STATE OF MINNESOTA

IN SUPREME COURT

A10-0101

Court of Appeals

Meyer, J.
Concurring in part and dissenting in part,
Anderson, Paul H., Dietzen, and Stras, JJ.
Concurring in part and dissenting in part, Stras, J.

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

Appellants,

vs.

Filed: November16, 2011
Office of Appellate Courts

State of Minnesota, et al.,

Respondents.

Randall G. Knutson, Daniel J. Bellig, Farrish Johnson Law Office, Chtd., Mankato, Minnesota; and

Sam Hanson, Briggs and Morgan, P.A., Minneapolis, Minnesota, for appellants.

Lori Swanson, Attorney General, Jocelyn F. Olson, Assistant Attorney General, St. Paul, Minnesota, for respondents.

S Y L L A B U S

1. The Genetic Privacy Act, Minn. Stat. § 13.386 (2010), restricts the collection, use, storage, and dissemination of blood samples collected pursuant to the newborn screening statutes, Minn. Stat. §§ 144.125-.128 (2010).

2. The newborn screening statutes provide an express exception to the Genetic Privacy Act only to the extent that the Department is authorized to administer newborn screening by testing the samples for heritable and congenital disorders, recording and reporting those test results, maintaining a registry of positive cases for the purpose of follow-up services, and storing those test results as required by federal law.

Reversed and remanded.

O P I N I O N

MEYER, Justice.

At issue in this case is the interplay between the newborn screening statutes, Minn. Stat. §§ 144.125-.128 (2010), and the Genetic Privacy Act, Minn. Stat. § 13.386 (2010).[1] The Minnesota Department of Health, as part of its newborn screening program, collects blood samples of newborn children to test for various disorders. The Department has retained the excess blood samples and the test results. The Department has used the blood samples for purposes other than the initial screening of newborn children and has allowed outside research organizations to use the blood samples to conduct health studies. Nine families (the appellants) sued the State of Minnesota, the Department, and the Commissioner of the Department over the Department's practice of collecting, using, storing, and disseminating the children's blood samples and test results without obtaining written informed consent in violation of the Genetic Privacy Act. The district court

[1] We refer to the genetic information section of the Minnesota Government Data Practices Act as the "Genetic Privacy Act."

granted the State's motion to dismiss or, in the alternative, the State's motion for summary judgment. The court of appeals affirmed. We reverse and remand to the district court.

Appellants are nine families with twenty-five children, born between 1998 and 2008, whose blood was sampled and tested for heritable and congenital disorders as part of the State's newborn screening program.[2] Appellants commenced an action against the State of Minnesota, the Department of Health, and the Commissioner of Health (collectively, the State), alleging a violation of the Genetic Privacy Act. Appellants claim that the Genetic Privacy Act requires written parental consent before the Department may store newborn blood specimens collected through the newborn screening program or authorize public-health research to be conducted with those samples. The complaint was later amended to include various tort and constitutional claims. The State moved to dismiss or, in the alternative, for summary judgment.

The district court granted the State's motion for summary judgment on all claims. The court held that appellants had failed to state a claim upon which relief could be granted on all claims except for the statutory claim. As to that claim, the court concluded (1) that the Genetic Privacy Act did not apply to children born before August 1, 2006,

[2] As originally filed, the complaint included nine families with twenty-three children. The complaint was later amended to include an additional family with five children. Another family withdrew from the case, leaving twenty-five children and their parents as parties. For simplicity, we refer to procedural actions as having been taken by "appellants" even where the appellants at the time of such action consisted of a different composition of parties than the current appellants.

(2) that the blood samples were not "genetic information" under the Genetic Privacy Act, and (3) that the Genetic Privacy Act did not supersede existing laws such as the newborn screening statutes.

On appeal, the court of appeals held that the blood samples qualified as "genetic information" under the Genetic Privacy Act. *Bearder v. State*, 788 N.W.2d 144, 150 n.6 (Minn. App. 2010). But the court affirmed the grant of summary judgment, concluding that the Department of Health possesses broad statutory authority to operate the newborn screening program and that the Genetic Privacy Act does not apply. *Id.* at 150. The court concluded that using newborn children's blood samples for purposes other than screening could violate the Genetic Privacy Act but that appellants had not presented specific facts to support their claims that the children's blood samples were being used improperly. *Id.* at 150-51. The court of appeals, therefore, affirmed summary judgment on all claims. *Id.* at 152. Appellants appeal the decision to affirm summary judgment on the Genetic Privacy Act claim.

I.

"On appeal from a grant of summary judgment, we must determine whether any genuine issues of material fact exist and whether the district court erred in its application of the law." *Patterson v. Wu Family Corp.*, 608 N.W.2d 863, 866 (Minn. 2000). We review a district court's decision to grant summary judgment to determine (1) whether any issues of material fact exist, and (2) whether the district court misapplied the law to the facts. *Bus. Bank v. Hanson*, 769 N.W.2d 285, 288 (Minn. 2009). We construe the facts in the light most favorable to the party opposing summary judgment and review

questions of law, including the interpretation of statutes, de novo. *See id.; see also Premier Bank v. Becker Dev., LLC*, 785 N.W.2d 753, 758 (Minn. 2010).

In 1965 Minnesota began to test newborns for certain metabolic disorders. *See* Act of Apr. 15, 1965, ch. 205, 1965 Minn. Laws 312 (codified as amended at Minn. Stat. §§ 144.125-.128). The current program screens newborns for more than 50 disorders. Each year, more than 73,000 Minnesota newborns are screened; approximately 100 are discovered to have a confirmed disorder.

