

No. A10-101

STATE OF MINNESOTA

IN COURT OF APPEALS

Alan and Keri Bearder, *et al.*,

Appellants,

vs.

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

Respondents.

RESPONDENTS' BRIEF AND APPENDIX

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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

- I. Did Respondents violate the Genetic Information Statute, Minn. Stat. § 13.386, by carrying out their responsibilities under the statutes and rules governing the Newborn Screening Program of the Minnesota Department of Health (“MDH”)?

This issue was raised in Appellants’ complaint and amended complaint and in the parties’ competing memoranda on Respondents’ motion to dismiss or, in the alternative, for summary judgment.¹ The district court held that Minn. Stat. § 13.386 did not govern MDH’s storage, use and dissemination of the minor Plaintiffs’ dried blood specimens and newborn screening tests results. The issue was preserved for appeal by the judgment entered on November 25, 2009. See attachment to Notice of Appeal.

Minn. Stat. § 13.386 (2008)
Minn. Stat. §§ 144.125-.128 (2008)

- II. Does sovereign immunity bar Appellants’ claims based upon 42 U.S.C. § 1983 and the federal constitution to the extent they are asserted against the State, MDH, and the Commissioner of Health (“Commissioner”) in her official capacity?

Section 1983 claims were raised in Appellants’ amended complaint. The defense of sovereign immunity was raised in the parties’ competing memoranda on Respondents’ motion to dismiss or, in the alternative, for summary judgment. The district court did not rule on the sovereign immunity issue. The district court held that Appellants’ Section 1983 claims were moot. The immunity issue was preserved for appeal by the judgment entered on November 25, 2009.

*Will v. Michigan, 491 U.S. 58 (1989)
Alabama v. Pugh, 438 U.S. 781 (1978)
Kentucky v. Graham, 473 U.S. 159 (1985)
Rico v. State, 458 N.W.2d 738 (Minn. Ct. App. 1990)*

¹ See complaint, Respondents’ Appendix (“RA-”) at RA-1; amended complaint, Appellants’ Appendix (“AA-“) AA-1; Defendants’ memorandum in support of its dispositive motion on Plaintiffs’ statutory claim based on Minn. Stat. § 13.386 (6/26/09); Defendants’ supplemental memorandum in support of its dispositive motion to dismiss the amended complaint (8/18/09); Plaintiffs’ memorandum in opposition to Defendants’ motion (9/30/09); Defendants’ reply memorandum (10/6/09).

- III. Does qualified immunity bar Appellants' damages claims against the Commissioner based upon 42 U.S.C. § 1983 and the federal constitutional right to privacy?

This issue was raised and preserved for appeal in the same manner as the second issue. The district court did not rule on the qualified immunity issue. The district court held that Appellants' Section 1983 claims were moot.

Pearson v. Callahan, ___ U.S. ___, 129 S. Ct. 808 (2009)
State v. Bartylla, 755 N.W.2d 8 (Minn. 2008), *cert. denied*, ___ U.S. ___, 129 S. Ct. 1624 (2009)

- IV. Does qualified immunity bar Appellants' damages claims against the Commissioner based upon 42 U.S.C. § 1983 and the Takings Clause of the Fifth Amendment to the United States Constitution?

This issue was raised and preserved for appeal in the same manner as the second issue. The district court did not rule on the qualified immunity issue. The district court held that Appellants' federal takings claim was moot.

Pearson v. Callahan, ___ U.S. ___, 129 S. Ct. 808 (2009)
Board of Regents v. Roth, 408 U.S. 564 (1972)
Minn. Stat. §§ 144.125-.128 (2008)

- V. Did the district court properly dismiss Appellants' damages claim based on a right to privacy under the Minnesota Constitution?

This issue was raised and preserved for appeal in the same manner as the second issue. The district court did not rule on the sovereign immunity issue. The district court held that Appellants' claim based on the Minnesota Constitution was moot.

Nieting v. Blondell, 235 N.W.2d 597 (1975)
Bird v. Dep't of Public Safety, 375 N.W.2d 36 (Minn. Ct. App. 1985)
Mitchell v. Steffen, 487 N.W.2d 896 (Minn. Ct. App. 1992), *aff'd*, 504 N.W.2d 198 (Minn. 1993)

- VI. Did the district court properly dismiss Appellants' claim for compensation under the Takings Clause of the Minnesota Constitution?

This issue was raised and preserved for appeal in the same manner as the second issue. The district court held that Appellants' state takings claim was moot.

Lukkason v. 1993 Chevrolet Extended Cab Pickup, 590 N.W.2d 803 (Minn. Ct. App. 1999)
Minn. Stat. §§ 144.125-.128 (2008)

- VII. Are Appellants' state common law claims (i.e., intrusion upon seclusion, negligence, negligent infliction of emotional distress, conversion and trespass to personal property, and fraud and misrepresentation) barred by statutory immunity, official immunity and/or vicarious official immunity?

This issue was raised and preserved for appeal in the same manner as the second issue. The district court did not rule on the statutory and/or official immunity issue. The district court held that Appellants' state common law claims were moot.

Watson by Hanson v. Metro. Transit Comm'n, 553 N.W.2d 406 (Minn. 1996)
Pletan v. Gaines, 494 N.W.2d 38 (Minn. 1992)

- VIII. Even if Appellants' state common law claims are not barred by statutory and/or official immunity, did the district court properly dismiss them?

This issue was raised and preserved for appeal in the same manner as the second issue. The district court held that Appellants' state common law claims were moot.

Lake v. Wal-Mart Stores, Inc., 582 N.W.2d 231 (Minn. 1998)
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STATEMENT OF THE CASE

In March 2009, nine families² sued the State of Minnesota and the Minnesota Department of Health (“MDH”), alleging violations of Minn. Stat. § 13.386 as the result of MDH’s implementation of the Newborn Screening Program (“NBS Program”). In June 2009, Appellants amended their complaint to add the Commissioner of Health (“Commissioner”) as a defendant and to assert additional claims for damages: eight common tort law claims, two federal constitutional claims, and two state constitutional claims. Appellants subsequently withdrew claims for battery and intentional infliction of emotional distress. Defendants moved to dismiss or, in the alternative, for summary judgment. On November 24, 2009, the district court granted the State’s motion. Judgment was entered on November 25, 2009.

STATEMENT OF FACTS

A. The Newborn Screening Program.

MDH’s NBS Program³ is governed by Minn. Stat. §§ 144.125-.128 (2008) and Minn. R. ch. 4615 (2009). The program was initiated in 1965 and screened all infants born in Minnesota for phenylketonuria (“PKU”), a recessive genetic disorder that causes problems with brain development if not detected and treated early. *See McCann Aff.*, AA-210. Today, the NBS Program screens for more than 50 rare heritable and congenital

² Since March 2009, one family (the Gaetano family) was added by amendment to the original complaint (*see* AA-1), and another family (the VanDemark family) was voluntarily dismissed out of the case (*see* RA-5).

³ Appellants characterize MDH as maintaining a “DNA warehouse” for storage of infant blood specimens and newborn screening test results. This is unsupported by the record, which does not address the storage location blood of specimens and test results.

disorders that, if left untreated, can lead to illness, physical disability, developmental delay or death. *See id.*; AA-218 (list of disorders).

Generally speaking, “responsible parties”⁴ must collect or arrange for collection of a “specimen” from each newborn within five days of birth. *See* Minn. Stat. § 144.125, subd. 1 and Minn. R. 4615.0500. A few drops of blood from the infant’s heel are put on a filter-paper “specimen card.” *See* AA-219; Minn. R. 4615.0400, subp. 8. Parental consent is not required; however, parents may “opt out” of the NBS program, in whole or in part. *See* Minn. Stat. § 144.125, subd. 3. “Responsible parties” must advise parents:

(1) that the *blood or tissue samples* used to perform testing as well as the results of the 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 the blood samples and records of test results be destroyed within 24 months of the testing.

Id. (emphasis added). A parental objection to testing or an election to require destruction of blood samples or test results must be in writing and signed by a parent or legal guardian and is part of the infant’s medical record. *See id.*

MDH’s brochure, “One simple test can make a difference for your child,” provides basic information about the NBS Program, including the fact that parents may opt out of newborn screening, and that stored leftover blood may be used for public health studies.

See McCann Aff., Ex. 2, AA-217 to AA-226.

⁴ “Responsible parties” include the person in charge of a hospital where the child is born and the physician in attendance at birth, or if not so attended, one of the parents. *See* Minn. R. 4615.0400, subp. 5.

Parents and adults tested as minors may at any time “direct that blood samples and test results be destroyed.” *See* Minn. Stat. § 144.128(4). MDH must “comply with a destruction request within 45 days after receiving it.” Minn. Stat. § 144.128(5). However, federal law⁵ does not allow MDH to destroy *test results* until after a two-year period has passed. *See* McCann Aff., AA-211. Blood samples are *not* subject to the federal retention requirement and may be destroyed promptly.

Specimen cards are sent to MDH within 24 hours after collection. *See* Minn. R. 4615.0500 (D). Specimens are analyzed at MDH’s laboratory and by MDH’s contractor⁶ Mayo Medical Laboratories (“Mayo”).⁷ *See* McCann Aff., AA-211. All but one of the tests are for substances in the blood. *See id.* Test results are reported to the newborns’ physicians. *See* Minn. Stat. § 144.128(1).

The NBS Program does not screen infant blood samples for the presence or absence of a specific DNA or RNA marker unless the “first level” test shows that immunoreactive trypsinogen is present in the blood. *See* McCann Aff., AA-212. If this occurs, MDH performs a “second level” genetic test on the sample to see if the newborn has two copies of the genes that can lead to cystic fibrosis. *See id.*

⁵ Federal law requires MDH’s laboratory to retain or be able to retrieve a copy of test reports for at least two years after the date of reporting. *See* 42 C.F.R. § 493.1105(a)(6).

