STATE OF MINNESOTA

COUNTY OF HENNEPIN

DISTRICT COURT

FOURTH JUDICIAL DISTRICT

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

Matthew and Stacy Brzica, individually and as parents and natural guardians of Madeline, Kate, Margaret and Matthew Jr. Brzica, minors;

Jerry Jr. and Rhonda Gaetano, individually and as parents and natural guardians of Abigail, Hannah, Naomi, Jerry III and Joshua Gaetano, minors;

Ryan and Gabrielle Hagelstrom, individually and as parents and natural guardians of Leif Hagelstrom, a minor;

Wade K. III and Julie Halvorson, individually and as parents and natural guardians of Reid, Benjamin, Gabriel, and Wade K. Halvorson IV, minors;

Adam and Andrea Kish-Bailey, individually and as parents and natural guardians of Anna, Meghan, and Clinton Kish-Bailey, minors;

Jennifer Nelson, individually and as the mother and natural guardian of Jenna Nelson, Hailey Nelson, and Caeden Sobania, minors;

David and Shay Rohde, individually and as parents and natural guardians of Madeline Rohde, a minor;

Brook and Amy VanderLeest, individually and as parents and natural guardians of Maya and Alex VanderLeest, minors,

Plaintiffs,

vs.

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

Defendants.

ORDER GRANTING MOTION TO DISMISS

Court File No. 27-CV-09-5615

The above-entitled matter came on before the Honorable Marilyn Brown Rosenbaum on October 9, 2009, for hearing on the Motion of Defendants to Dismiss or, in the alternative, for Summary Judgment.

Randall G. Knutson, Esq. and Daniel J. Bellig, Esq. appeared on behalf of Plaintiffs.

Jocelyn F. Olson, Assistant Attorney General, appeared on behalf of Defendants.

Based on the files, records, and proceedings herein, and being fully informed in the premises, the Court makes the following:

ORDER

1. The Motion of Defendants to Dismiss or, in the alternative, for Summary Judgment is granted.

2. Plaintiffs' Amended Complaint is dismissed with prejudice.

3. The attached Memorandum is incorporated herein.

LET JUDGMENT BE ENTERED ACCORDINGLY

Dated: November 24, 2009

Marilyn B Rosenbaum

The Honorable Marilyn Brown Rosenbaum
Judge of District Court

MEMORANDUM

STATEMENT OF UNDISPUTED FACTS

The facts do not appear to be in dispute. This is a matter of the application of two Minnesota statutes: (1) the Minnesota Department of Health ("MDH") Newborn Screening Program ("NBS Program"), Minn. Stat. §§ 144.125-.128 and Minn. R. ch. 4615; and (2) the Genetic Privacy Act ("GPA"), Minn. Stat. § 13.386.

Plaintiffs are nine families consisting of seventeen parents ("Parents") and twenty-five children ("Children"). The Children were born between July 1998 and December 2008, and, pursuant to the NBS Program, blood samples were drawn and tested for over fifty rare heritable and congenital disorders, which, if left untreated, can lead to illness, physical disability, developmental delay and/or death.

Defendants are responsible for carrying out certain duties under the NBS Program, including testing the blood samples and providing information to parents regarding the NBS Program, its benefits, and their right to opt out and/or request the destruction of blood samples and test results.

The NBS Program ensures that within five days of birth, a sample of dried blood is collected from each newborn on a filter-paper specimen card provided by MDH. Minn. R. 4615.0500. The blood samples are sent to the MDH laboratory for testing within twenty-four hours of collection. *Id.* Test results may also be sent to the Mayo Clinic, a contractor for the MDH, for testing. Test results must be provided to each newborn's physician and referrals must be made for the necessary treatment of any diagnosed heritable or congenital disorder. Minn. Stat. § 144.128(1), (2). During the testing, anywhere from twenty-five to one-hundred percent of the blood sample may be used, and any remaining blood sample material and the test results are indefinitely stored by MDH unless the parents request destruction of either. Minn. Stat. § 144.125, subd. 3.

Parents of newborns are informed about the screening pursuant to Minn. Stat. § 144.125, subd. 3, which states, in pertinent part:

> Persons with a duty to perform testing . . . 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) to 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. If the parents of an infant object in writing to testing for heritable and congenital disorders 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 or legal guardian and made part of the infant's medical record. A written objection exempts an infant from the requirements of this section . . . .

The NBS Program does not include a requirement for written parental informed consent.

