

**INFORMATION BRIEF**

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## **Genetic Privacy Law and the *Bearder* Case**

In 2006, the legislature enacted legislation that governed the treatment of genetic information held by government entities, known as the genetic privacy law. In the years that followed, a dispute arose as to whether the state’s newborn screening program was subject to the newly enacted restrictions of the genetic privacy law. (The newborn screening program screens newborns for heritable and congenital disorders and is administered by the Minnesota Department of Health (MDH).)

This dispute led to the state being sued over the issue. The case eventually made its way to the Minnesota Supreme Court, which ruled that blood samples are “genetic information” but that statutes governing newborn screening provide express authorization for certain MDH activities. As a result of the court decision, the legislature subsequently passed legislation dealing with the interaction between the genetic privacy law and the newborn screening program.

This information brief provides information on the genetic privacy law; its interaction with the state newborn screening program pursuant to the Minnesota Supreme Court decision in *Bearder v. State*, 806 N.W.2d 766 (Minn. 2011); and legislation enacted in response to that decision.

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## The Genetic Privacy Law

In 2006, the legislature enacted a provision in the Minnesota Government Data Practices Act that governs the treatment of genetic information held by government entities. [Minnesota Statutes, section 13.386](#), (the “genetic privacy law”) defines “genetic information” broadly:

- (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.

The genetic privacy law classifies genetic information held by a government entity as private data on individuals. By definition, this classification means that genetic information held by a government entity is not public, but is accessible to the individual who is the subject of the data.<sup>1</sup>

As originally enacted, the genetic privacy law restricts government’s collection, storage, use, and dissemination of genetic information. The law requires that, unless otherwise *expressly* provided in law, a government entity must have written informed consent before collecting genetic information about an individual. Likewise, the genetic privacy law permits the government to store and use genetic information only for the period of time and the purposes to which the individual consented. With regard to dissemination of genetic information, the law requires written informed consent for dissemination, and it is permitted only to the extent necessary to accomplish the purpose to which the individual consented. Additionally, the genetic privacy law limits the duration of consent to disseminate genetic information and is valid to the lesser of either one year or the period specified in the consent.

To summarize, the genetic privacy law established a standard that applies broadly to cases where a government entity collects, stores, uses, or disseminates genetic information. However, the requirements of the genetic privacy law do not apply in cases where a government entity is handling information that is not “genetic information” or in cases where the law *expressly* authorizes or requires a government entity to handle genetic information in a manner different from that required by the genetic privacy law.

In the years following enactment of the genetic privacy law, a dispute arose as to whether the state’s newborn screening program, which is administered by the Minnesota Department of Health (MDH) and governed by [Minnesota Statutes, sections 144.125](#) to 144.128, was subject to the restrictions of the genetic privacy law or whether it fell under the “unless otherwise expressly provided in law” exception. Under the state’s newborn screening programs, every infant born in

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<sup>1</sup> [Minn. Stat. § 13.02](#), subd. 12.

the state is tested for heritable and congenital disorders, including hearing loss and critical congenital heart disease.

The dispute over whether the newborn screening program was governed by the genetic privacy law continued over the course of years and ultimately reached the Minnesota Supreme Court. The decision in that case, *Bearder v. State*, was issued in November 2011.<sup>2</sup>

## The *Bearder* Decision

### Background

Under the state newborn screening program, which began in 1965, hospitals and others in charge of caring for newborn infants are required to administer to every infant a test for heritable and congenital disorders. The Commissioner of Health determines the list of disorders for which infants are tested and the blood samples are sent to MDH for screening. Currently, MDH screens infants for more than 50 heritable and congenital disorders.