Newborn screening is conducted under the authority of the newborn screening statutes, which (1) require the Commissioner of Health to prescribe the manner of testing, recording, and reporting of newborn screening results; (2) require those who perform screenings to advise parents that the blood samples and test results may be retained by the Department of Health; and (3) permit parents either to decline to have their infants tested or to require destruction of the blood samples and test results following screening. *See* Minn. Stat. §§ 144.125-.128; Minn. R. 4615.0300-.0700 (2011).

The newborn screening program requires certain individuals to collect blood samples from newborn children by the fifth day after birth. Minn. R. 4615.0500. A sample consists of a few blood drops collected on a specimen card. The blood sample is sent to the Department within 24 hours of collection. *Id.* Screening tests are then run on the blood sample.

Almost all of the screening tests analyze the blood sample for the presence of substances that indicate the possible presence of a disorder. The only test that analyzes the DNA or RNA of the blood is the second-level test for cystic fibrosis, which is

performed only if the first test indicates the presence of a certain substance in the blood. The screening process typically uses 70% of the sample.

If a portion of the blood sample remains after the screening tests are completed, the sample is retained indefinitely unless there is a specific request to have it destroyed. As of December 31, 2008, there were more than 800,000 newborn screening samples in storage, dating back to samples taken as early as 1997. More than 50,000 blood samples have been used in studies for purposes beyond the initial screening of the newborn children. These studies have included developing new tests and assuring the quality of existing tests. Blood samples have also been used for studies unrelated to the newborn screening program. A blood sample is capable of being used for research for up to 20 years.

The State asserts that a federal law requires the Department to retain newborn screening test results for two years. *See* 42 C.F.R. § 493.1105 (2010). After this two-year period, the test results are retained indefinitely unless the Department receives a request to destroy the results. The Department currently has electronic test results dating back to 1986 and "a small amount of paper records dating back to the 1960s." The appellants allege that the Department possesses more than 1.5 million screening test results.

The Department of Health contracts with Mayo Medical Laboratories to perform screening tests on newborn children's blood samples. This contract allows Mayo to use excess blood samples for studies unrelated to the newborn screening program if—in addition to other requirements—the samples have been de-identified or Mayo has

received written consent from the children's parent or legal guardian. The majority of the studies performed by outside research institutions use de-identified blood samples.

In 2006 the Legislature amended the Minnesota Government Data Practices Act to include a section regulating the treatment of genetic information. Act of June 1, 2006, ch. 253, § 4, 2006 Minn. Laws 424, 426 (codified at Minn. Stat. § 13.386). This amendment prohibits the collection, use, storage, or dissemination of a person's genetic information without the written informed consent of that person:

> Unless otherwise expressly provided by law, genetic information about an individual:
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> (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;
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> (2) may be used only for purposes to which the individual has given written informed consent;
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> (3) may be stored only for a period of time to which the individual has given written informed consent; and
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> (4) may be disseminated only:
>
> (i) with the individual's written informed consent; or
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> (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.

Minn. Stat. § 13.386, subd. 3. This provision "applies to genetic information collected on or after" August 1, 2006. Act of June 1, 2006, ch. 253, § 4, 2006 Minn. Laws 424, 426.

Appellants argue that the Genetic Privacy Act requires the Department of Health to obtain informed consent before it may collect, use, store, or disseminate the blood samples that remain after newborn health screening is complete. The State argues that the Genetic Privacy Act does not limit the Department's handling of the samples because (1) blood samples received by the Department of Health are not "genetic information" under the Act, and (2) the newborn screening statutes "expressly provide" that the Department of Health may use, store, and disseminate the genetic information without first obtaining written informed consent.

II.

Our first task is to determine whether the blood samples collected and stored by the Department are "genetic information," as that term is used in the Genetic Privacy Act, requiring the Department to obtain informed consent before it may use, store, or disseminate the blood samples that remain after the newborn health screening is complete. Appellants argue that the Genetic Privacy Act applies to blood samples because those samples contain information in the form of DNA.[3] The State argues that

[3] Appellants also argue that the State waived review of the court of appeals' holding that blood specimens fit the Genetic Privacy Act's definition of "genetic information" because that issue was decided adversely to the State in the court of appeals and the State did not request cross-review. We disagree. Appellants' petition for review stated the issue for review as whether the Department of Health must "obtain written, informed consent as required by the Genetic Privacy Act before it can store and use newborn blood samples and test results after newborn screening is complete." Review of that issue requires us to interpret whether the term "genetic information," as used in the Genetic Privacy Act, includes blood samples.

the Genetic Privacy Act does not apply to blood samples because the Act treats those samples as biological *specimens*, not genetic *information*.

When interpreting a statute, we first look to "whether the statute's language, on its face, is clear or ambiguous." *Am. Family Ins. Grp. v. Schroedl*, 616 N.W.2d 273, 277 (Minn. 2000). A statute is ambiguous if its language is subject to more than one reasonable interpretation. *Id.* If the statutory language is clear and free from ambiguity, we apply its plain meaning. Minn. Stat. § 645.16 (2010); *Wynkoop v. Carpenter*, 574 N.W.2d 422, 425 (Minn. 1998). Under the rules of statutory interpretation, words and phrases are to be given their ordinary meaning. Minn. Stat. § 645.08(1) (2010); *Hince v. O'Keefe*, 632 N.W.2d 577, 582 (Minn. 2001).

The language of Minn. Stat. § 13.386, subd. 1, includes two definitions for the term "genetic information":

> (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:
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> (1) the individual's biological information or specimen; or
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> (2) the biological information or specimen of a person to whom the individual is related.
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> (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.

Appellants and the State generally agree that genetic information under (a) does not include the blood samples because, by its express terms, the information must have been

obtained from "an analysis" of biological information. In other words, definition (a) protects the privacy of the test results, and not the specimen or source of the information. It is self-evident that the biological information being subject to analysis includes blood samples. But the blood samples themselves are not protected under definition (a).