MDH has also created a pamphlet for parents about the screening entitled "One simple test can make a difference for your child." The pamphlet informs parents:

> Minnesota law requires hospitals, doctors, and midwives to collect a few drops of blood from every baby and send them on a card to the Minnesota Department of Health. The card also has information that identifies the baby. Your baby's blood will be tested unless you refuse in writing. Any bit of blood left after testing will be kept on the card by the Department of Health unless you request in writing that it be destroyed.
>
> ....
>
> If you refuse to have your baby's blood tested or you object to storage of your baby's card and screening results, you must sign a form. . . . . Only authorized Health Department staff can see information about your baby. Any bit of leftover blood (without baby's personal information) may be used for public health studies and research to improve screening and protect babies.

Pursuant to Minn. Stat. § 144.128(5) and (6), MDH must comply with any request to destroy the blood sample or test results within forty-five days and notify the requestors of the destruction. However, federal law and regulations require that the MDH laboratory retain a copy of test reports for at least two years after reporting. *See* Clinical Laboratories Improvement Amendments of 1988; 42 C.F.R. § 493.1105(a)(6).

The blood samples retained by the NBS Program are securely stored and the test results are handled as "private data on individuals" under Minn. Stat. § 13.3805. The blood samples and test results are not public, but accessible to the subject of the data. Minn. Stat. § 13.02, subd. 12. Occasionally, the blood samples are used for public health studies. Prior, written parental consent is obtained if the blood samples are used with personally identifiable information. Pursuant to 45 C.F.R. § 46.102, no informed consent is required if the blood samples are de-identified.

In 2005, the Minnesota legislature directed the Commissioner of Administration to review the laws, rules, and policies governing the state's handling of genetic

information. Act of May 31, 2005, ch. 163, § 87, 2005 Minn. Laws 1877. On January 13, 2006, the Commissioner of Administration issued a report recommending the legislature create a definition for genetic information and "give direction on how genetic information should be collected, stored, used and disseminated, and address those situations not already covered in existing law."

In 2006, the Minnesota legislature adopted the Genetic Privacy Act ("GPA"), which states, in pertinent part:

> **13.386. Treatment of genetic information held by government entities and other persons**
>
> **Subdivision 1. Definition.** (a) "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.
>
> (b) "Genetic information" also 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.
>
> ....
>
> **Subd. 3. Collection, storage, use, and dissemination of genetic information.** Unless otherwise expressly provided by law, genetic information about an individual:
>
> (1) may be collected by a government entity, as defined in section 13.02, subdivision 7a, or any other person only with the written informed consent of the individual;
>
> (2) may be used only for purposes to which the individual has given written informed consent;
>
> (3) may be stored only for a period of time to which the individual has given written informed consent; and
>
> (4) may be disseminated only:
>
> (i) with the individual's written informed consent; or
>
> (ii) if necessary in order to accomplish purposes described by clause (2). A consent to disseminate genetic information under item (i) must be signed and dated. Unless otherwise provided by law, such a consent is valid for one year or for a lesser period specified in the consent.

The GPA became effective as of August 1, 2006, and applied to genetic information collected on or after that date. During floor discussion of the GPA, Representative

Holberg, the author of the GPA, indicated that the GPA does not preclude collection of data otherwise allowed by current law.

In 2005, MDH began the process of proposed amendments and additions to the NBS Program rules. After publishing the rules in the State Register, and after formal hearing on January 23, 2007, the proposed rules were reviewed by Administrative Law Judge Barbara L. Neilson ("ALJ"). The ALJ concluded that "the newborn screening statute expressly authorizes the collection of genetic information . . . without written informed consent," but found MDH's

> contention that the "opt-out" nature of the initial testing also expressly authorizes indefinite retention and dissemination of the genetic information for other purposes to lack support in the newborn screening statute. The only direct reference in the newborn screening statute to the ability of the Department to retain the information is contained in Minn. Stat. § 144.125, subd. 3(1), which simply indicates that parents shall be advised that the samples as well as the results of such testing "may be retained by the Department." This can hardly be said to constitute express authority for the Department to retain the information indefinitely.

The ALJ recommended adopting the proposed rules with the correction of certain defects. On March 27, 2007, the Chief Administrative Law Judge ("Chief ALJ") reviewed and confirmed the ALJ's report. On June 27, 2007, the Commissioner of Health requested the Chief ALJ to reconsider the ALJ's findings. On July 3, 2007, the Chief ALJ denied the request. Pursuant to Minn. Stat. § 14.26, MDH cannot adopt rules which the Chief ALJ finds defective unless and until the defects have been corrected. The Commissioner of MDH declined to adopt the proposed rules. It is apparent that, as a result of the failure to adopt the proposed rules, Plaintiffs have turned to the Court to do what the Plaintiffs believe the Legislature and MDH have failed to do.

Pursuant to the NBS Program, all twenty-eight Children initially included in the First Amended Complaint were screened within the first week of life. At the time of collection, there was one request for the blood sample to be destroyed and one request for the blood sample and the test results to be destroyed. There were no requests for destruction of either blood samples or test results for the other twenty-six Children. On September 21, 2009, one of the families, consisting of two parents and three children, withdrew from this proceeding. It is not clear whether the two children whose parents made the destruction requests remain in the case.