⁶ Minn. Stat. § 144.0742 (2008) authorizes the Commissioner to contract with any public or private entity to perform statutorily required public health services on behalf of MDH.

⁷ Generally speaking, Mayo performs certain tests using its special expertise in the use of tandem mass spectrometry and performs “second level” tests as discussed below. *See* McCann Aff., AA-211. When Mayo receives “private data” pursuant to its contract with MDH, it must maintain the data in accordance with the statutes applicable to MDH. *See* Minn. Stat. § 13.05, subd. 6 (2008).

Unless a destruction directive has been received, MDH indefinitely stores test results and any blood spot material that is not used up in the test. *See* McCann Aff., AA-212. The data stored by MDH are classified by Minn. Stat. § 13.3805 (2008) as “private data on individuals” and handled by MDH in accordance with the statute. “Private data on individuals” is: (1) not public and (2) accessible to the subject of the data. *See* Minn. Stat. § 13.02, subd. 12 (2008). The Commissioner must maintain an inventory of records (e.g., newborn screening test results) in her custody and establish the time period for retention and disposal of such records. *See* Minn. Stat. § 138.17, subd. 7 (2008).

The Commissioner is authorized to “conduct studies and investigations, collect and analyze health and vital data, and identify and describe health problems” for the purpose of “protecting, maintaining, and improving the health of citizens.” Minn. Stat. § 144.05, subd. 1(a) (2008). Infant blood samples are sometimes utilized in public health studies (e.g., for development of new newborn screening tests), using either “de-identified” blood samples without obtaining additional consent; or using identified blood samples after obtaining prior consent in writing from the parents. *See* McCann Aff., AA-212. A “de-identified” blood sample is a sample that is not accompanied by information that identifies the infant. *See id.*

In the past, MDH has collaborated with independent research organizations to conduct public health studies. *See id.* These projects must be reviewed and approved by

MDH's Institutional Review Board ("IRB").⁸ *See id.* In addition, independent research organizations must receive approval from their own IRBs in order to conduct research on human subjects. *See id.*; *see generally*, 45 C.F.R. Part 46, Protection of Human Subjects. Under 45 C.F.R. § 46.102, informed consent from the subject is not required if the blood sample is not "individually identifiable."

B. Legislative Developments, 2005-2007

In 2005, the Legislature directed the Commissioner of Administration to review existing laws, rules, and policies to determine whether the state handles genetic information on individuals appropriately and to report to the Legislature. Act of June 3, 2005, ch. 163, § 87, 2005 Minn. Laws 1877.

In January 2006, the Commissioner of Administration issued "A Report on Genetic Information and How it is Currently Treated Under Minnesota Law" ("2006 Report"). *See* Orren Aff., Ex. 1, AA-185. The 2006 Report recommended the creation of a work group. *See* AA-201. The 2006 Report also recommended that the Legislature enact a definition for "genetic information"; give direction on how genetic information should be collected, stored, used and disseminated; and "*address those situations not already covered in existing law.*" *See* AA-201 (emphasis added). The report stated: "The initial legislation should also provide other general guidance that would serve in those situations where there is not specific statutory authority." *See id.*

⁸ At page 6 of their brief, Appellants erroneously suggest that MDH's contract with Mayo gives Mayo unlimited discretion to use infant blood specimens to perform its own research. Mayo must obtain written authorization from MDH, Mayo's IRB, and MDH's IRB and, if identifiable specimens or data are to be used, Mayo must obtain the written consent of the subject's parent or legal guardian. *See* AA-140.

Although the report itself did not *recommend* a specific definition of “genetic information,” it used a “working definition” for the purposes of the study. *See* AA-190.

Senate File 3132 was enacted by the Legislature and signed by the Governor. *See* Act of June 1, 2006, ch. 253, 2006 Minn. Laws 424-37 (“Chapter 253”). Sections 4, 9 and 22 of Chapter 253 are pertinent to this lawsuit.

1. Section 4, Minn. Stat. § 13.386.

Section 4 of Chapter 253, is codified as Minn. Stat. § 13.386 (“Section 13.386”). *See* 2006 Minn. Laws 426. Section 13.386 was “effective August 1, 2006, and applies to genetic information collected on or after that date.” *Id.* Its definition of “genetic information” is substantively identical to the “working definition” set forth in the 2006 Report (AA-190). Subdivision 2 classifies “genetic information” held by a government entity as “private data on individuals.” Subdivision 3 restricts the collection, storage and use of genetic information, “unless otherwise expressly provided by law.”

During the discussion of Senate File 3132 on the House Floor, a question was posed to the author, Representative Holberg, concerning Section 13.386, as follows:

Representative Lieblich Thank you. Representative Holberg, I just have to ask you, the section that’s in here on genetic information is that going to impact the Mayo Clinic’s ability to do medical research, collect samples, and use it years later to cure diseases that we didn’t even know that, that we had? I just wonder if you have been through the process with them and had hearings that in which you learned a little bit about how that might impact medical research in the state? . . . I am talking about Section 4 of the DE2 amendment . . .

Representative Holberg Mr. Speaker and Representative Lieblich, this governs the collection of data by government entities and does not preclude that collection if it’s otherwise allowed by current

law. This was a recommendation of the genetic information study group. . . .

See Hughes Aff., Ex. 4 at 6, AA-261.

2. Section 9, Amendments to the Newborn Screening Statute.

Section 9 of Chapter 253 amends an NBS Program statute to add three new requirements: preparation of a form for use by parents or by adults who were tested as minors to direct that blood samples and test results be destroyed; compliance with a destruction request within 45 days of receipt; and notification to the individuals who request destruction of samples and test results that the samples and test results have been destroyed. *See* 2006 Minn. Laws 429 and Minn. Stat. § 144.128(4) - (6).

3. Section 22, Creation of a Work Group.

Section 22 of Chapter 253 required the creation of a work group “to develop principles for public policy on the use of genetic information.” 2006 Minn. Laws 436. The law required the work group to report to the Legislature⁹ concerning “options for resolving questions of secondary uses of genetic information” and “retention schedules for genetic information held by government entities.” *Id.*, subs. 1-2.

C. Rulemaking Proceedings To Amend The Newborn Screening Rules.

In December 2005, MDH began the process to amend the newborn screening rules. *See Orren Aff.*, AA-183. The proposed rules were published in the State Register. *See* 42 *State Register* 663 (Nov. 20, 2006). In January 2007, a rulemaking hearing was

⁹ In January 2009, a report entitled “Genetic Information in Minnesota” was issued. *See Orren Aff.*, AA-183 and Ex. 2, AA-206. The report contains recommendations for future legislative consideration and a statement that “There is a need for additional guidance from the Legislature regarding Minnesota Statutes, section 13.386.” *Id.* However, the 2009 Legislature did not amend Section 13.386. *See Orren Aff.*, AA-183.

held before an administrative law judge (“ALJ”). *See* Orren Aff., AA-184. The ALJ, *sua sponte*, raised the issue of whether Section 13.386 applies to the NBS Program. *See* March 23, 2007, ALJ Report, dated, Finding 64, AA-37. The ALJ concluded that existing law expressly authorizes MDH and responsible parties to initially collect “genetic information” without written informed consent but does not expressly authorize storing or disseminating it without the written informed consent required by Section 13.386. *See id.*, Finding 65. As a result, the ALJ found a defect in the rules and suggested ways to correct the defect. *See id.*, Finding 67, AA-38. The ALJ recommended adopting the proposed rules, “except where noted otherwise.” *See* AA-52.

On March 27, 2007, the Chief ALJ affirmed the ALJ’s Report in all respects. Orren Aff., AA-184. The Commissioner requested the Chief ALJ to reconsider the ALJ’s defect findings. *See id.* On July 3, 2007, the Chief ALJ denied the request. *See id.* MDH chose not to adopt the proposed rules. *See* Orren Aff., AA-184.

D. THE NEWBORN SCREENING PROGRAM AS APPLIED TO APPELLANTS.

Appellants are nine families: 17 parents (the “parent Plaintiffs”) and 25 children (the “minor Plaintiffs”). *See* Notice of Appeal. The minor Plaintiffs were born between July 1998 and December 2008. *See* Zerby Aff., AA-180. Blood specimens from all 25 minor Plaintiffs were collected within the first week of life and received and tested by the NBS Program. *See id.* At the time of the collection of specimens, MDH received two parental destruction directives: one to destroy the specimen and test results of one newborn; and the other to destroy only the test results of another newborn. *See id.* MDH

did not at the time of collection of their blood specimens receive directives to destroy the specimens and/or test results of the other 23 minor Plaintiffs. *See id.*

No “second level” test for cystic fibrosis (i.e., a test for the presence or absence of a specific DNA or RNA marker) was performed on any of the minor Plaintiffs’ blood specimens. *See Zerby Aff.*, AA-180 No blood specimen from 23 of the minor Plaintiffs was used in public health studies or research. *See id.*, AA-181. With respect to the remaining two children, MDH has no records indicating that their specimens were used in public health studies or research. *See id.*

STANDARD OF REVIEW

The district court granted the State’s motion to dismiss or, in the alternative, for summary judgment. *See AA-268.* Because the district court considered matters outside the pleadings, this Court’s review is under a summary judgment standard. *Peoples State Bank Truman v. Triplett*, 633 N.W.2d 533, 537 (Minn. Ct. App. 2001). Consideration of affidavits attached to the motion to dismiss and not referenced in or a part of the pleading constitutes going “outside” the pleading. *See N. States Power Co. v. Minnesota Metro. Council*, 684 N.W.2d 485, 491 (Minn. 2004). Judge Rosenbaum clearly considered the affidavits submitted by the parties. *See, e.g.*, district court Memorandum, AA-270, quoting from the MDH brochure (*see AA-217*) attached to the McCann Affidavit.