We therefore consider whether the blood samples are "genetic information" under the definition contained in subdivision 1(b). Under subdivision (b), genetic information "also means medical or biological information collected from an individual." Unlike definition (a), definition (b) does not limit its protection to information "obtained" from an analysis of a "biological specimen." Rather, the definition is broader in scope because it encompasses "medical or biological information" about an individual. As noted under our analysis of subdivision 1(a), biological information includes blood samples. Therefore, an individual's blood samples are biological information subject to protection under definition (b).

Aside from the Legislature's unambiguous intent to include blood samples within the ambit of "biological information" that can be analyzed to glean "genetic information," the common understanding of "biological information collected from an individual" is the information contained in blood cells via DNA.[4] The blood samples

[4] *See, e.g.*, *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1350 (Fed. Cir. 2003) (referring to "genetic information contained in a DNA nucleotide sequence"); *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 194 (S.D.N.Y. 2010) (noting that genes, which are composed of segments of DNA, "contain[] the information used by the body" to produce proteins), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011); *Sigma-Aldrich, Inc. v. Open Biosystems, Inc.*, 521 F. Supp. 2d 975, 978 (E.D. Mo. 2007) (noting that the linear sequence of nucleotides in

(Footnote continued on next page.)

collected from the appellants in this case unquestionably contain biological information. The blood samples are also "biological information" under definition (b) because the genetic information in the samples may be used to provide medical care to the individuals. *See United States v. Kincade*, 379 F.3d 813, 842 n.3 (9th Cir. 2004) (Gould, J., concurring) (noting that DNA contains information about a "person's health [and] propensity for particular disease"); Tania Simoncelli, *Dangerous Excursions: The Case Against Expanding Forensic DNA Databases to Innocent Persons*, 34 J.L. Med. & Ethics 390, 392 (2006) (stating that DNA "can provide insights into personal family relationships, disease predisposition, physical attributes, and ancestry"). It is the DNA within the blood samples that is the information that brings the blood sample within the protection of the Genetic Privacy Act. Thus, the blood samples fit within the common understanding of "medical or biological information collected from an individual."

The State argues that blood samples are not "genetic information" because the "genetic information" comes from analysis of the blood samples. The State's argument is essentially that the Genetic Privacy Act applies only after blood samples have been analyzed. The State relies primarily on two areas of the statutory definition for its argument. First, it relies on subdivision 1(a), which defines genetic information as the *result* of "an analysis of . . . the . . . biological information or specimen." Second, the

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DNA "carries genetic information"); *id.* at 979 ("DNA stores genetic information."); *Armstead v. State*, 673 A.2d 221, 227 (Md. 1996) ("It is the sequence of the nucleotides [in DNA] that conveys . . . information, in effect 'spelling out' the genetic instructions.").

State argues that the use of the term "biological information or specimen" in subdivision 1(a) implies that the Legislature intended a "biological *specimen*" to have a meaning distinct from "biological *information*."

We conclude that this is not a reasonable interpretation of the language of the statute. Definitions (a) and (b) must be read together, *see Christensen v. Hennepin Transp. Co.*, 215 Minn. 394, 409, 10 N.W.2d 406, 415 (1943) (explaining that we do not construe the provisions of a statute in isolation but "as a whole"), but each definition describes a different type of genetic information. The "genetic information" defined in subdivision 1(a) is information obtained from an analysis of biological samples or from an analysis of information already obtained from biological samples. But the "genetic information" defined in subdivision 1(b) includes "biological information" *itself* collected from an individual, not just the analysis of the biological information. *See* Minn. Stat. § 13.386, subd. 1(b). We also do not read into the plain language of subdivision 1(a)'s use of the phrase "biological information or specimen" a distinction between "biological information" and a "biological specimen" that is meant to apply in subdivision 1(b), where the phrase used is "medical or biological information." *See* Minn. Stat. § 13.386, subd. 1.

We conclude that "genetic information" under Minn. Stat. § 13.386, subd. 1(b), includes the actual blood samples as "medical or biological" information. We also note that even if the Genetic Privacy Act did not define the blood samples themselves as "genetic information," those samples unquestionably *contain* genetic information. The

Act limits the collection, use, storage, or dissemination of genetic information. It would be impossible to collect, use, store, or disseminate those samples without also collecting, using, storing, or disseminating the genetic information contained in those samples.

In sum, because the definition of "genetic information" is not subject to two reasonable interpretations, it is not ambiguous. *See Schroedl*, 616 N.W.2d at 277. We hold that the blood samples collected by the Department of Health fit the definition of "biological information collected from an individual" under Minn. Stat. § 13.386, subd. 1(b), and, therefore, the Genetic Privacy Act applies to the blood samples. Unless otherwise expressly provided by law, the Department must have written informed consent to collect, use, store, or disseminate those samples.

III.

Having concluded that the blood samples collected and stored by the Department are "genetic information" and subject to the restrictions of the Genetic Privacy Act, we turn to the question of whether the Department is exempted from those restrictions because they are "expressly provided" with authority to collect, use, store, and disseminate the information. *See* Minn. Stat. § 13.386, subd. 3 (requiring that "[u]nless otherwise expressly provided by law," the State must have written informed consent to collect, use, store, or disseminate genetic information). Thus, the Department may collect, use, store, or disseminate blood samples collected as part of the newborn screening program only to the extent expressly authorized by Minn. Stat. §§ 144.125-.128 (the newborn screening statutes). We examine each of the restrictions of the Genetic Privacy Act to determine the extent to which the newborn screening statutes give the

Department the express authority to collect, use, store, or disseminate blood samples without written informed consent.