All of the Children remaining in this lawsuit were born between July 5, 1998 and December 23, 2008. Of those twenty-five Children, sixteen were born before the GPA was enacted on August 1, 2006.

Plaintiffs filed their Complaint on March 11, 2009, claiming that Defendants State of Minnesota and MDH violated Minn. Stat. § 13.386 by collecting, storing, using, and disseminating Plaintiffs' children's blood and genetic information without written informed consent.

On June 30, 2009, Plaintiffs, including an additional family with five children, filed their Amended Complaint, adding Dr. Sanne Magnan, Commissioner of MDH ("Commissioner Magnan"), as a Defendant. In addition to the violation of Minn. Stat. § 13.386, Plaintiffs added these claims: Intrusion Upon Seclusion; Battery; Negligence; Negligent Infliction of Emotional Distress; Intentional Infliction of Emotional Distress; Conversion; Trespass to Personalty; Fraud & Misrepresentation; State Fundamental Right Claims—Intrusion upon Plaintiffs' Right to Privacy and Bodily Integrity; Federal Fundamental Right Claims—Invasion of Plaintiffs' Right to Privacy in Violation of the First, Fourth, Fifth, Ninth and Fourteenth Amendments to the United States Constitution, as incorporated through the Fourteenth Amendment; and Government Taking Claims under the Minnesota and United States Constitutions. It appears from the Joint Statement of the Case, filed on November 6, 2009, that Plaintiffs have withdrawn their claims of Battery and Intentional Infliction of Emotional Distress.

Defendants seek dismissal of Plaintiffs' Amended Complaint in its entirety. Defendants argue that the GPA does not apply to the NBS Program, and that, even if it does apply, the GPA does not apply to the sixteen Children born before August 1, 2006. Defendants further claim that MDH has not disseminated any of Plaintiffs' genetic information. Defendants also argue that (1) Plaintiffs' state common law claims are barred by statutory and official immunity or, if not barred, fail to state a basis for relief; (2) Plaintiffs' federal law claims are barred by sovereign and/or qualified immunity; and (3) Plaintiffs' claims for damages based on the Minnesota Constitution fail to state a claim upon which relief may be granted.

STANDARD OF REVIEW

Rule 12, Minnesota Rules of Civil Procedure

Minnesota Rule of Civil Procedure 12.02(e) provides for the dismissal of claims when a Complaint fails to state a claim upon which relief can be granted. On a motion to dismiss for failure to state a claim, the Court considers "whether the complaint sets forth a legally sufficient claim for relief." *Geldert v. Am. Nat'l Bank*, 506 N.W.2d 22, 25 (Minn. App. 1993). Where a Complaint fails to state a claim upon which relief can be granted, dismissal with prejudice and on the merits is appropriate. *Martens v. Minnesota Mining & Mfg. Co.*, 616 N.W.2d 732, 735 (Minn. 2000). The pleadings are construed in a light most favorable to Plaintiff, and the allegations in the Complaint must be taken as true. *Marquette Nat'l Bank of Minneapolis v. Norris*, 270 N.W.2d 290, 292 (Minn. 1978).

Where matters outside the pleadings are presented, the motion generally should be treated as one for summary judgment. Minn. R. Civ. P. 12.02. However, in addressing such motions, courts may consider "documents referenced in a *complaint* without converting the motion to dismiss to one for summary judgment." *N. States Power Co. v. Minnesota Metro. Council*, 684 N.W.2d 485, 490 (Minn. 2004) (emphasis in original).

Summary Judgment

Summary judgment shall be granted when there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law. Minn. R. Civ. P. 56. *See Hinrichs v. Farmers Co-op. Grain & Seed Ass'n*, 333 N.W.2d 639 (Minn. 1983); *see also Lindgren v. Sparks*, 58 N.W.2d 317 (Minn. 1953). A material fact that will preclude issuance of a summary judgment is one that "will affect the result or outcome of the case depending on its resolution." *Zappa v. Fahey*, 245 N.W.2d 258, 259-60 (Minn. 1976).