Summary judgment is proper when there is no genuine issue of material fact and “either party is entitled to a judgment as a matter of law.” Minn. R. Civ. P. 56.03; *see DLH, Inc. v. Russ*, 566 N.W.2d 60, 69 (Minn. 1997). The applicable standard of

review of a grant of summary judgment is de novo. See *Minnesota Voyageur Houseboats, Inc. v. Las Vegas Marine Supply, Inc.*, 708 N.W.2d 521, 524 (Minn. 2006).

ARGUMENT

I. THE STATE, THROUGH ITS NBS PROGRAM, DID NOT VIOLATE SECTION 13.386.

A. Section 13.386 Does Not Apply To The NBS Program.

The State's implementation of the NBS Program with respect to Appellants did not violate Section 13.386. Section 13.386 does not apply to the NBS Program.

1. Section 13.386 does not define "genetic information" to include biological specimens.

As defined by Section 13.386, "genetic information" does not include biological specimens. "Genetic information" means:

(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.

Minn. Stat. § 13.386, subd. 1 (emphasis added). Under this definition, a biological specimen is not *itself* genetic information; rather, genetic information is information "obtained from the analysis of" a biological specimen. Therefore, a blood specimen does not meet the statutory definition of "genetic information." Thus, the limitations on

collection, storage, use and dissemination of genetic information set forth in subdivision 3 of Section 13.386 do not apply to blood specimens.

Appellants urge the Court to interpret the definition of “genetic information” in a manner that ignores the phrase “information . . . which has been *obtained from* . . . an *analysis of* . . . the individual’s biological information or specimen” (emphasis added). However, “[a] statute should be interpreted, whenever possible, to give effect to all of its provisions; ‘no word, phrase, or sentence should be deemed superfluous, void, or insignificant.’” *Am. Family Ins. Group v. Schroedl*, 616 N.W.2d 273, 277 (Minn. 2000) (citations omitted). The fact that blood specimens *contain* DNA information does not bring the specimens themselves within the statutory definition. If the Legislature intended to include biological specimens in the definition, it could have done so.

Appellants further argue that this Court should interpret “genetic information” to *include* biological specimens in order to give effect to the intention of the Legislature. This argument flies in the face of Minn. Stat. § 645.16: “When the words of a law in their application to an existing situation are clear and free from all ambiguity, the letter of the law shall not be disregarded under the pretext of pursuing the spirit.” The statutory language is not ambiguous; it clearly excludes biological specimens from the definition of “genetic information.”

Finally, Appellants argue that the legislative history supports an interpretation of the definition of “genetic information” to include biological specimens. Under Minn. Stat. § 645.16(7) (2008), this Court may consider “contemporaneous” legislative history in ascertaining legislative intent *only if* the word of the law are not explicit. The

definition of genetic information is explicit with respect to biological specimens. Moreover, the brief discussion of Section 13.386 on the House Floor (*see* AA-261) did not address the “biological specimen” issue. The legislative history does not support Appellants’ argument that that the plain language of the law should be disregarded.

2. Section 13.386 does not apply to programs already covered by existing law.

a. The express language of Section 13.386 leaves existing law in full force.

Subdivision 3 of Section 13.386 requires that *unless otherwise expressly provided by law*,¹⁰ “genetic information” about an individual may only be collected with the written informed consent of the individual, and the use, storage and dissemination of the information is subject to any restrictions contained in the consent. The express language of Section 13.386 indicates that its limitations related to “genetic information” do not apply to an existing program if there is already a law in place that governs the handling of “genetic information” in the possession of that program.

If the language of a statute is unclear, the statute should be interpreted as consistently as possible with the purpose of the act. *See Stansell v. City of Northfield*, 618 N.W.2d 814, 819-20 (Minn. Ct. App. 2000). In this case, the meaning of the language of the statute is clear: Section 13.386 does not displace or override existing laws governing genetic information.

¹⁰ Appellants argue that Section 13.386 generally applies to the NBS Program, but due to the “express language” of sections 144.125-.128, Section 13.386 “allows newborn screening to proceed with the ‘opt-out’ system.” Appellants’ Brief (“App. Br.”) at 23. However, Section 13.386 does not apply to the NBS Program, either in part or in whole.

To the extent newborn screening test results constitute “genetic information,” the handling of that data is already governed by Minn. Stat. §§ 144.125-128 and Section 13.3805. After receiving blood specimen cards, MDH analyzes the blood specimens and results are reported to the newborns’ physicians. *See* Minn. Stat. § 144.128(1). Parents who do not opt out of newborn screening have the right to direct that their child’s test results be destroyed. *See* Minn. Stat. §§ 144.125, subd. 3(3)(ii); 144.128(5). If test results are not destroyed pursuant to a parental destruction request, their handling is governed by Minn. Stat. § 13.3805, Public Health Data. “Public health data” means “data on individuals created, collected, received, or maintained by the Department of Health . . . relating to the identification, description, prevention, and control of a disease.” *Id.*, subd. 1(2). Public health data is classified as “private data on individuals,” i.e., not public but accessible to the subject of the data. *See* Minn. Stat. § 13.02, subd. 12 (2008). Private data may also be disclosed pursuant to Minn. Stat. § 13.05, subd. 4(d) (2008) if the subjects of the data have given written informed consent. Thus, newborn screening test results are clearly covered by existing law.

b. The legislative history of the Section 13.386 shows that it was not intended to displace or override existing law.

The legislative history of Chapter 253 shows that Section 13.386’s limitations on collection, storage, use and dissemination of genetic information were meant to cover situations not covered by existing laws, and that the Legislature did not intend for Section 13.386 to change the existing newborn screening laws. The genesis of the statute was the 2006 Report, which recommended that the Legislature give direction on the

handling of genetic information and also “*address those situations not already covered in existing law.*” Orren Aff., Ex. 1, AA-201 (emphasis added). The 2006 Report further recommended that the initial legislation provide guidance to serve “in those situations where there is not specific statutory authority.” These recommendations are reflected by the inclusion of “unless expressly provided by law” language. Indeed, on the House Floor, Representative Holberg, stated that Section 13.386 “governs the collection of data by government entities and does not preclude the collection if it’s otherwise allowed by current law.” Clearly, the Legislature did not intend for the enactment of Section 13.386 to serve as an amendment to the existing laws relating to newborn screening.

The legislative history specifically shows that the Legislature did not intend for Section 13.386 to displace or override existing newborn screening laws. Section 9 of Chapter 253 amended Minn. Stat. § 144.128 to add three new requirements: prepare a separate form for use by parents or adults who were tested as minors to direct that blood samples and test results be destroyed; comply with a destruction request within 45 days after receiving it; and notify individuals who request destruction and test results that the samples and test results have been destroyed. *See* 2006 Minn. Laws 429. The Legislature did not alter the “opt out” statutory scheme embodied in Minn. Stat. § 144.125 or impose additional consent requirements to the NBS Program. Because the Legislature clearly did not intend to disturb existing laws relating to the NBS Programs, Section 13.386 does not apply to newborn screening test results.

3. The rulemaking report of an ALJ has no binding legal effect outside the context of the rulemaking proceeding.

For their argument that the State violated Section 13.386, Appellants rely upon the March 2007 ALJ Report, *see* AA-17, ruling on the legality of proposed amendments to the newborn screening rules, Minn. R. ch. 4615. The district court properly found the ALJ proceedings to be “not relevant” and “not binding on the court.” AA-276.

Outside the context of the rulemaking proceeding, which terminated when MDH decided not to adopt the proposed rules, the ALJ Report is not binding on MDH. The Office of Administrative Hearings (“OAH”) is a state agency. *See* Minn. Stat. § 14.48 (2008). OAH conducts rulemaking hearings for other state agencies. The adoption of rules is a legislative-type function. *See Eagle Lake of Becker County Lake Ass’n v. Becker County Bd. of Comm’rs*, 738 N.W.2d 788, 793-94 (Minn. Ct. App. 2007). After the ALJ and Chief ALJ agreed that the rules had a defect, MDH had a choice: either to correct the “defect” or withdraw the rules. *See* Minn. Stat. § 14.16, subd. 2 (2008). When MDH withdrew the proposed rules, the rulemaking proceeding was complete. There is no legal authority indicating that OAH’s interpretation of a statute in a rulemaking proceeding has a continuing binding effect on the state agency.

Indisputably, the ALJ’s decision is not binding on the courts. Minn. Const. art. VI vests the judicial power of the state in the courts. ALJ jurisdiction is “inferior to the district court’s jurisdiction.” *Holmberg v. Holmberg*, 588 N.W.2d 720, 726 (Minn. 1999). This Court is fully empowered to interpret Section 13.386.

Even if the ALJ's adverse ruling on the proposed rules were to be considered, it is not persuasive. The ALJ did not take into account the legislative history indicating the legislative intent that Section 13.386 cover situations involving the handling of genetic *data* not already addressed by existing law. In addition, the ALJ erroneously interpreted the term "genetic information" to include biological specimens. See ALJ Report, Findings 63-67, AA-36 to AA-39. For this reason, her analysis is flawed.

B. The State Could Not Have Violated Section 13.386 With Respect To The 16 Minor Plaintiffs Whose Blood Specimens Were Collected And Tested Prior To The Statute's Effective Date.

Section 4 of Chapter 253 provides the following effective date for Section 13.386:

EFFECTIVE DATE. This section is effective August 1, 2006, and applies to genetic information *collected on or after that date.*

(Emphasis added.) Even if Section 13.386 applied to the NBS Program in general, it did not apply to genetic information that was collected and tested prior to the August 1, 2006 effective date of Section 13.386. The minor Plaintiffs' blood specimens were collected within the first week of life. Zerby Aff., AA-180. A review of the birth dates of 16 minor Plaintiffs (*see id.*, initials R.H., B.H., A.G., H.G., M.K., M.B., N.G., K.B., G.H., M.V., J.G., W.H., J.N., C.K., J.B., and L.H.) shows that 16 of them were born before August 1, 2006.¹¹ Because Section 13.386 does not apply to these children, the State could not have violated the statute as to them.

