only reason for storing any of the plaintiff children's genetic information, along with another 1,500,000 test results and 800,000 blood samples, is to provide the opportunity to use them for additional testing or study beyond newborn screening. The uncertainty of whether MDH will perform additional testing or disseminate samples for private research exists for each of the 25 children. MDH admits to performing non-newborn screening related tests on over 50,000 blood samples (AA, pp. 143-144) and, for some inexplicable reason, could not deny that these tests were performed on two of the plaintiff children (AA, p. 181).¹¹

Even if Respondents have not yet used the genetic information of the plaintiff children, their ongoing program of dissemination and research creates a clear and certain threat that they will do so in the future. Threat of future abuse confers standing. *See Holiday Acres No. 3 v. Midwest Federal Savings and Loan Association of Minneapolis*, 271 N.W.2d 445, 448 (Minn. 1978) *rehearing denied* Nov. 27, 1978 ("ripening seeds of an actual controversy" support claims for declaratory relief); Minn. Stat. § 13.08, subd. 2 (injunctive relief appropriate against government entity "which violates or *proposes* to violate" the GPA).

¹¹ Again, Plaintiffs have not been permitted to conduct discovery to determine whether the MDH has conducted public health testing on these two blood samples (to see whether they are part of the 50,000 samples that had been subjected to additional testing) or seek an explanation for why MDH cannot account for what happens to samples in its possession.

The plaintiff parents, in their individual capacities, also have a privacy interest in preventing further testing or dissemination because each child's genetic code contains information concerning their parents' genetic makeup. *See* Minn. Stat. § 13.386, subd. 1 (genetic information means information derived from a specimen of a person to whom the individual is related; genetic information also means medical or biological information that is or might be used to provide medical care to that individual's family members).

Respondents cannot legitimately argue that the opt-out system that they have employed, which allows parents to request destruction of the samples or test results, provides an adequate remedy at law. The GPA establishes an opt-in system and does not permit the Respondents to shift the burden to the parents to opt-out. Plaintiffs are entitled to a judicial declaration that the law does not require them to take affirmative action to ensure the blood spots and test results are destroyed or not disseminated to private entities without consent. *See Minneapolis Federation of Teachers v. Minneapolis Public Schools*, 512 N.W.2d 107 (Minn. Ct. App. 1994) (persons with information held by the government had standing to seek injunctive relief concerning their privacy rights).

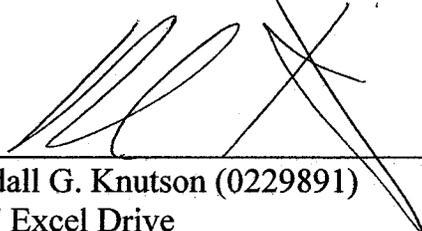
Finally, all Plaintiffs have a sufficiently direct interest in the application of the GPA to the Respondents actions under the NBS to be proper parties to seek a declaratory judgment under Minn. Stat. § 13.08, subdiv. 4, compelling respondents to comply with Minn. Stat. § 13.386.

CONCLUSION

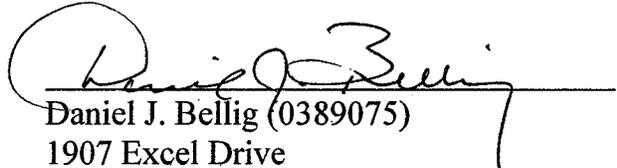
Plaintiffs respectfully request that the court of appeals' decision be *reversed* and this case be remanded to the district court for trial and a permanent injunction.

Dated: December 14, 2010

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CASE NO. A10-101

**State of Minnesota
In Supreme Court**

Alan and Keri Bearder, individually and as parents and
natural guardians of Josiah and Alexa Bearder, minors; et al.,

Appellants,

vs.

State of Minnesota, Minnesota Department of Health, and Dr.
Sanne Magnan, Commissioner of the Minnesota Department
of Health,

Respondents.

CERTIFICATION OF BRIEF LENGTH

I hereby certify that this brief conforms to the requirements of Minn. R. Civ. App.
P. 132.01, Subds. 1 and 3, for a brief produced with a proportional font. The length of
this brief is 9,031 words. This brief was prepared using Microsoft Office Word 2003.

Dated: 12-14-2010


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