Summary judgment is the proper remedy where the facts in a case are not in dispute and where the decision is made on questions of law only. *Bennett v. Storz Broadcasting Co.*, 134 N.W.2d 892 (Minn. 1965); *Greaton v. Enich*, 185 N.W.2d 876 (Minn. 1971). "Although summary judgment is intended to secure a just, speedy, and inexpensive disposition, it is not designed to afford a substitute for a trial where there are

issues to be determined." *Ahlm v. Rooney*, 143 N.W.2d 65, 68 (Minn. 1966) (citing *Sauter v. Sauter*, 70 N.W.2d 351 (Minn. 1955) and *Bustad v. Bustad*, 116 N.W.2d 552, 556 (Minn. 1962)). "[T]he purpose of the rule is not to cut litigants off from their right of trial by jury if they really have issues to try." *Abdallah, Inc. v. Martin*, 65 N.W.2d 641, 646 (Minn. 1954) (citing *Sartor v. Arkansas Gas Corp.*, 321 U.S. 620, 627 (1944)). "A motion for summary judgment should be denied if reasonable persons might draw different conclusions from the evidence presented." *Illinois Farmers Ins. Co. v. Tapemark Co.*, 273 N.W.2d 630, 633 (Minn. 1978) (citing *Anderson v. Twin City Rapid Transit Co.*, 84 N.W.2d 593, 595 (Minn. 1957)).

A party moving for summary judgment has the burden of showing that there are no genuine issues as to any material facts; "the nonmoving party has the benefit of that view of the evidence which is most favorable to him." *Sauter*, 70 N.W.2d at 353. Where affidavits are submitted in support of a motion for summary judgment, the nonmoving party cannot simply rely on general statements in a complaint; the "adverse party must present specific facts showing a genuine issue for trial unless, of course, the facts asserted by the moving party fail to adequately negate any issue of fact raised by the pleading." *Ahlm*, 143 N.W.2d at 68 (cited and emphasized in *First Fiduciary Corp. v. Blanco*, 276 N.W.2d 30, 32-3 (Minn. 1979)). In addition, "all inferences from circumstantial evidence and all doubts must be resolved against the movant, without undertaking to determine credibility." *Forsblad v. Jepson*, 195 N.W.2d 429, 430 (Minn. 1972). "[I]f any doubt exists as to the existence of a genuine issue as to a material fact, the doubt must be resolved in favor of finding that the fact issue exists." *Rathbun v. W.T. Grant Co.*, 219 N.W.2d 641, 646 (Minn. 1974). Even if the record "leads one to suspect that it is unlikely [that a party] will prevail upon trial, that fact is not a sufficient basis for refusing [that party] his day in court with respect to issues which are not shown to be sham, frivolous or so unsubstantial that it would obviously be futile to try them." *Dempsey v. Jaroscak*, 188 N.W.2d 779, 783 (Minn. 1971) (quoting *Whisler v. Findeisen*, 160 N.W.2d 153, 155 (Minn. 1968)).

DECISION

Defendants have followed the mandates of the NBS Program. In attempting to conform record retention and use of the blood samples and test results, Plaintiffs contend Defendants violated the GPA by failing to obtain written informed consent for any use of blood samples and test results beyond newborn screening.

Plaintiffs' contention that Defendants have violated Minn. Stat. § 13.386 are not persuasive. Plaintiffs admit that the initial taking of samples under the NBS Program is lawful, but argue that the retention, use, and/or dissemination of the blood samples after collection and/or the reporting of positive results to physicians for follow-up care are unlawful.

The GPA became effective as of August 1, 2006, and "applies to genetic information collected on or after that date." 2006 Minn. Laws ch. 253, § 4. Since sixteen of the Children were born before August 1, 2006, and were tested at birth pursuant to the NBS Program, the GPA does not apply to them.

In the alternative, and concerning the nine Children born after the enactment of the GPA, Plaintiffs' claims still fail. The blood samples taken pursuant to the NBS Program are biological samples, not genetic information as defined in the GPA. Even if these blood samples are considered genetic information under the GPA, the GPA expressly states that it applies to the collection, storage, use, and dissemination of genetic information "unless otherwise expressly provided by law." Minn. Stat. § 13.386, subd. 3. The GPA does not supersede specific existing law such as the NBS Program, Minn. Stat. § 144.125-.128.

Plaintiffs rely heavily on the ALJ's report and the confirmation of the report by the Chief ALJ. The ALJ proceedings are not relevant to this proceeding and are not binding on the Court.

Despite voluminous filings and a myriad of counts, the Court is unable to uncover any viable claim. The remedy sought is not one the Court can impose. Plaintiffs' concerns regarding retention and use of the blood samples and test results are fully addressed by the remedies in the NBS Program statute and Plaintiffs can avail themselves of these remedies at any time. Plaintiffs should press their concerns to the legislature if they deem these remedies unsatisfactory.

In the absence of a cognizable claim, the Court acknowledges its inability to cite to, or refer to, any applicable case law. Plaintiffs simply have failed to state a claim upon which relief can be granted and the numerous appended claims must be dismissed.

Plaintiffs' State Common Law claims, the Federal claims, the Constitutional challenges, and the "Fundamental Right Claims" are rendered moot.

The Motion of Defendants to Dismiss or, in the alternative, for Summary Judgment should be granted and Plaintiffs' Amended Complaint should be dismissed in its entirety.

MBR