¹¹ Appellants assert at page 26 of their brief that these children "still have viable claims for actual, constructive and proposed violation of the GPA." There is no authority whatsoever to support the proposition that Minn. Stat. § 13.08 provides a remedy for "constructive" and "proposed" violations of Section 13.386.

Appellants argue that notwithstanding the effective date of Section 13.386, the State must obtain written informed consent in order to store, use or disseminate blood specimens and test results obtained after August 1, 2006. Appellants' interpretation is erroneous. First, a blood specimen falls outside the definition of "genetic information" and is not governed by Section 13.386. Second, application of the law to genetic information collected *prior to* August 1, 2006, would give the statute retroactive effect. "No law shall be construed to be retroactive unless clearly and manifestly so intended by the legislature." Minn. Stat. § 645.21 (2008). A statute is afforded retroactive application only if there is clear evidence that the Legislature intended the law to be retroactive, e.g., mention of the word "retroactive." See *In re Estate of Edlund*, 444 N.W.2d 861, 862 (Minn. Ct. App. 1989). The "effective date" language used by the Legislature for Section 13.386 is unambiguous and contains no indication of intent to apply the law retroactively.

C. Even If Section 13.386 Applies To The NBS Program, MDH Did Not "Disseminate" The Minor Plaintiffs' Genetic Information.

Appellants alleged that the State violated Section 13.386 by "disseminating" their blood specimens to outside organizations for research. Even if the Court should find that Section 13.386 applies to the NBS Program, this claim lacks merit.

As discussed *supra*, blood specimens are not "genetic information." Appellants' claims based on "dissemination" of blood specimens fail. But even if blood specimens are "genetic information," the State was entitled to summary judgment. The evidence in the record indicates that no blood specimen from any of 23 of the minor Plaintiffs was

used in public health studies or research. *See* Zerby Aff., AA-181. MDH has no records indicating that the specimens of the remaining two minor Plaintiffs were used in public health studies or research. *See id.* Appellants presented no evidence to the contrary.¹²

II. APPELLANTS' FEDERAL LAW CLAIMS AGAINST THE STATE, MDH, AND THE COMMISSIONER IN HER OFFICIAL CAPACITY ARE BARRED BY SOVEREIGN IMMUNITY.

Appellants asserted two claims for damages under the United States Constitution: (1) a claim of invasion of their right to privacy and (2) a claim of a "taking" of private property for public use without just compensation. Appellants allege that they entitled to damages under 42 U.S.C. § 1983 ("Section 1983"). Sovereign immunity bars these claims as to the State of Minnesota, MDH, and the Commissioner in her official capacity.

The Eleventh Amendment to the United States Constitution bars suits by private parties seeking to impose a liability that must be paid from public funds in the state treasury. *See Edelman v. Jordan*, 415 U.S. 651, 663 (1974). Although sovereign immunity may be waived, waiver will be found "only where stated by the most express language or by such overwhelming implications from the text as [will] leave no room for any other reasonable construction." *Id.* at 673 (citation and internal punctuation omitted). Minnesota has not waived Eleventh Amendment immunity for alleged violations of the

¹² Appellants failed to provide the trial court with any information indicating that their own blood samples or test results were used in *any* public health study. Nevertheless, they argue that there are genuine issues of fact in dispute as to whether blood samples and test results of infants were completely de-identified by researchers. *See* App. Br. at 24-25. A material fact is one that will affect the outcome of the case. *See Zappa v. Fahey*, 245 N.W.2d 258, 259-60 (Minn. 1976). Appellants have not shown a material issue of fact. A resisting summary judgment "may not simply rest on its pleadings but must produce affirmative evidence to show an issue of material fact." *Brookfield Trade Ctr. v. County of Ramsey*, 609 N.W.2d 868, 874 (Minn. 2000).

federal constitution or for violations based on civil rights statutes. *See Hahn v. Bauer*, ___ F. Supp.2d ___, No. 09-2220, 2010 WL 396228 *14 (D. Minn. Jan. 27, 2010).

Section 1983 applies only to “persons.” Neither a state¹³ nor a state agency¹⁴ is a “person” subject to suit under Section 1983, and thus the Eleventh Amendment bars a Section 1983 action against these entities. Appellants’ federal claims against the State of Minnesota and MDH are barred.

Sovereign immunity also bars a Section 1983 claim for damages against the Commissioner in her official capacity.¹⁵ *See Kentucky v. Graham*, 473 U.S. 159, 169 (1985). *See also Rico v. State*, 458 N.W.2d 738, 740-41 (Minn. Ct. App. 1990) (Section 1983 actions against state officials in their official capacities are barred).

III. APPELLANTS’ SECTION 1983 DAMAGES CLAIMS AGAINST THE COMMISSIONER IN HER INDIVIDUAL CAPACITY ARE BARRED BY QUALIFIED IMMUNITY.

Under the doctrine of qualified immunity, the Commissioner is immune from claims for damages with respect to Appellants’ federal constitutional claims. The purpose of qualified immunity for state employees acting within the scope of their official duties is to make sure that they are on notice that their conduct is unlawful before being subjected to suit. *See Pearson v. Callahan*, ___ U.S. ___, 129 S. Ct. 808, 822 (2009).

¹³ *See Will v. Michigan Dep’t of State Police*, 491 U.S. 58, 65 (1989); *Stone v. Badgerow*, 511 N.W.2d 747, 751 n.3 (Minn. Ct. App. 1994).

¹⁴ *See Alabama v. Pugh*, 438 U.S. 781, 782 (1978); *Bird v. Dep’t of Public Safety*, 375 N.W.2d 36, 43 (Minn. Ct. App. 1985).

¹⁵ State officials in their *individual* capacities are “persons” within the meaning of Section 1983. *See Hafer v. Melo*, 502 U.S. 21, 30 (1991). In addition, a state official sued in his or her official capacity does not have Eleventh Amendment immunity where the relief sought is prospective and not compensatory. *See Heartland Academy Cmty. Church v. Waddle*, 427 F.3d 525, 530 (8th Cir. 2005).

Qualified immunity protects government officials “from liability for civil damages insofar as their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have known.” *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982)); *see also Williams v. Bd. of Regents of the Univ. of Minnesota*, 763 N.W.2d 646, 654 (Minn. Ct. App. 2009). Qualified immunity analysis turns on the “objective legal reasonableness” of the official’s action. *Wilson v. Layne*, 526 U.S. 603, 614 (1999). For a constitutional right to be clearly established, the right must be sufficiently clear that, in light of pre-existing law, a reasonable official would understand that what his or her conduct violates that right.¹⁶ *Anderson v. Creighton*, 483 U.S. 635, 640 (1987). The doctrine “is broad enough to protect all but the plainly incompetent or those who knowingly violate the law.” *Dokman v. County of Hennepin*, 637 N.W.2d 286, 292 (Minn. Ct. App. 2001) (citations and internal punctuation omitted).

The Commissioner’s conduct did not violate clearly established rights under the United States Constitution when she administered MDH’s NBS Program with respect to Appellants.

A. The Commissioner’s Conduct Did Not Violate A Clearly Established Constitutional Right To Privacy.

Appellants allege that the NBS Program violated their right under the Fourth Amendment to the United States Constitution to be free from unreasonable searches by

¹⁶ Recently, the United States Supreme Court held that judges may exercise their sound discretion in deciding which of the two prongs of the qualified immunity analysis (*i.e.*, a determination of whether the facts show violation of a constitutional right; and whether the right was clearly established) should be addressed first in light of the particular case at hand. *See Pearson*, ___ U.S. ___, 129 S. Ct. at 816, 818.

retaining the minor Plaintiffs' blood specimens and test results after NBS testing was complete.¹⁷ The "overriding function of the Fourth Amendment is to protect personal privacy and dignity against *unwarranted* intrusion," i.e., intrusions which are "not justified in the circumstances, or which are made in an improper manner. *Schmerber v. State of California*, 384 U.S. 757, 767-68 (1966) (emphasis added). The Fourth Amendment only proscribes searches and seizures which are unreasonable. *Skinner v. Ry. Labor Executives' Ass'n*, 489 U.S. 602, 619 (1989).

Under Fourth Amendment analysis, a compelled intrusion into the body for blood constitutes a search, and the ensuing chemical analysis is a further search. *See State v. Jackson*, 741 N.W.2d 146, 152 (Minn. Ct. App. 2007) (citing *Skinner*, 489 U.S. at 616), *rev. denied* (Minn. Oct. 21, 2008). However, the retention of the minor Plaintiffs' blood samples and test results did not constitute a Fourth Amendment "search." In *Jackson*, the defendant was identified due to a match between DNA obtained from a biological sample at the crime scene and his DNA profile in the state's DNA database. He argued that it was unconstitutional for the government to retain his DNA profile and "re-search" it through the DNA database. *See* 741 N.W.2d at 149. The court rejected this argument, stating: "Here, 'the search' was complete when the appellant's blood sample was obtained . . . and DNA testing was performed on it." *Id.* at 152. *See also Johnson v.*

¹⁷ Appellants also make a claim, utterly unsupported by the record, that their retained blood samples were re-tested for DNA as part of research, and they argue that this conduct constituted additional "searches." The record is devoid of any evidence of use of the minor Plaintiffs' blood specimens or test results in public health studies or research.

Quander, 440 F.3d 489, 499-500 (D.C. Cir. 2006) (state's retention of blood sample used to obtain DNA profile was not a "search" for Fourth Amendment purposes).