The Genetic Privacy Act's first restriction is on collection. Minn. Stat. § 13.386, subd. 3(1). Under the Act, genetic information "may be collected . . . only with the written informed consent of the individual." *Id*. Although the language of the newborn screening statutes do not explicitly state that the Department may collect blood samples, the statutes' provisions authorizing the Department to conduct tests and providing for destruction of samples require that the Department be able to collect samples to be tested and destroyed. *See* Minn. Stat. §§ 144.125, 144.128. Despite the fact that this constitutes implied rather than express authorization, we conclude that the newborn screening statutes authorize the collection of blood samples to the extent necessary to allow the Department to conduct the tests expressly authorized by statute.

The Genetic Privacy Act's second restriction is on use. *See* Minn. Stat. § 13.386, subd. 3(2). The Act provides that genetic information "may be used only for purposes to which the individual has given written informed consent." *Id*. The newborn screening statutes authorize the Commissioner to conduct "tests for heritable and congenital disorders," Minn. Stat. § 144.125, subd. 1, and require the Commissioner to "maintain a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services," Minn. Stat. § 144.128(3). The newborn screening statutes therefore expressly authorize the Commissioner to use the blood samples without written informed consent only to the extent necessary to conduct tests for heritable and congenital disorders and conduct follow-up services.

The court of appeals held that the broad authority given to the Commissioner to perform various functions expressly allowed the Department of Health to use genetic information to improve its screening methods. *Bearder*, 788 N.W.2d at 149-50. These statutes (1) authorize the Commissioner to "[c]onduct studies and investigations, collect and analyze health and vital data, and identify and describe health problems," Minn. Stat. § 144.05, subd. 1(a) (2010); (2) require that "[t]esting and the recording and reporting of test results shall be performed at the times and in the manner prescribed by the commissioner of health," Minn. Stat. § 144.125, subd. 1; and (3) establish an advisory committee to collect information on "the efficacy and reliability of various tests," for heritable and congenital disorders," "the availability and efficacy of treatments for heritable and congenital disorders," and "the severity of medical conditions caused by heritable and congenital disorders," Minn. Stat. § 144.1255, subd. (1)-(3). None of these provisions expressly requires the use of genetic information or blood samples or conflict with the Genetic Privacy Act's requirement of obtaining informed written consent. The Commissioner's power to conduct health studies does not include unlimited authority to use the genetic information obtained from newborns for screening purposes in those health studies. Use of genetic information for purposes other than the screening of newborn children and for follow-up services requires written informed consent.

The Genetic Privacy Act also restricts storage. *See* Minn. Stat. § 13.386, subd. 3(3). The Act requires that genetic information "may be stored only for a period of time to which the individual has given written informed consent." *Id.* The newborn screening statutes require the Commissioner to "maintain a registry of the cases of

heritable and congenital disorders detected by the screening program for the purpose of follow-up services." Minn. Stat. § 144.128(3). This language creates an express exception to the Genetic Privacy Act that allows the Commissioner to maintain blood samples from positive test results unless a child's parents object pursuant to section 144.125, subdivision 3.

The State argues that the newborn screening statutes provide two other express exceptions to the Genetic Privacy Act. First, it argues that the newborn screening statutes' requirement that the Commissioner "comply with a destruction request within 45 days after receiving it," Minn. Stat. § 144.128(5), authorizes the Commissioner to retain information for 45 days. But even if this provision authorizes the Commissioner to retain genetic information for 45 days before complying with a destruction request, it does not expressly provide for indefinite storage when no destruction request is received. Section 144.128 is silent on the question of how long genetic information may be retained, and therefore the statute cannot be an "express" exception to the Genetic Privacy Act's opt-in framework.

Second, the State argues that language in Minn. Stat. § 144.125, subd. 3, requiring "responsible parties" to advise parents "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," expressly requires the Department to retain blood samples because if the Department were not allowed to do so, the statement would be false. At best, this language provides only implicit authorization for the Department to retain blood samples. A requirement that "responsible parties" inform parents that blood samples may

be retained *implies* that the Department is in fact authorized to do so, but it does not *expressly* authorize retention of those samples. Furthermore, the use of the word "may" indicates that blood samples might not be retained.

The Genetic Privacy Act's final restriction is on dissemination. *See* Minn. Stat. § 13.386, subd. 3(4). The Act allows genetic information to be "disseminated only: (i) with the individual's written informed consent; or (ii) if necessary in order to accomplish purposes" for which informed consent was given. *Id*. The newborn screening statutes expressly authorize the "reporting of test results." Minn. Stat. § 144.125, subd. 1. The Commissioner is also expressly authorized to contract with a private entity to perform the Department's functions. *See* Minn. Stat. § 144.0742 (2010) ("The commissioner of health is authorized to enter into contractual agreements with any public or private entity for the provision of statutorily prescribed public health services by the department."). But there is no other source of law authorizing the dissemination of blood samples or genetic information beyond that expressly authorized for the reporting of newborn test results.

We conclude that the newborn screening statutes provide an express exception to the Genetic Privacy Act only to the extent that the Department is authorized to administer newborn screening by testing the samples for heritable and congenital disorders, recording and reporting those test results, maintaining a registry of positive cases for the purpose of follow-up services, and storing those test results as required by federal law. The newborn screening statutes do not expressly authorize the Department to conduct any other use, storage, or dissemination of the blood samples.

IV.

