

## Vote NO - HF 1760 will REPEAL Genetic Privacy Rights and Eliminate Informed Written Parent Consent Requirements

### Focus on lines 1.18 to 2.8 of the bill.

This legislation is **not** about newborn screening (**genetic testing of infants**). HF 1760 changes control over genetic test results and the DNA of newborn citizens *after* the testing is done. If passed, State government will be given first dibs to newborn DNA. These four lines repeal *current* genetic privacy rights and informed written consent requirements regarding the genetic test results, and DNA of newborn citizens. The remaining newborn screening sections are what the MN Dept. of Health (MDH) promises to do *after* these rights are eliminated.

**MDH is violating the state genetic privacy law.** On March 23, 2007, a judge (ALJ) ruled that MDH is violating state law by not obtaining parent consent prior to storage, use or dissemination of newborn genetic tests and baby DNA as required by M.S. 13.386. MDH refused to comply. On March 11, 2009, nine families sued MDH. This bill eliminates the law that MDH refuses to follow.

### These four lines will eliminate *current* citizen rights by:

- Repealing *current* genetic privacy rights for children currently in the baby DNA warehouse and the State genetic registry (> 819,000 children in DNA warehouse; > 1.5 million in State genetic registry).
- Repealing genetic privacy rights at birth for all future generations. *Government has first dibs on DNA.*
- Eliminating *current* informed written consent rights for *over*-collection, storage, use, and dissemination of newborn genetic test results and DNA. *This includes test development research.*
- Eliminating *current* strong legal protections (including the right to sue) under Chapter 13 (Government Data Practices Act) by exempting collection, storage, use and dissemination from Chapter 13.
- Excluding DNA from state genetic privacy law protections. By parsing out 'blood specimens' from 'genetic information' (line 2.6), the bill claims the specimen **and its DNA** are **not** genetic information and thus not protected by the genetic privacy law (13.386) which only protects 'genetic information.'
  - If passed, this would set a precedent, allowing DNA analysis without patient consent of all biological specimens left behind at clinics, hospitals, and laboratories. This would include: tissues, organs, blood, urine, skin cell, hair, etc.

1.18 Section 1. Minnesota Statutes 2008, section 13.386, subdivision 3, is amended to read:  
 1.19 Subd. 3. **Collection, storage, use, and dissemination of genetic information. (a)**  
 1.20 Unless otherwise expressly provided by law, genetic information about an individual:  
 1.21 (1) may be **collected** by a government entity, as defined in section 13.02, subdivision  
 1.22 7a, or any other person only with the written informed consent of the individual;  
 1.23 (2) may be **used** only for purposes to which the individual has given written  
 1.24 informed consent;  
 1.25 (3) may be **stored** only for a period of time to which the individual has given written  
 1.26 informed consent; and  
 1.27 (4) may be **disseminated** only:  
 1.28 (i) with the individual's written informed consent; or  
 2.1 (ii) if necessary in order to accomplish purposes described by clause (2). A consent  
 2.2 to disseminate genetic information under item (i) must be signed and dated. Unless  
 2.3 otherwise provided by law, such a consent is valid for one year or for a lesser period  
 2.4 specified in the consent.  
 2.5 (b) Notwithstanding paragraph (a), the Department of Health's collection, storage,  
 2.6 use, and dissemination of genetic information and blood specimens for testing infants for  
 2.7 heritable and congenital disorders are governed by sections 144.125 to 144.128.  
 2.8 **EFFECTIVE DATE.** This section is effective the day following final enactment.

Current MN  
 Genetic  
 Privacy Law  
 (Sec. 13.386,  
 subd. 3, which  
 is in Chpt 13)

Proposed  
Repeal of  
 Genetic  
 Privacy Law  
 regarding  
 storage, use,  
 and  
 dissemination  
 of newborn  
 test results and  
 DNA

**Vote NO on HF 1760!**

**Table 1. Use of Baby Blood for Research  
Without Parent Permission**

Very Willing	11%
Somewhat Willing	17%
Somewhat Unwilling	16%
Very Unwilling	<b>56%</b>

**Table 1 data from:** Beth A. Tarini, MD, MS [Assistant Professor of Pediatrics, Child Health Evaluation and Research Unit, University of Michigan]. “**Not Without Consent:** Parents’ Willingness to Permit Use of NBS Sample for Research & Storage.” Powerpoint Presentation from 2008 Newborn Screening and Genetics Testing Symposium, November 5, 2008.

Furthermore, of those *not* willing to permit research, 33% were willing to have their baby’s blood specimen stored **and 67% were not willing to have their baby’s blood stored.**

### Concerns to Consider

**Mary Ann Baily, The Hastings Center (NY), 2008, wrote:**

“The United States has sturdy societal values respecting the rights of individuals to decide what treatments they will have, whether they will participate in research, and what can be done with their personal information and their bodily tissues, including blood samples. (Because only a fraction of each blood sample taken for newborn screening is used in the screening, the remainder is a valuable potential resource for research and program evaluation.) Since parents are normally considered the appropriate people to make decisions on behalf of their children, parental informed consent is ethically required for the medical treatment of children and for the involvement of children in research.” ...[T]here is an urgent need to clarify the ethical requirements with respect to parental consent for using leftover blood spots for newborn screening quality improvement, research related to newborn screening, and research on questions not directly related to newborn screening.” *[emphasis added]*

**From The Changing Moral Focus of Newborn Screening, the December 2008 report issued by The President’s Council on Bioethics:**

“Suppose that expanded screening of an infant reveals not a fatal and incurable disease but instead a host of genetic variants, each of which merely confers elevated risk for some condition or other. Who is to say at what point an uncovered defect becomes serious enough to warrant preventing the birth of other children who might carry it? At what point have we crossed the line from legitimate family planning to capricious and morally dubious eugenics?” *[emphasis added]*

**J.A Gupta, in the *Journal of Bioethical Inquiry*, November 22, 2007, writes:**

“I then discuss the recently launched newborn screening programme as an example of public eugenics.”

**Søren Holm writes in the book, A Companion to Genethics:**

"Newborn screening, which is usually mandated by governments to identify and treat diseases of infancy, has been limited, *for ethical reasons*, to disorders where early diagnosis and treatment would benefit the newborn, but with multiplex tests the focus of testing may be expanding to include some nontreatable disorders. Kitcher (1996) foresees the day when parents will receive an entire ‘genetic report card’ at the child’s birth predicting lifetime health." *[emphasis added]*

**“NIH Data Sharing Policy for Genome-wide Association Studies” Steven Hirschfeld, 5/10/07:** “Genomic data is the ultimate identifier: what is not identifiable now is plausible to be so in the future.”

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