The Commissioner did not draw blood samples from the minor Plaintiffs' bodies and, under Minn. Stat. § 144.125, blood samples are not compelled; parents may choose not to have their infant tested. The Commissioner's role was to test the newborn blood samples she received. Under these circumstances, the Commissioner did not conduct a "search," and Fourth Amendment analysis does not apply.

Even if the Commissioner can be said to have conducted a search, however, that is not the end of the inquiry. The Minnesota Supreme Court has ruled that a "totality-of-the-circumstances" test is applicable when reviewing the reasonableness of a warrantless, suspicionless search under *both* the Fourth Amendment *and* its Minnesota counter part, Minn. Const. art. I, § 10. *See State v. Bartylla*, 755 N.W.2d 8, 17-19 (Minn. 2008)¹⁸ (upholding a statute requiring offenders to provide a biological specimen for DNA analysis), *cert. denied*, ___ U.S. ___, 129 S. Ct. 1624 (2009). *See also Mell v. Comm'r of Pub. Safety*, 757 N.W.2d 702, 709-12 (Minn. Ct. App. 2008) (applying totality-of-the-circumstances test; upholding administration of breath tests during jail booking for non-alcohol-related offenses). Under this test, the court determines whether a search is reasonable "by assessing, on the one hand, the degree to which it intrudes upon an

¹⁸ The court in *Bartylla* followed *Samson*, 547 U.S. at 848-56 (2006) (applying totality-of-the-circumstances test to suspicionless searches of convicts on parole). The court also extensively surveyed case law concerning challenges to various state DNA profiling laws and found that the courts had either applied the "totality-of-the-circumstances" test or a "special needs" test. The court's survey of cases indicates the DNA profiling statutes have been invariably upheld under either test. *See Bartylla*, 755 N.W.2d at 16-18.

individual's privacy and, on the other, the degree to which it is needed for the promotion of legitimate governmental interests." *Samson v. California*, 547 U.S. 843, 848 (2006) (citation omitted).

The "individuals" whose privacy is at issue in this case are the minor Plaintiffs and not the parent Plaintiffs, because "Fourth Amendment rights are personal and cannot be asserted vicariously." *State v. McBride*, 666 N.W.2d 351, 360 (Minn. 2003) (citing *Rakas v. Illinois*, 439 U.S. 128, 133-34 (1978)).¹⁹ The intrusion into the minor Plaintiffs' bodies occurred soon after their births and consisted of the collection of "a few drops of blood from [the] baby's heel." See *McCann Aff.*, Ex. 2, AA-219. The United States Supreme Court has recognized in *Schmerber* that blood tests constitute minor imposition on an individual's privacy and bodily integrity. The Court noted that the "experience with [blood sampling] teaches that the quantity of blood extracted is minimal, and that for most people the procedure involves virtually no risk, trauma, or pain." 384 U.S. at 771. The infants' blood samples were sent to MDH for testing and were thereafter securely stored by MDH; the results were handled by MDH as "private data" pursuant to Minn. Stat. § 13.3805. Any intrusion upon the minor Plaintiffs' privacy was de minimis.

Balanced against this minor intrusion into minor Plaintiffs' privacy is the State's legitimate interest in maintaining the health of newborns. As explained in MDH's newborn screening brochure:

¹⁹ See also *Ferguson v. City of Charleston*, 308 F.3d 380, 395-96 (4th Cir. 2002) (general rule is that expectation of privacy does not arise from one's relationship to the person searched; mother had no reasonable expectation of privacy in her newborn child's urine).

About every day a baby is born in Minnesota with a hidden, rare disorder that can be found by newborn screening. These babies seem healthy at birth, but they need treatment right away. Finding these babies early and treating them before they show signs of sickness can prevent serious permanent problems or even death.

McCann Aff., Ex. 2, AA-220. It is beyond dispute that the State has a legitimate interest in maintaining the health of its children. In *Minnesota State Bd. of Health v. City of Brainerd*, 241 N.W.2d 624 (Minn. 1976), the Minnesota Supreme Court stated:

[T]he state has a direct interest in maintaining public health. The health of one's children is not exclusively a personal or individual concern. . . . The health of the children of a community is of vital interest and great importance to all the inhabitants of the community.

241 N.W.2d at 632 (footnote and citation omitted). Collecting and testing blood samples for rare heritable and congenital disorders unquestionably promotes the State's interest in the health of children. Moreover, the means chosen to accomplish this task are reasonable and are fully protective of the privacy interests of both children and parents. Participation in newborn screening is optional, in whole or in part. *See* Minn. Stat. § 144.125, subd. 3. After testing, parents who do not want MDH to have possession of their children's blood samples or test results are entitled to direct that they be destroyed. *See id.*; Minn. Stat. § 144.128. Under the totality-of-the-circumstances test, such a "search" of the minor Plaintiffs was reasonable.

The Commissioner did violate Appellants' clearly established Fourth Amendment rights. No caselaw exists that would have informed the Commissioner that the NBS Program violates Appellants' Fourth Amendment rights. In fact, Nebraska's more restrictive newborn screening program survived a Fourth Amendment challenge.

See Spiering v. Heineman, 448 F. Supp.2d 1129 (D. Neb. 2006). In Nebraska, newborn screening is not optional, and if the parents object, the requirement may be enforced by court order. *See id.* at 1133, 1142. The court held that “no Fourth Amendment violation has been made out and none is threatened.” *Id.* at 1142. In contrast to Nebraska parents, Minnesota parents have the right to refuse to have their children tested.

Knowledge of the cases relied upon by Appellants would not inform the Commissioner that, in the absence of a parental destruction request, she could not lawfully retain newborn blood samples and test results. *In re Welfare of C.T.L.*, 722 N.W.2d 484 (Minn. Ct. App. 2006) involved allegations that a juvenile aided and abetted serious crimes. The court struck down a statute directing law enforcement to take biological specimens from juveniles who have had a probable-cause determination, but not a conviction, of criminal offenses. Unlike the juveniles in *C.T.L.*, parents of newborns may refuse the newborn screening test. In *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260 (9th Cir. 1998), an employer required prospective employees to undergo a medical examination. Biological samples were tested for syphilis, sickle cell trait, and/or pregnancy. The court stated that under the Fourth Amendment: “[W]e must balance the government’s interest in conducting these particular tests against the plaintiffs’ expectation of privacy.” *Id.* at 1269. The court reversed the grant of summary judgment to defendants because there were material issues of fact. *Id.* at 1270. Contrary to Appellants’ assertion (App. Br. at 41), the court did not hold that “unauthorized testing and analysis of blood samples [is] unconstitutional.”

B. The Commissioner's Conduct Did Not Constitute A Taking In Violation Of The Fifth Amendment To The United States Constitution.

Appellants alleged that the State's actions violated the Takings Clause of the Fifth Amendment to the United States Constitution. The Commissioner is entitled to qualified immunity with respect to this claim²⁰ because her conduct did not violate a clearly established right of Appellants for compensation for the minor Plaintiffs' blood specimens. Whether a taking has occurred under the Fifth Amendment is a question of law. *See Cary v. United States*, 552 F.3d 1373, 1376 (Fed. Cir.), *cert. denied*, __ U.S. __, 129 S. Ct. 2878 (Jun. 29, 2009). Appellants' taking claim fails because: (1) Appellants have no protected property interest in the blood specimens stored by MDH²¹ and (2) the State cannot be required to compensate an owner for property lawfully acquired under the exercise of authority other than the power of eminent domain.

1. Appellants have no protected property interest.

The constitutional prohibition against takings applies to the government's taking of "private property" for public use without compensation. *See* U.S. Const. amend. 5. Interests in property are protected, not created, by these constitutional provisions. *See Phillips v. Washington Legal Found.*, 524 U.S. 156, 164 (1998). Appellants have no protected property interest in the blood specimens stored by MDH.

²⁰ *See Dokman*, 637 N.W.2d at 295 (in Section 1983 action, federal takings claim was disposed of by the application of official and qualified immunity); *Get Away Club, Inc. v. Coleman*, 969 F.2d 664, 668 (8th Cir. 1992) (state troopers entitled to qualified immunity on federal takings claims).

²¹ The State did not "take" the newborn screening test results from Appellants, physically or otherwise, because the test results are data created by MDH or its contractor, Mayo.

Although it is obvious that certain things constitute “property” (e.g., land is real property, furniture is personal property), the term is not susceptible to a concrete definition.²² As the court stated in *Alevizos v. Metro. Airports Comm’n*, 216 N.W.2d 651, 661 (Minn. 1974): “[a]ny statement of what constitutes ‘property’ can only be nebulous at best.” Black’s Law Dictionary defines “property” in terms of “rights,” as follows: “The right to possess, use, and enjoy a determinate thing”; the “right of ownership”; or an “external thing over which the rights of possession, use, and enjoyment are exercised.” BLACK’S LAW DICTIONARY 1335-36 (9th ed. 2009).

Property interests “are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law.” *Board of Regents v. Roth*, 408 U.S. 564, 577 (1972). In this case, Minn. Stat. §§ 144.125-.128 define the extent to which parents have the right to control the blood specimens of their newborns. Under Minn. Stat. § 144.125, subd. 3,²³ responsible parties must inform parents of their opportunity to object to the test or, in the alternative, elect to have the test performed but have the blood specimen destroyed by MDH. The same statute provides that the blood or tissue samples used to perform the testing “may be retained” by MDH. At any time, parents and also adults who were tested as minors may direct MDH to

²² Appellants go to great lengths to establish that human tissue constitutes “property.” See App. Br. at 27-33. The State does not dispute that the minor Plaintiffs’ blood specimens are property; rather, the issue here is whether, under the applicable laws and rules, Appellants have a *protected property interest* in them.