Finally, we turn to the question of the appropriate remedy. The district court did not find a violation of the Genetic Privacy Act and held that the "remedy sought is not one the Court can impose." The court of appeals concluded that the use of blood samples of newborn children in studies unrelated to the newborn screening program would violate the Genetic Privacy Act, but held that appellants had presented no specific evidence that any of the children's blood had been so used. *Bearder*, 788 N.W.2d at 150-51. Because the district court concluded that the Department had not violated the Genetic Privacy Act, the court did not consider the availability of remedies to particular parties or whether any parties had established the facts necessary to show that their children's blood samples had been used, stored, or disseminated in violation of the Act. Because the record is insufficient to allow us to determine whether any of the appellants are entitled to remedies for such violation, we remand to the district court for further proceedings consistent with this opinion.

Reversed and remanded.

C O N C U R R E N C E & D I S S E N T

ANDERSON, Paul H., Justice (concurring in part, dissenting in part).

I concur in part and dissent in part. I agree with the majority that test results generated by the Department of Health's newborn screening program are "genetic information" subject to the requirements of Minn. Stat. § 13.386 (2010), the Genetic Privacy Act, except to the extent otherwise expressly authorized by law. I also agree with the majority's conclusion that "the newborn screening statutes provide an express exception to the Genetic Privacy Act only to the extent that the Department is authorized to administer newborn screening by testing the samples for heritable and congenital disorders, recording and reporting those test results, maintaining a registry of positive cases for the purpose of follow-up services, and storing those test results as required by federal law." To the extent that this conclusion applies to newborn screening test results, I concur.

But I disagree with the majority's conclusion that the Genetic Privacy Act applies to blood samples obtained in the newborn screening program. The Genetic Privacy Act applies to "genetic information," which, as defined by the statute, does not include specimens. Because newborn children's blood samples are specimens, blood samples do not meet the definition of genetic information and the Genetic Privacy Act does not apply to them.

I.

The fundamental issue in this case is whether the Genetic Privacy Act applies to the test results and the blood samples collected pursuant to the newborn screening

program. This dispute centers on the interaction of two sets of statutes: the newborn screening statutes, Minn. Stat. §§ 144.125-.128 (2010), and the Genetic Privacy Act, Minn. Stat. § 13.386. A review of the current version of these statutes and the history of each will be helpful to understanding the issue presented in this case.

Newborn Screening Statutes

The newborn screening statutes are codified at Minn. Stat. §§ 144.125-.128. These statutes provide for the testing of newborn children by the Minnesota Department of Health for more than 50 heritable and congenital disorders. Section 144.125 outlines the fundamental aspects and scope of the screening program.[1] Subdivision 1 states who is responsible for arranging to have a newborn child's blood sample sent to the Department of Health for testing. Minn. Stat. § 144.125, subd. 1. Subdivision 2 provides that the Commissioner of Health shall revise the list of tests the Department will use on the newborn children's blood samples. *Id*., subd. 2. Subdivision 3 requires the individual responsible for arranging collection of the blood samples to inform the parents (1) that the Department may retain the blood sample and test results, (2) of the benefits of

[1] Administrative rules provide more detail as to the mechanics of the program but are somewhat out-of-date. For example, the current program tests for more than 50 disorders, whereas the rules state that the purpose and scope of the program is to screen newborns for only five listed disorders. *See* Minn. R. 4615.0300 (2011). There are eight newborn screening program administrative rules. *See* Minn. R. 4615.0300-.0760 (2011). The first five rules provide the scope of the rules, define the terms used, and outline the duties of various parties with respect to newborn testing. The remaining three outline the scope, define various terms, and outline the responsibilities of the Department of Health with respect to follow-up services.

retention, and (3) that the parents have the right to refuse testing or to have the blood sample and test results destroyed. *Id.*, subd. 3.

Section 144.1255 establishes an advisory committee and assigns to the committee various responsibilities. Some of these responsibilities include collecting information on the efficacy and reliability of tests for heritable and congenital disorders and the efficacy and availability of treatments for heritable and congenital disorders. Minn. Stat. § 144.1255, subd. 2(1), (2). Responsibilities also include assessing the costs and benefits of performing certain tests and assessing the "ethical considerations surrounding the testing, treatment, and handling of data and specimens generated by the testing requirements" of the statutes. *Id.*, subd. 2(4), (5).

Section 144.128 outlines the duties of the Commissioner. In addition to adopting rules to carry out the newborn screening program, the Commissioner must "maintain a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services," comply with any requests to destroy test results and blood samples within 45 days, and notify the requesting individuals that the destruction has occurred.

The newborn screening program has undergone several changes since its inception over 46 years ago. The Legislature's first statute establishing the newborn screening program was passed in 1965 as a program to test for "phenylketonuria and other inborn errors of metabolism causing mental retardation." Act of April 15, 1965, ch. 205, § 1, 1965 Minn. Laws 312, 313 (codified as amended at Minn. Stat. § 144.125). Parents could object to the test on religious grounds. *Id.* The Legislature amended the statute in

subsequent years in order to make certain minor changes. *See, e.g.*, Act of May 27, 1977, ch. 305, § 45, 1977 Minn. Laws 575, 594 (codified as amended at Minn. Stat. § 144.125) (changing the use of "board of health" to the "commissioner"). The Commissioner's duties were revised by statute in 1985, which included maintaining a registry of positive cases, and arranging treatment of diagnosed cases for uninsured poor families. Act of June 27, 1985, ch. 9, art. 2, § 10, 1985 Minn. Laws 1st Spec. Sess. 1694, 1726 (codified as amended at Minn. Stat. § 144.128).[2]