The program is conducted under the authority of [Minnesota Statutes, sections 144.125 to 144.128](#), which: (1) requires the Commissioner of Health to prescribe the manner of testing, recording, and reporting of newborn screening results; (2) requires those who perform the screenings to advise parents that blood samples and test results may be retained by MDH; and (3) permits parents to decline the screening or to require destruction of the samples or test results.<sup>3</sup> According to the facts set out in *Bearder*, if a portion of a blood sample remained after testing, the sample was retained indefinitely unless there was a request to destroy it.<sup>4</sup> More than 50,000 blood samples were used in studies for purposes beyond the initial screening, including studies to develop new tests and assuring quality of existing tests.<sup>5</sup>

As for test results, MDH asserted that federal law requires them to retain newborn screening test results for two years after testing, and then, following that two-year period, the test results were retained indefinitely unless there was a request to destroy them.<sup>6</sup>

Also of importance to the case, MDH contracted with Mayo Medical Laboratories to perform some of the screening tests on blood samples. Under that contract, Mayo was allowed to use excess blood samples for unrelated studies provided that the samples were de-identified or Mayo had received written consent from the children's parents.<sup>7</sup>

Plaintiffs in *Bearder* sued the state, the Commissioner of Health, and MDH alleging that certain MDH activities under the newborn screening program, specifically storing blood samples and

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<sup>2</sup> 806 N.W.2d 766 (Minn. 2011).

<sup>3</sup> [Minn. Stat. §§ 144.125 to 144.128](#); [Minn. Rules, parts 4615.0330 to 4615.0700](#) (2012).

<sup>4</sup> *Bearder*, *supra* note 2, at 770–71.

<sup>5</sup> *Id.* at 771.

<sup>6</sup> *Id.*; *see also* 42 C.F.R. § 493.1105 (2010).

<sup>7</sup> *Bearder*, *supra* note 2, at 771.

authorizing public health research on those samples without obtaining written informed consent, were in violation of the genetic privacy law. The plaintiffs included nine families with 25 children among them, born between 1998 and 2008, whose blood samples were collected and tested as part of the newborn screening program. The state initially moved to dismiss the case or, in the alternative, for summary judgment.<sup>8</sup> The district court granted the state's motion for summary judgment and found that: (1) the genetic privacy law did not apply to children born before August 1, 2006 (the effective date of the genetic privacy law); (2) blood samples were not "genetic information" under the genetic privacy law; and (3) the genetic privacy law did not supersede existing laws.

On appeal, the court of appeals affirmed the lower court's grant of summary judgment and found that MDH had broad statutory authority to operate the newborn screening program and that the genetic privacy law did not apply. The court of appeals also concluded that using blood samples for purposes other than screening might be a violation, but that the appellants had not provided specific facts to support their claim that the state was using blood samples improperly.

## Issues Presented

The Minnesota Supreme Court considered the following questions:

- Are blood samples collected and stored by MDH "genetic information," as that term is used in the genetic privacy law, requiring MDH to obtain written informed consent before it may use, store, or disseminate the blood samples that remain after the newborn health screening is complete?
- Is MDH exempted from the restrictions of the genetic privacy law because they are "expressly provided" with authority to collect, use, store, and disseminate the information under the newborn screening program?

## Decision of the State Supreme Court

### Blood samples are "genetic information."

The Minnesota Supreme Court held that blood samples collected by MDH are "genetic information" because they fit under the definition of "biological information collected from an individual" under [Minnesota Statutes, section 13.386](#), subdivision 1, paragraph (b).<sup>9</sup> Therefore, the genetic privacy law applies to the blood samples.<sup>10</sup>

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<sup>8</sup> A judgment granted by the court on a claim about which there is no genuine issue of material fact and upon which the state (in this case) prevails as a matter of law. Summary judgment results in speedy disposition of the case without trial.

<sup>9</sup> *Id.* at 774.

<sup>10</sup> There was a dissenting opinion in this case, written by Justice Anderson and joined by two other justices, that would have found that blood samples are not included in the definition of "genetic information" and, therefore, are not subject to the genetic privacy law.

