MINNESOTA

Bearder v. State

806 N.W.2d 766 · Decided November 16, 2011

SUMMARY

The Minnesota Supreme Court considered whether newborn blood samples retained by the Minnesota Department of Health constitute genetic information under the Genetic Privacy Act. The court held that the blood samples are protected biological information and that the newborn screening statutes expressly authorize their collection, limited use, certain storage, and reporting only to the extent necessary for the screening program and follow-up services. The court reversed summary judgment and remanded for further proceedings concerning potential violations and available remedies.

OPINION

MEYER, J.

OPINION 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 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) 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 *770information" 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 *771samples 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-identi-fied 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: (1) may be collected by a government entity, as defined in section 13.02, subdivision 7a, or any other person only with the written informed consent of the individual; (2) may be used only for purposes to which the individual has given written informed consent; (3) may be stored only for a period of time to which the individual has given written informed consent; and (4) may be disseminated only: (i) with the individual's written informed consent; or (ii) if necessary in order to accomplish purposes described by clause (2).

A consent to disseminate genetic information under item (i) must be signed and dated. Unless otherwise provided by law, such a consent is valid for one year or for a lesser period specified in the consent. 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 *772may 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 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); Wynlcoop 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: (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.

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 subdivi*773sion 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 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 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 *774definition 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 l(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 "[ujnless 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 consti*775tutes 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 MinmStat. § 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]est-ing 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 *776days.

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 followup 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 *777their 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..

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

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), off 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 DNA "carries genetic information"); id. at 979 ("DNA stores genetic information."); Armstead v. State, 342 Md. 38, 673 A.2d 221, 227 (1996) ("It is the

sequence of the nucleotides [in DNA] that conveys... information, in effect ‘spelling out’ the genetic instructions.”).