In 1988, the Legislature provided that another specific disorder be tested for and required the Commissioner to charge laboratory fees. Act of April 28, 1988, ch. 689, art. 2, § 31, 1988 Minn. Laws 1279, 1312 (codified as amended at Minn. Stat. § 144.125). In 1994, the Legislature eliminated the language allowing parents to object to the testing on religious grounds. Act of May 10, 1994, ch. 636, art. 2, § 2, 1994 Minn. Laws 2170, 2188. In 1997, the Legislature modified the calculation of laboratory fees. The laboratory fees collected would be calculated using the costs of conducting the test and "implementing and maintaining a system to follow-up infants with inborn metabolic errors." Act of June 2, 1997, ch. 203, art. 2, § 11, 1997 Minn. Laws 1587, 1638 (codified as amended at Minn. Stat. § 144.125). Also in 1997, the Legislature stopped listing

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[2] The same act also required the Commissioner to provide "treatment control tests for which approved laboratory procedures are available for phenylketonuria and other metabolic" disorders. Act of June 27, 1985, ch. 9, art. 2, § 9, 1985 Minn. Laws 1st Spec. Sess. 1694, 1726 (codified at Minn. Stat. § 144.126). This provision has since been repealed. Act of June 5, 2003, ch. 14, art. 7, § 89, 2003 Minn. Laws 1st Spec. Sess. 1751, 2104.

specific disorders for the Department to test, leaving the tests to the discretion of the Commissioner. Act of May 22, 1997, ch. 205, § 19, 1997 Minn. Laws 1880, 1891 (codified as amended at Minn. Stat. § 144.125).

In 2003, the Legislature made dramatic changes to the statute and the newborn screening process and procedures took on their current form. The Legislature changed the name of the types of diseases to screen for, switching "inborn metabolic errors" to "heritable and congenital disorders." The Legislature set the fee for performing the tests, and provided more guidance for the Commissioner in developing the list of tests to be performed. The Legislature added the requirement that responsible parties inform parents of their right to object to the tests or to have their infant's blood samples and test results destroyed. Act of June 5, 2003, ch. 14, art. 7, § 26, 2003 Minn. Laws 1st Spec. Sess. 1751, 2073-75 (codified as amended at Minn. Stat. § 144.125). The 2003 Act also created the advisory committee discussed earlier. Act of June 5, 2003, ch. 14, art. 7, § 27, 2003 Minn. Laws 1st Spec. Sess. 1751, 2075-76 (codified at Minn. Stat. § 144.1255). Finally, the 2003 changes required the Commissioner to provide referrals for children who tested positive for a heritable or congenital disorder, rather than arrange for treatment for uninsured poor families. The Act also added a requirement that the Commissioner notify the newborn child's physician of the tests performed by the Department. Act of June 5, 2003, ch. 14, art. 7, § 28, 2003 Minn. Laws 1st Spec. Sess. 1751, 2076 (codified as amended at Minn. Stat. § 144.128).

In 2006, the Legislature added to the Commissioner's duties, primarily with respect to destruction requests for test results and blood samples. The Commissioner was

required to develop forms for requesting destruction of test results and blood samples, to comply with a destruction request within 45 days, and to notify the requesting individual when destruction was complete. Act of June 1, 2006, ch. 253, § 9, 2006 Minn. Laws 424, 429 (codified at Minn. Stat. § 144.128).

In 2007 and 2009, the Legislature raised the fee and allocated a portion of the fee to a specific follow-up system. Act of May 25, 2007, ch. 147, art. 16, § 7, 2007 Minn. Laws 1804, 2164 (codified as amended at Minn. Stat. § 144.125); Act of May 14, 2009, ch. 79, art. 10, § 5, 2009 Minn. Laws 690, 945 (codified at Minn. Stat. § 144.125).

Genetic Privacy Act

The Genetic Privacy Act is codified at Minn. Stat. § 13.386 (2010). In 2006, the Legislature added the Genetic Privacy Act to the Minnesota Government Data Practices Act. Act of June 1, 2006, ch. 253, § 4, 2006 Minn. Laws 424, 426 (codified at Minn. Stat. § 13.386). The act that created the definition of "genetic information" at issue in this case is the same act that added duties to the Commissioner in the newborn screening statute—requiring the Commissioner to develop destruction request forms, to comply with destruction requests, and to notify individuals when destruction has been completed. Act of June 1, 2006, ch. 253, § 9, 2006 Minn. Laws 424, 429.

The Genetic Privacy Act currently requires written informed consent for the collection, use, storage, and dissemination of genetic information "[u]nless otherwise

expressly provided by law."[3] Minn. Stat. § 13.386, subd. 3. The statute applies to "genetic information," which has two narrow definitions:

> (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.

II.

With the foregoing statutory framework in mind, I now address the central issue in this case—whether the Genetic Privacy Act applies to the test results and the blood samples obtained for use in the newborn screening program. If the Genetic Privacy Act applies, then written informed consent is required to collect, use, store, or disseminate the test results or blood samples "[u]nless otherwise expressly provided by law." Minn. Stat. § 13.386, subd. 3. Here, I concur with the conclusion of the majority that the test results obtained in the newborn screening program are subject to the Genetic Privacy Act. Before the Department may collect, use, store, or disseminate test results, there must be

[3] The statute also allows dissemination "if necessary in order to accomplish purposes" for which an individual has given informed consent. Minn. Stat. § 13.386, subd. 3(4).

express written informed consent "[u]nless otherwise expressly provided by law." *See id*. But I do not agree that blood samples are subject to the Genetic Privacy Act and, therefore, the Department does not need to obtain written informed consent for the collection, use, storage, or dissemination of the blood samples.

Blood Samples Are Not "Genetic Information" Under the Genetic Privacy Act

The plain reading of the two definitions indicates that blood samples, which are a type of specimen,[4] are not included in the definition of "genetic information." Subdivision 1(a) of the Genetic Privacy Act states the following:

> "Genetic information" means information about an identifiable individual derived from the presence, absence, alteration, or mutation of a gene, or the presence or absence of a specific DNA or RNA marker, which has been obtained from an analysis of:
>
> (1) the individual's biological information or specimen; or
>
> (2) the biological information or specimen of a person to whom the individual is related.