As described above, the genetic privacy law provides a broad, two-part definition of 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.<sup>11</sup>

The Minnesota Supreme Court found that the statutory definition is unambiguous and that blood samples collected by MDH unquestionably contain biological information. The court reasoned that 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.”<sup>12</sup> Further, it would be impossible to collect, use, store, or disseminate the blood samples without also collecting, using, storing, or disseminating the genetic information contained in those samples. Therefore, the court concluded that the definition provided in [Minnesota Statutes, section 13.386](#), subdivision 1, paragraph (b), includes the actual samples as “biological information.”<sup>13</sup>

**Newborn screening statutes do provide an express exception for certain MDH activities.**

Having found that blood samples collected by MDH are genetic information and, therefore, are subject to the genetic privacy law, the court turned to the question of whether MDH was exempt from the restrictions of the genetic privacy law because it was “expressly provided” with authority to collect, use, store, and disseminate the information under the newborn screening program.

The court found that the newborn screening statutes do provide an “express exception” to the genetic privacy law, but only to the extent that MDH is authorized to: (1) administer newborn screening by testing samples for heritable and congenital disorders; (2) record and report test results; (3) maintain a registry of positive cases for follow-up services; and (4) store test results as required by federal law.<sup>14</sup>

As to the issue of collection of blood samples, the genetic privacy law requires “written informed consent of the individual” prior to collecting genetic information.<sup>15</sup> The newborn screening

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<sup>11</sup> [Minn. Stat. § 13.386](#), subd. 1.

<sup>12</sup> *Bearder*, *supra* note 2, at 773.

<sup>13</sup> *Id.* at 774.

<sup>14</sup> *Id.* at 776.

<sup>15</sup> [Minn. Stat. § 13.386](#), sub. 3.

statutes authorize MDH to conduct testing and provide for the destruction of samples;<sup>16</sup> therefore, the court found that the newborn screening statutes authorize MDH to collect blood samples in order for MDH to conduct the testing that is required by statute.<sup>17</sup>

With regard to the use of blood samples, the genetic privacy law limits use to “purposes to which the individual has given written informed consent.”<sup>18</sup> However, the newborn screening statutes specifically authorize MDH to conduct “tests for heritable and congenital disorders” and require MDH to maintain a registry for follow-up services.<sup>19</sup> Therefore, the court determined that MDH has express authority to use the blood samples without obtaining written informed consent, but only to the “extent necessary to conduct tests for heritable and congenital disorders and conduct follow-up services.”<sup>20</sup> Further, the court concluded that use of genetic information for any purpose other than screening newborn infants and follow-up services requires written informed consent.<sup>21</sup>

The genetic privacy law also limits storage to the period of time to which the individual gave written informed consent.<sup>22</sup> The newborn screening law requires MDH to “maintain a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services.”<sup>23</sup> The court concluded that this creates an express exception to the genetic privacy law, so MDH can store blood samples from positive test results pursuant to the newborn screening statutes.<sup>24</sup>

Finally, the genetic privacy law limits dissemination of genetic information by requiring “the individual’s written informed consent” or permitting dissemination “if necessary in order to accomplish purposes” for which consent was given.<sup>25</sup> The Commissioner of Health has express authorization to report test results and to contract with a private entity to perform the department’s functions.<sup>26</sup> Therefore, MDH may disseminate blood samples or genetic information only for the purpose of reporting test results.<sup>27</sup>

The Minnesota Supreme Court then remanded the case to district court to determine whether appellants were entitled to any remedies consistent with the Supreme Court opinion.

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<sup>16</sup> Minn. Stat. §§ 144.125; 144.128.

<sup>17</sup> *Bearder*, *supra* note 2, at 775.

<sup>18</sup> Minn. Stat. § 13.386, subd. 3, cl. (2).

<sup>19</sup> Minn. Stat. §§ 144.125, subd. 1; 144.128, para. (a), cl. (3).

<sup>20</sup> *Bearder*, *supra* note 2, at 775.