²³ Minn. Stat. § 144.125, subd. 3, was enacted in 2003 and became effective June 6, 2003. See Act of June 5, 2003, ch. 14, art. 7, § 26, 2003 Minn. Laws 1st Sp. Sess. 2073-75, effective the day following final enactment. Prior to this effective date, the newborn screening statutes were silent as to the ultimate disposition of blood specimens and thus did not confer any property rights upon Appellants.

destroy blood samples and/or test results. *See* Minn. Stat. § 144.128(4). If parents do not direct MDH to destroy blood specimens, neither Minnesota law nor any other source of law affords a right to the parents or children to possess or control the blood specimens stored by MDH. Thus, the law does not confer upon Appellants a property interest in those blood specimens.

There is no case law in Minnesota²⁴ or other jurisdictions that provides authority for Appellants' taking claim. There is, however, contrary authority. In *Boling v. Romer*, 101 F.3d 1336 (10th Cir. 1996), inmates challenged a state law requiring them to provide DNA (blood) samples before their release on parole. The court gave their takings claim short shrift, finding the takings argument "unpersuasive." *See id.* at 1340-41. Courts have rejected takings claims with respect to the South Carolina DNA Act requiring a blood sample. *See Collins v. Hodges* No. 2:01-2343, 2007 WL 3145492 at *4 (D.S.C. Oct. 24, 2007) ("A legally seized blood sample does not constitute property to which the protections of the taking clause attach"); *see also Blackburn v. South Carolina*, ___ F. Supp.2d ___, No. 2:00-3215, 2009 WL 4640647 at *12 (D.S.C. Dec. 7, 2009) ("No authority has been presented to indicate that any of the plaintiffs enjoyed a property interest in their blood"). Other courts have dismissed as frivolous takings claims regarding DNA samples (blood) as required by Texas law. *See Scheanette v. Riggins*,

²⁴ At page 27 of their brief, Appellants urge this Court to "adopt a rule of law in which genetic information is property protected by the state and federal constitutions." As this Court recognized in *Stubbs v. N. Mem'l Med. Ctr.*, 448 N.W.2d 78, 81 (Minn. Ct. App. 1989): "It is not . . . the function of this court to establish new causes of action."

No. Civ.A.9:05CV34, 2006 WL 722212 *1-2 (E.D. Tex. 2006); *Holliman v. Texas Dep't of Criminal Justice*, No. 2:00-CV-0291, 2001 WL 167847 *1, *3 (N.D. Tex. 2001).

In the district court, Appellants conceded that “[w]hether genetic material is property under the takings clauses of the U. S. and Minnesota Constitution appears to be an issue of first impression.” Plaintiffs’ Memorandum of Law at 37. Property rights in genetic information have not been established, much less “clearly established.”

2. The government is not required to compensate an owner for property it has already lawfully acquired under the exercise of governmental authority other than eminent domain.

Under the federal Takings Clause, the government is not required to “compensate an owner for property which it has already lawfully acquired under the exercise of governmental authority other than the power of eminent domain.” *Bennis v. Michigan*, 516 U.S. 442, 452 (1996). In *Bennis*, the Court rejected a takings claim regarding a forfeited automobile on the grounds that the automobile was legally obtained by the government under state statutes. MDH lawfully acquired blood specimens from the minor Plaintiffs pursuant to Minn. Stat. § 144.125, and the State is not required to compensate Appellants.

IV. APPELLANTS’ CLAIMS FOR DAMAGES BASED ON THE MINNESOTA CONSTITUTION WERE PROPERLY DISMISSED.

A. Appellants’ Claim Based On The Right To Privacy Under the Minnesota Constitution Was Properly Dismissed.

1. Appellants’ claim is barred by sovereign immunity.

Appellants asserted a claim for damages based on a right to privacy guaranteed by the state counterpart to the Fourth Amendment, Minn. Const. art. I, § 10, and by the state

constitutional right to privacy first recognized in *State v. Gray*, 413 N.W.2d 107 (Minn. 1987). This claim is barred by sovereign immunity.

At common law, the government could not be sued under the doctrine of sovereign immunity, which “originated with the courts.” See *Nieting v. Blondell*, 235 N.W.2d 597, 600 (Minn. 1975). *Nieting* abolished Minnesota’s tort immunity “subject to any appropriate action taken by the legislature.” *Id.* at 603. The Legislature has enacted the Tort Claims Act, Minn. Stat. § 3.736, but it has not enacted a counterpart to Section 1983 to provide a cause of action for damages for violation of the Minnesota Constitution.

In addition, Minnesota courts have not recognized the existence of a cause of action for damages directly under the Minnesota Constitution. See *Mitchell v. Steffen*, 487 N.W.2d 896, 905 (Minn. Ct. App. 1992) (damages claim based on equal protection clause of the Minnesota Constitution would be barred by sovereign immunity), *aff’d on other grounds*, 504 N.W.2d 198 (Minn. 1993); *Bird*, 375 N.W.2d at 40 (Minnesota Supreme Court has not recognized a cause of action for deprivation of due process).²⁵ In February of this year, a panel of this Court rejected a damages claim brought pursuant to Minn. Const. art. I, § 10 on the grounds that no cause of action for damages for violations of the Minnesota Constitution has been recognized. See *Mlnarik v. City of Minnetrista*, No. A09-910, 2010 WL 346402 at *1 (Minn. Ct. App. Feb. 2, 2010).²⁶ Appellants’ claim for damages based directly on the Minnesota Constitution is barred.

²⁵ See also *Riehm v. Engelking*, 538 F.3d 952, 969 (8th Cir. 2008) (“Minnesota courts explicitly refuse to find causes of action for damages under the Minnesota Constitution on their own unless the Minnesota Supreme Court has recognized the cause of action.”)

²⁶ A copy of this decision is reproduced in Respondents’ Appendix at RA-9.

Appellants cite three cases²⁷ to dispute the State's claim of sovereign immunity. None of these cases supports Appellants' argument. First, in *Wegner and McGovern*, plaintiffs' claims were brought under the takings clause of Minn. Const. art. I, § 13. Takings claims may be brought directly under the Minnesota Constitution. See *Wegner*, 479 N.W.2d at 40. Second, *Thiede* does not hold that money damages claims can be brought directly under the Minnesota Constitution. In *Thiede*, the court discussed the plaintiff's constitutional rights but explicitly held that the misconduct of town officials "constituted a trespass upon plaintiff's property and an assault upon her person, for both of which the law furnishes a remedy." 14 N.W. at 231. Thiede's action was allowed to go forward because Thiede stated a cause of action in tort.

2. Even if Appellants' privacy claim is not barred by sovereign immunity, it was properly dismissed.

Even if Appellants' state constitutional right-to-privacy claim is not barred by sovereign immunity, it must be rejected. In *Bartylla*, the Minnesota Supreme Court adopted a totality-of-the-circumstances test for reviewing the constitutionality of a warrantless, suspicionless search (i.e., a requirement to provide a biological specimen for DNA analysis) under not only the Fourth Amendment but also under Minn. Const. art. I, § 10. *Bartylla*, 755 N.W.2d at 17-19. The court specifically declined to adopt a more stringent test for the state constitutional claim, stating:

[W]e conclude that the *Samson* totality-of-the-circumstances test we adopt today is neither a sharp nor radical departure from the Court's previous

²⁷ See *Thiede v. Town of Scandia Valley*, 14 N.W.2d 400 (Minn. 1944); *Wegner v. Milwaukee Mut. Ins. Co.*, 479 N.W.2d 38 (Minn. 1991); and *McGovern v. City of Minneapolis*, 480 N.W.2d 121 (Minn. Ct. App. 1992).

decisions or approach to the law. . . . [O]n the precise issue before us in this case, we are satisfied that the protections adopted by the federal courts provide adequate protection for the basic rights and liberties of Minnesota's citizens. Therefore, we decline, in this case, to interpret Article I, Section 10, of the Minnesota Constitution more broadly than the Fourth Amendment.

Id. at 18-19. The court held that because the challenged DNA collection statute did not violate the Fourth Amendment, it also did not violate Minn. Const. art. I, § 10. *Id.* at 19. The same result is compelled in this case. As discussed *supra* at 25-27, the application of the totality-of-circumstances test to this case shows that the State has not violated the Fourth Amendment; therefore, it has not violated Minn. Const. art. I, § 10.

The state constitutional right to privacy first recognized in *Gray* "begins with protecting the integrity of one's body and includes the right not to have it altered or invaded without consent." *Jarvis v. Levine*, 418 N.W.2d 139, 148 (Minn. 1988). The right is not absolute; when there is an allegation of interference by the state, the court must balance the privacy interest against the state's need to intrude on that privacy. *State v. Mellett*, 642 N.W.2d 779, 784 (Minn. Ct. App. 2002). As shown by the discussion *supra* at 27, the State's has a legitimate interest in preventing newborns from developing serious permanent problems or dying from hidden, rare disorders that can be identified by testing newborn blood samples. The NBS Program furthers this legitimate interest with only a minor intrusion into the infant's body, and manner in which the minor Plaintiffs' blood samples were received, tested, and retained (in the absence of a parental destruction directive) are reasonable and fully protective of the privacy interest of children and parents.

There is no evidence that the State has in any way mishandled, misused, or disseminated the minor Plaintiffs' blood samples, either identified or de-identified, for public health research. Therefore, the gravamen of Appellants' complaint is "fear of the use of their genetic information by government and private entities for unknown purposes." See AA-6. To establish a justiciable controversy, a party must show a "direct and imminent injury." *State v. Colsch*, 284 N.W.2d 839, 841 (Minn. 1979). Issues that "have no existence other than in the realm of future possibility . . . are not justiciable." *Id.* at 842 (citation omitted). Fear of the unknown is not a direct and imminent injury. See *Wilson v. Collins*, 517 F.3d 421, 429 (6th Cir. 2008) (contention that DNA sample could be "mined" in the future for personal and medical information did not substantiate a justiciable controversy); *Banks v. United States*, 490 F.2d 1178, 1191-92 (10th Cir. 2007) (recognizing potential for abuse of DNA information despite statutory safeguards but, in the absence of evidence of abuse, refusing to adjudicate based on speculation).