Minn. Stat. § 13.386, subd. 1(a). This definition essentially states that "genetic information" results from certain types of analyses of an individual's (or related individual's) biological information or specimen. Subdivision 1(a) does not say that the biological information or specimen itself is genetic information, only that results of certain analyses of either is genetic information. Therefore, I conclude, as does the majority, that the blood sample cannot meet the first definition of "genetic information."

[4] For the purposes of the newborn screening program rules, a "specimen" is the dried blood collected on a specimen card. Minn. R. 4615.0400, subp. 7.

But subdivision 1(a) provides relevant information for our interpretation. Importantly, the definition in subdivision 1(a) uses the phrase "biological information *or specimen*." Minn. Stat. § 13.386, subd. 1(a) (emphasis added). By using both the terms "biological information" and "specimen," the statute draws a distinction between the two terms, and therefore, specimens cannot be "biological information." *See* Minn. Stat. § 645.16 (2010) ("Every law shall be construed, if possible, to give effect to all its provisions."); *Cnty. of St. Louis v. Fed. Land Bank of St. Paul*, 338 N.W.2d 741, 744 (Minn. 1983) (stating that "every word and phrase of the statute should be given meaning if possible"). As a result, a blood sample, because it is a specimen, cannot be "biological information." *See* Minn. R. 4615.0400 (defining "specimen" for the purposes of the newborn screening rules as "a specimen of dried blood from the newborn infant collected on a specimen card"). If biological information included specimens, the term "specimen" would be rendered superfluous in the statute.

The definition of "genetic information" provided in subdivision 1(b), reads as follows:

> "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(b). This definition includes certain types of medical or biological information but omits the term "specimen," which term was included in the definition in subdivision 1(a). This omission leads to the inevitable conclusion that the definition in subdivision 1(b) does not include "specimens." *See Johnson v. Cook Cnty.*,

786 N.W.2d 291, 295 (Minn. 2010) ("We may not add words to a statute that the Legislature has not supplied."). And, because blood samples are specimens and not biological or medical information, the definition in subdivision 1(b) does not apply to blood samples.

Because neither definition of "genetic information" applies to the blood samples, I conclude that the Genetic Privacy Act does not apply to the blood samples collected for the newborn screening program. Therefore, I would hold that the Department of Health is not limited by the Genetic Privacy Act's opt-in framework for the collection, use, storage, and dissemination of blood samples.

The Majority's Conclusion that the Blood Samples Are "Genetic Information" Is Erroneous

The majority concludes that the definition of "genetic information" includes the blood samples collected in the newborn screening program. There are numerous problems with the majority's analysis and conclusion.

First, the only way for the majority to reach its conclusion that a blood sample meets the second definition of "genetic information" is to interpret the term "biological information" to have two different meanings when used in the same statute and subdivision. The two uses of "biological information," however, are separated by fewer than 20 words. For instance, in definition (a), the majority should acknowledge that "biological information" does not include "specimen" because otherwise "specimen" would be rendered superfluous. Minn. Stat. § 645.16 ("Every law shall be construed, if possible, to give effect to all its provisions."). But in definition (b), the majority

concludes that "biological information" does include "specimen." This conclusion has no foundation and is contrary to settled rules of statutory interpretation.

Second, the majority's conclusion conflicts with the Data Practices Act requirement that copies of the information be made available to the subject of the data. The Genetic Privacy Act classifies "genetic information" as "private data on individuals as defined by" Minn. Stat. § 13.02, subd. 12 (2010). Minn. Stat. § 13.386, subd. 2. Private data on individuals means that the information is "(a) not public; and (b) accessible to the individual subject of that data." Minn. Stat. § 13.02, subd. 12. The individual who is the subject of the data has certain rights outlined in Minn. Stat. § 13.04 (2010). "The responsible authority or designee shall provide copies of the private or public data upon request by the individual subject of the data." Minn. Stat. § 13.04, subd. 3. Therefore, under the majority's interpretation of the definition of "genetic information," the Department would be required to provide a copy of an individual's blood sample upon request. Notably, because the majority concludes that the blood sample itself is "genetic information," the Department would be required to provide a copy of the blood sample itself. In other words, the Department would somehow need to copy the physical blood sample, because a copy of a report based on the blood sample would not be a copy of the blood sample.

Third, and more fundamentally, the majority's reliance on the common understanding of the term "genetic information" is flawed. First, when the statute provides an explicit definition of "genetic information," the common understanding of the term "genetic information" is unhelpful. Moreover, the common understanding of the

term "information" does not support the majority's conclusion. "Genetic information" is partly defined with the terms "medical or biological information." Information is not a physical object but is an intangible noun. The American Heritage Dictionary defines "information" as "[k]nowledge derived from study, experience, or instruction," "[k]nowledge of a specific event or situation; intelligence," "[a] collection of facts or data," or "[t]he act of informing or the condition of being informed." *The American Heritage Dictionary of the English Language* 927 (3d ed. 1992). A blood sample is a tangible object that conveys no information without analysis, and therefore, it cannot be "biological information." The majority acknowledges that a blood sample is not information itself when it states "blood samples collected from the appellants in this case unquestionably *contain* biological information." (Emphasis added.) I agree that a blood sample contains biological information, in the same way that a computer or a person can contain information. But the definition of "genetic information" is not "an object containing biological information." Therefore, because the blood sample is not "biological information," it cannot be "genetic information" under Minn. Stat. § 13.386, subd. 1.