<sup>21</sup> *Id.*

<sup>22</sup> Minn. Stat. § 13.386, subd. 3, cl. (3).

<sup>23</sup> Minn. Stat. § 144.128, para. (a), cl. (3).

<sup>24</sup> *Bearder*, *supra* note 2, at 775.

<sup>25</sup> Minn. Stat. § 13.386, subd. 3, cl. (4).

<sup>26</sup> Minn. Stat. §§ 144.125, subd. 1; 144.0742.

<sup>27</sup> *Bearder*, *supra* note 2, at 776.

## Legislative Response

Following the *Bearder* decision, the legislature passed related statutory changes in two parts. First, in 2012, legislation was passed to clarify the Commissioner of Health's authority and duties under the newborn screening program.<sup>28</sup> That legislation also added a temporary public health exception to the genetic privacy law. The public health exception permitted MDH to continue for approximately one year its other activities with regard to collecting, storing, using, and disseminating genetic information, including biological information or specimens.<sup>29</sup> This exception was intended to give MDH time to determine whether there were other public health activities at the department "where express authorization is not already provided in law," which was required by the genetic privacy law and the *Bearder* decision.<sup>30</sup> The legislature required MDH, after its analysis of existing activities, to propose any legislation necessary to expressly authorize collection, storage, use, and dissemination of genetic information for existing public health activities unrelated to the newborn screening program.<sup>31</sup>

In 2013, MDH brought forward legislation as required by the 2012 law. As enacted, the law applies to all MDH activities, other than the newborn screening program, that involve the collection, use, storage, or dissemination of biological specimens or health data.<sup>32</sup> The law provides MDH with broad authorization to "collect, use, store, and disseminate biological specimens and health data to conduct program operations activities, public health practice activities, and health oversight activities."<sup>33</sup> The statute expressly states that, "unless required under other applicable law, consent of an individual is not required" for these activities.<sup>34</sup>

The 2013 law also amended the genetic privacy law by specifying that the newborn screening program is subject to the requirements of the genetic privacy law, consistent with the *Bearder* decision, but that other public health programs involving biological specimens and health data are not subject to the genetic privacy law, but are governed by the newly enacted [Minnesota Statutes, section 144.192](#).

Several other provisions related to the state's newborn screening programs and other MDH activities that involve biological specimens were enacted as part of the 2013 data practices omnibus bill. Those provisions include the following:

- (1) requiring MDH to take an annual inventory of all biological specimens, registries, and health data and databases collected or maintained by the

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<sup>28</sup> [Laws 2012, ch. 292](#), art. 4, §§ 3 to 11, 22, 24.

<sup>29</sup> *Id.* § 1.

<sup>30</sup> *Id.* § 23.

<sup>31</sup> *Id.*

<sup>32</sup> The terms "biological specimen" and "health data" are defined in [Laws 2013, ch. 82](#), § 11, subd. 1.

<sup>33</sup> [Laws 2013, ch. 82](#), § 11.

<sup>34</sup> *Id.*

department and to provide storage schedules for health data and biological specimens<sup>35</sup>

(2) changes to the newborn hearing screening program, including specifying that activities under this program shall not be construed as newborn screening conducted under [Minnesota Statutes, sections 144.125](#) to 144.128, and that data collected under the hearing screening program are not genetic information<sup>36</sup>

(3) requiring MDH to conduct a study to evaluate the scientific and medical validity of a comprehensive and sustainable long-term storage and use plan for test results collected under the newborn screening program<sup>37</sup>

For more information about newborn screening, see the House Research publication [Minnesota Newborn Screening Programs, June 2012](#). For more information about data practices, visit the state government area of our website, [www.house.mn/hrd/](http://www.house.mn/hrd/).

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<sup>35</sup> *Id.* at § 12.

<sup>36</sup> *Id.* at §§ 13 to 16.

<sup>37</sup> *Id.* at § 39.