B. Appellants' State Takings Claim Fails Was Properly Dismissed.

Appellants allege that the State's actions constituted a "taking" of private property for public use without just compensation, in violation of the Minn. Const. art. I, § 13. The question of whether a governmental agency's action amounts to a taking is a question of law. *Alevizos*, 216 N.W.2d at 660.

Like their federal takings claim, Appellants' state takings claim is fatally flawed for lack of a protected property interest. Second, under the Takings Clauses of the Minnesota Constitution, the government is not required to "compensate an owner for property that it has already lawfully acquired under the exercise of governmental

authority other than the power of eminent domain.” *Lukkason v. 1993 Chevrolet Extended Cab Pickup*, 590 N.W.2d 803, 807 (Minn. Ct. App. 1999) (citing *Bennis*, 516 U.S. at 452). Because MDH lawfully acquired blood specimens from the minor Plaintiffs, the State is not required to compensate Appellants for them.

V. APPELLANTS’ STATE COMMON LAW CLAIMS WERE PROPERLY DISMISSED.

The district court properly dismissed Appellants’ common law claims for intrusion upon seclusion; negligence; negligent infliction of emotional distress; conversion; trespass to personal property; and fraud and misrepresentation.

A. All State Common Law Claims Are Barred By Statutory Immunity, Official Immunity And/Or Vicarious Official Immunity.

Appellants’ common law claims against the State are barred by statutory immunity, official immunity, and/or vicarious official immunity.

Statutory immunity refers to the Legislature’s **declaration** that “the state and its employees are not liable for . . . a loss caused by the performance or failure to perform a discretionary duty, whether or not the discretion is abused.” Minn. Stat. § 3.736, subd. 3 and 3(b) (2008). Statutory immunity attaches to planning level decisions²⁸ involving questions of public policy and the evaluation of factors such as the financial, political, economic, and social effects of a given plan or policy. *See Watson by Hanson v. Metro. Transit Comm’n*, 553 N.W.2d 406, 412-13 (Minn. 1996). Actions based on professional

²⁸ It is the State’s burden to show that it is immune under the discretionary function exception. *See Nussbaum v. County of Blue Earth*, 422 N.W.2d 713, 722 n.6 (Minn. 1988). However, the Minnesota Supreme Court has recognized that some government conduct facially involves a balancing of policy objectives. *See id.* In those cases, “it may be unnecessary for the state to produce evidence of how the decision precipitating the challenged conduct was made.” *Id.*

and scientific judgments constitute planning level decisions if the decisions involve “balancing of financial, political, economic and social considerations.” *Norton v. County of Le Sueur*, 565 N.W.2d 447, 450 (Minn. Ct. App. 1997).

Official immunity protects public officials charged by law with duties that call for the exercise of judgment or discretion on an operational rather than a policymaking level. *Pletan v. Gaines*, 494 N.W.2d 38, 40 (Minn. 1992). Application of the doctrine requires a two-step analysis. *See Bailey v. City of St. Paul*, 678 N.W.2d 697, 701 (Minn. Ct. App. 2004). The first step is to determine whether the challenged conduct was discretionary or ministerial. *See id.* Discretionary acts involve the use of professional judgment and weighing of relevant factors. *See Schroeder v. St. Louis County*, 708 N.W.2d 497, 506 (Minn. 2006). A ministerial act involves execution of a specific duty arising from fixed and designated facts. *Id.* In the second step, the court must determine whether the challenged conduct was malicious or willful and therefore not subject to the protections of official immunity. *See Bailey*, 678 N.W.2d at 701.

Vicarious official immunity protects a government entity from liability for the alleged negligent acts of its employees. *See Ireland v. Crow's Nest Yachts, Inc.*, 552 N.W.2d 269, 272 (Minn. Ct. App. 1996). Generally, if the employee has immunity, the claim against the employer has been dismissed. *See Pletan*, 494 N.W.2d at 42.

Appellants base their tort claims on MDH's decisions to retain blood specimens and to use some of them in public health studies.²⁹ These decisions are, on their face,

²⁹ As noted repeatedly in this Brief, the undisputed evidence in the record indicates that no blood specimens from 23 of the minor Plaintiffs were used in public health studies or

planning level decisions involving balancing of financial, political, economic and social considerations, and, on an operational level, discretionary decisions involving the use of professional judgment and weighing of relevant factors. Retention of blood samples is not mandatory; Minn. Stat. § 144.125, subd. 3 specifically provides that “blood samples or tissue samples used to perform testing . . . *may be retained* by the Department of Health.” (Emphasis added.) MDH resources (money and staff) are controlled by the Legislature and must be wisely allocated among dozens of programs that promote various aspects of public health. Allocating some of those resources to the NBS Program for storage of blood specimens and development of new newborn screening tests involves budget and policy decisions at the planning level. MDH’s decision to use stored blood specimens for research involves competing public health and the privacy interests of the blood specimen donors and their parents. MDH’s decisions have benefitted all Minnesotans by allowing early detection and treatment of over 50 rare heritable or congenital disorders through newborn screening, as compared to the one disorder (PKU) that could be detected in 1965. *See McCann Aff., AA-210.*

The Commissioner’s entitlement to official immunity is not defeated by any malicious or willful conduct. The Commissioner’s actions were objectively reasonable. The minor Plaintiffs’ blood specimens and test results were handled in a manner that respected all Appellants’ privacy.

research; and there is no evidence that the blood specimens of the other two minor Plaintiffs were used in public health studies or research.

B. Even If Appellants' State Common Law Claims Are Not Barred By Statutory Or Official Immunity, The State Was Entitled To Judgment.

1. Intrusion upon seclusion.

Intrusion upon seclusion occurs when one "intentionally intrudes, physically or otherwise, upon the solitude or seclusion of another or his private affairs or concerns . . . if the intrusion would be highly offensive to a reasonable person." *See Lake v. Wal-Mart Stores, Inc.*, 582 N.W.2d 231, 233 (Minn. 1998). The intentional interference with seclusion must be "substantial." *Swarthout v. Mut. Serv. Live Ins. Co.*, 632 N.W.2d 741, 745 (Minn. Ct. App. 2001). The intrusion may be physical (e.g., a person, over objection, insists upon entering another person's home) or surreptitious (e.g., eavesdropping on private affairs, looking into windows, using a recording device to listen to conversations). *See* Restatement (Second) of Torts § 652B cmt. b (1977).

The facts alleged in Appellants' amended complaint do not come close to stating a claim for intrusion on seclusion. The State did not physically intrude into Appellants' homes and subject them to unwanted blood sampling, nor did the State obtain any of Appellants' private information surreptitiously. Indeed, Appellants do not dispute that under both Section 13.386 and Minn. Stat. § 144.125, blood specimens may lawfully be collected from infants at birth unless parents "opt out" of the NBS Program. *See* App. Br. at 23. Appellants did not allege that MDH tested their blood specimens in defiance of any "opt out" parental directive. MDH's conduct with respect to the minor Plaintiffs' blood specimens was in accordance with the law and was not wrongful.

2. Negligence.

A defendant in a negligence suit is “entitled to summary judgment when the record reflects a complete lack of proof on any of the four essential elements of the negligence claim.” *See Funchess v. Cecil Newman Corp.*, 632 N.W.2d 666, 672 (Minn. 2001). Essential elements of a negligence claim include the existence of a duty of care, breach of the duty, and injury, and the breach of the duty being the proximate cause of injury. *See id.* “Existence of a duty in a negligence case is a question of law.” *Id.* Without a persuasive showing that the State owed a legal duty to Appellants, Appellants’ negligence claim must fail. *See id.*

Appellants asserted a “negligence per se” claim against the State based on their allegations that the State violated Section 13.386. *See App. Br.* at 36. They asserted that Section 13.386 created a legal duty toward Appellants that the State breached by failing to destroy the minor Plaintiffs’ blood specimens after testing was complete. However, Section 13.386 does not apply to biological specimens or to the NBS Program as a whole. The State could not have violated Section 13.386, and Appellants’ negligence per se claim fails for a lack of a duty of care and lack of a breach of a duty of care.

Appellants also failed to allege any injury of which the proximate cause was the State’s alleged negligent failure to destroy blood specimens after testing. Appellants’ negligence claim thus fails for lack of all of the essential elements of a negligence claim.

3. Negligent infliction of emotional distress.

Appellants asserted a claim for negligent infliction of emotional distress (“negligent infliction”). Appellants alleged that they “fear for the use of their genetic information by government and private entities for unknown purposes.” *See* AA-6.

In addition to the normal elements of negligence, a plaintiff asserting a negligent infliction claim must allege three special elements:

[S]he (1) was within a zone of danger of physical impact; (2) reasonably feared for her own safety; and (3) suffered severe emotional distress with attendant physical manifestations.

Stead-Bowers v. Langley, 636 N.W.2d 334, 343 (Minn. Ct. App. 2001).

Appellants did not allege any of these elements. The “zone of danger” analysis “encompass[es] plaintiffs who have been in some *actual personal physical danger* caused by defendant’s negligence.” *K.A.C. v. Benson*, 527 N.W.2d 553, 558 (Minn. 1995) (emphasis added). Appellants’ alleged fear that their genetic information will be used for unknown purposes falls far short of actual personal physical danger.

A valid claim for negligent infliction requires “physical symptoms” resulting from the anxiety of being in situation involving grave personal peril. *Wall v. Fairview Hosp. and Healthcare Servs.*, 584 N.W.2d 395, 408 (Minn. 1998). This requirement is designed to assure the genuineness of the emotional distress. *See Leao v. Washington County*, 397 N.W.2d 867, 875 (Minn. 1986). Appellants did not allege that any physical manifestations resulted from their fear.