Fourth, the majority's conclusion that the Genetic Privacy Act applies to blood samples significantly, or even drastically, complicates the interpretation of the newborn screening program statute, Minn. Stat. § 144.125. The Genetic Privacy Act forbids the storage of genetic information without written informed consent, unless the authority is "otherwise expressly provided by law." Minn. Stat. § 13.386, subd. 3. Further, subdivision 3 of Minn. Stat. § 144.125 requires responsible parties to tell parents of

newborn children that blood samples and test results may be retained (and therefore stored) by the Department and that the parents have the option of opting out of the retention of blood samples and test results. Minn. Stat. § 144.125, subd. 3. But, if the blood samples are genetic information, then as the majority concludes, there is no express authority that allows the Department to retain the blood samples. Therefore, if the blood samples are "genetic information," the newborn screening program statutes would require responsible parties to misinform parents of newborns as to the Department's authority to retain blood samples and whether the parents are required to opt-out of the retention, or required to opt-in.[5] However, if blood samples are not considered "genetic information," as I conclude, this subdivision requires no misleading information be given to parents of newborn children.

Underlying the majority's opinion appears to be a belief that it makes no sense for the Genetic Privacy Act to apply to the test results but not to the blood samples that are the source of the test results. The majority concludes that even if the definition of "genetic information" did not apply to blood samples, the Genetic Privacy Act would

[5] The majority attempts to avoid this conclusion by inventing express authority for the retention of blood samples in the newborn screening statutes. The majority concludes that the Commissioner's duty to "maintain a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services" provides express authority to retain blood samples for that purpose. I agree that this provision requires that the Commissioner retain the name and some personal details about the individuals who have tested positively for a disorder in order to maintain a registry of positive cases. But I am unaware of how the majority can conclude that this language provides express authority to store the blood samples of those who have tested positively for a disorder.

nonetheless apply because the blood samples "unquestionably *contain* genetic information." But the majority overlooks the actual, narrow definition of "genetic information" in the statute to arrive at this conclusion. Blood samples do not, in every situation, contain genetic information, as defined by the Genetic Privacy Act.

Two examples illustrate this point. First, the second definition applies only to medical or biological information collected "about a particular genetic condition." Minn. Stat. § 13.386, subd. 1(b). Even if we were to assume a blood sample *can be* genetic information, a blood sample collected with no intention of testing it for a particular genetic condition would not be "genetic information" under the plain terms of the statute. Secondly, the second definition applies only to medical or biological information that is capable of being used to treat the individual *who provided the information* or that individual's family members. *Id.* Therefore, if an individual provided the government with medical or biological information only to be used to treat an unrelated friend's genetic condition, it would not be "genetic information" because the medical or biological information would not be used to provide medical care to the individual who supplied the information, or that individual's family members.

In conclusion, the majority repeatedly ignores the narrow definition of "genetic information" and relies instead on what it subjectively believes the term genetic information ought to mean. Just because an object may contain information does not necessarily make that object information itself. Looking at the Genetic Privacy Act, and only the statute, the only reasonable interpretation is that blood samples are not included

in the definition of "genetic information." Therefore, I would conclude that blood samples are not subject to the Genetic Privacy Act.

III.

At this point, a final comment is in order. The majority appears to be motivated by a policy concern that I share. The Department's assertion that it can use, store, and disseminate the more than 800,000 blood samples it has on file without violating the Genetic Privacy Act is troubling. While the policy implications of this case should not overshadow the plain language of the statute, it should be noted that these policy concerns, while very real, are not as severe as they initially appear.

The newborn screening statutes restrict what the Department may do with the blood samples it collects in the newborn screening program. First, the parties responsible for collecting the newborn blood samples are statutorily required to inform parents of their ability to refuse testing and to have their test results and blood samples destroyed. *See* Minn. Stat. § 144.125, subd. 3. In other words, parents may receive the testing that is beneficial to their newborns and still have the blood samples and test results destroyed upon request. The parents do not face the dilemma of choosing between testing accompanied by the Department's retention of blood samples or no testing at all. Second, the Commissioner of the Department is statutorily required to destroy blood samples within 45 days of receiving a request. Minn. Stat. § 144.128(5). The parents may decide later that they want their child's blood sample to be destroyed, and the Commissioner is obligated to do so. Third, the children are able to request that their own blood samples and test results be destroyed once they reach the age of majority. *See* Minn. Stat.

§ 144.128(4) (requiring the Commissioner to create a destruction request form for "adults who were tested as minors").

In conclusion, I, unlike the majority, would hold that the Department is not violating Minn. Stat. § 13.386 by collecting, using, storing, or disseminating blood samples without written consent, because section 13.386 does not apply to specimens.

DIETZEN, Justice (concurring in part, dissenting in part).

I join in the concurrence and dissent of Justice Paul H. Anderson.

STRAS, Justice (concurring in part, dissenting in part).

I join in the concurrence and dissent of Justice Paul H. Anderson.

C O N C U R R E N C E & D I S S E N T

STRAS, Justice (concurring in part, dissenting in part).

In my view, the court reaches the correct policy result. If I were a legislator, I would vote for legislation protecting blood samples under the Genetic Privacy Act. However, my role as a judge is not to implement my own policy preferences, but to interpret the law as written.

In this case, the court's conclusion that blood samples are "genetic information" is at odds with the plain and unambiguous language of the Genetic Privacy Act for all of the reasons stated by Justice Paul H. Anderson in his opinion concurring in part and dissenting in part. The only reasonable reading of the Genetic Privacy Act is that blood samples are "specimens," not "biological information," which means that the protections of the Act are inapplicable to blood samples because they do not qualify as "genetic information." It is simply unreasonable to conclude, as the court does, that the term "biological information" can have two different meanings in the same subdivision of the same statute. For these reasons, I respectfully dissent from the court's conclusion that the Genetic Privacy Act applies to blood samples collected from newborn children.