Appellants claim that that they come within an exception to the “zone of danger” rule that allows recovery of damages for mental anguish or suffering “for a direct

invasion of his rights, such as defamation, malicious prosecution, or other willful, wanton or malicious conduct.” *Bohdan v. Alltool Mfg. Co.*, 411 N.W.2d 902, 907 (Minn. Ct. App. 1987). In the absence of a viable tort claim involving a direct invasion of Appellants’ rights, a claim for negligent infliction fails. *See Doan v. Medtronic, Inc.*, 560 N.W.2d 100, 106-07 (Minn. Ct. App. 1997). Appellants have no viable tort claim involving a direct invasion of their rights, and thus their negligent infliction claim fails.

4. Conversion and trespass to personal property.

The elements of the tort of trespass and conversion of personal property are:

One who dispossesses another of a chattel is subject to liability in trespass for the damages done. If the dispossession seriously interferes with the right of another to control the chattel, the actor may also be subject to liability for conversion.

Herrmann v. Fossum, 270 N.W.2d 18, 20 (Minn. 1978). “Conversion” is “an act of willful interference with a chattel, *done without lawful justification*, by which any person entitled thereto is deprived of the use and possession.” *Naegle Outdoor Advertising, Inc. v. Minneapolis Comty. Dev. Agency*, 551 N.W.2d 235, 238 (Minn. Ct. App. 1996) (emphasis added; citation omitted). If the actor has authority to acquire the property, a claim of conversion is defeated. *See id.* (community development agency had legal authority to acquire land upon which advertiser had maintained signs and was not liable for conversion).

Appellants alleged that the State wrongfully “exercised dominion” and “possessed” the minor Plaintiffs’ blood specimens and genetic information. *See* AA-6. This claim is defeated because MDH lawfully acquired the minor Plaintiffs’ blood

specimens and tested them for rare heritable and congenital disorders. MDH's receipt and testing of the minor Plaintiffs' blood specimens was not wrongful.

Recently, the court of appeals rejected a claim of conversion related to the taking of a urine sample. In *Doe v. Health Partners, Inc.*, No. A06-1169, 2007 WL 1412936 (Minn. Ct. App. May 15, 2007),³⁰ a hospital employee collected a urine sample from the appellant for the purpose of a rape screen, but prior to obtaining test results, the urine sample was lost. The district court held Minnesota does not recognize a property right in urine. *See id.* at *1. That court of appeals did not reach the property right issue but affirmed the dismissal of the appellant's conversion claim, stating:

[E]ven if we were to assume that appellant had a property interest in her urine sample, the conversion claim fails because appellant did not expect to retain possession of her urine following testing by respondent. *See, e.g., Moore v. Regents of the Univ. of Calif.*, 793 P.2d 479, 488-89 (Cal. 1990) . . . Appellant had no expectation that her urine sample would be returned. Although appellant did expect to receive test results based on the urine sample she gave to respondent, appellant does not have a property interest in such test results because they are the product of respondent's labor and expertise.

Id. at *2. Similarly, in this case, Appellants had no expectation that the blood samples of the minor Plaintiffs would be returned; and the test results from the blood specimens are the product of the labor and expertise of MDH.

Caselaw from other jurisdictions support dismissal of Appellants' conversion claim. In *Moore v. Regents of the Univ. of Calif.*, 793 P.2d 479 (Cal. 1990), the plaintiff underwent treatment for leukemia. Blood and other bodily substances were taken from him. 793 P.2d at 481. Moore signed a written consent form but was not informed of

³⁰ A copy of this decision is reproduced in Respondents' Appendix at RA-7.

plans to conduct research using his tissues. *Id.* The defendants obtained a patent on a cell line established from Moore's cells. Moore asserted a claim for conversion, arguing that he owned his cells after removal and that he never consented to their use in medical research. The court found that Moore had no ownership interest in his excised cells. *Id.* at 488-89, 492. The court declined to extend the tort of conversion to human biological materials for several policy reasons, including the obstacles to medical research that would result, *e.g.*, the threat to innocent researchers who do not know that use of a particular cell sample is against the donor's wishes. *See id.* at 493-96. The court indicated that problems in this area are better suited to legislative resolutions, noting that specialized statutes relating to transplantable organs, blood, fetuses, pituitary glands, corneal tissue and dead bodies "regulat[e] their disposition to achieve policy goals rather than abandon[] them to the general laws of personal property." *Id.* at 496.

In *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003), families provided blood and other tissues to be used in research to find a cure for Caravan disease. *See id.* at 1066-67. The researchers isolated the gene for Caravan disease, and the hospital obtained a patent. The court dismissed Greenberg's conversion claim, holding that the body tissue and genetic information were donated without any contemporaneous expectation that body tissue and genetic samples would be returned and that the plaintiffs had "no cognizable property interest" therein. *See id.* at 1074. The court stated that if plaintiffs' "expansive" theory of conversion were to be adopted, it would "cripple medical research as it would bestow a continuing right for donors to possess the results of any research conducted by the hospital." *Id.* at 1076.

5. Fraud And Misrepresentation.

The elements of fraudulent misrepresentation are: (1) a representation; (2) the representation must be false; (3) the representation must relate to a past or present fact; (4) the fact must be material; (5) the fact must be susceptible of knowledge; (6) the representer must know it to be false or assert it as of his/her own knowledge without knowing it is true or false; (7) the representer must intend to have the other person induced to act or justified in acting upon it; (8) the person must be so induced as to act or so justified in acting; (9) the person's action must be in reliance on the representation; (10) the person must suffer damage; and (11) the damage must be the proximate cause of the injury. *See Johnson Bldg. Co. v. River Bluff Dev. Co.*, 374 N.W.2d 187, 193-94 (Minn. Ct. App. 1985).

Appellants alleged that the State knowingly made a false representation to them that "the blood would be taken solely for the purposes of newborn screening" and, relying on this representation, parent Plaintiffs "allowed taking of their minor Plaintiffs' blood." *See* AA-7. Of the 17 parent Plaintiffs, only two submitted affidavits in the district court. Neither affidavit supports the allegation quoted above. Appellant Rohde states that she was "never given any written documents or information about the reasons for the taking of the blood test at the hospital." AA-10. She further states that she agreed to the blood test after a pediatrician convinced her that the test "was not a DNA test."³¹ *See* AA-11. The unsigned and unsworn affidavit of Appellant Kish-Bailey (*see* AA-12 to

³¹ As stated *supra*, the NBS Program only tests for the presence or absence of a specific DNA or RNA in a "second level" test. No "second level" test was performed on any of the minor Plaintiffs. Zerby Aff., AA-180.

AA-13) does not mention any representation by anyone about the purpose of the blood samples taken from her children. Appellants simply failed to produce any evidence to support their allegations.³²

Although Appellants made no claim of “agency” in their amended complaint, they claim that the alleged fraudulent misrepresentations were made by “agents” of MDH, i.e., by unidentified doctors, nurses, and others present at the time of the minor Plaintiffs’ births. This claim is frivolous. In the absence of any persuasive evidence of the existence of the elements of agency, there is no principal-and-agent relationship as a matter of law. *See Jacobs v. Cable Constructors, Inc.*, 704 N.W.2d 205, 209 (Minn. Ct. App. 2005). Agency is a fiduciary relationship involving: (1) a manifestation of mutual consent between the principal and another that the other will act on the principal’s behalf; and (2) the right of control by the principal over the agent. *See A. Gay Jenson Farms Co. v. Cargill, Inc.*, 309 N.W.2d 285, 290 (Minn. 1981). The party alleging the agency relationship bears the burden of proof. *See Plate v. St. Mary’s Help of Christians Church*, 520 N.W.2d 17, 20 (Minn. 1994).

Appellants failed to present facts that support a finding of *any* of the elements of an agency relationship between MDH and every doctor, nurse or other person who speaks to a parent concerning the NBS Program. Under Appellants’ theory, the potential

³² In addition, failure to plead fraud with sufficient particularity justifies dismissal for failure to state a claim for which relief may be granted. *See Martens v. Minnesota Mining and Mfg. Co.*, 616 N.W.2d 732, 747-48 (Minn. 2000). Vague allegations concerning the circumstances constituting the fraud are insufficient. *See Khalifa v State*, 397 N.W.2d 383, 390 (Minn. Ct. App. 1986). Appellants failed to plead fraud with particularity. Nothing in the complaint sheds light on who made the alleged representations, when they were made, and who heard them.

number of such "agents" could be thousands of people. It defies logic to assert that MDH has the ability to control the actions and statements every doctor, nurse, hospital employee, midwife, or other person interacting with the parent of a newborn with respect to newborn screening. Appellants' fraud and misrepresentation claim is utterly meritless.

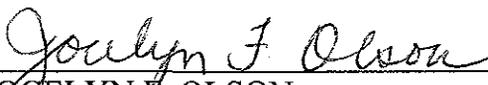
CONCLUSION

Because no material fact dispute exists and the district court did not err in its legal conclusions, the State respectfully requests that the Court affirm the district court's decision.

Dated: March 12, 2010

Respectfully submitted,

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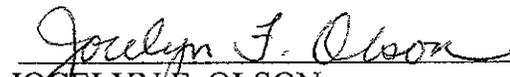
ATTORNEYS FOR RESPONDENTS

CERTIFICATE OF COMPLIANCE

WITH MINN. R. APP. P 132.01, Subd. 3

The undersigned certifies that the Brief submitted herein contains 13,787 words and complies with the type/volume limitations of the Minnesota Rules of Appellate Procedure 132. This Brief was prepared using a proportional spaced font size of 13 pt. The word count is stated in reliance on Microsoft Word 2003, the word processing system used to prepare this Brief.

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