

# Impact of Lawsuit Settlement and Recent Legislation to the Minnesota Newborn Screening Program

Minnesota Newborn Screening Program

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# Genetic Privacy Laws

- Genetic Information Nondiscrimination Act (GINA)- 2008
- Each State is Different
  - 30+ states have so-called genetic privacy laws
    - Mostly focused on health insurance discrimination on the basis of genetic information
  - Many of these laws make it illegal to:
    - Collect, analyze, transfer, or store genetic information ***without consent***
    - Definitions of “genetic information” vary



# MN Statutes, 13.386: MN's Genetic Privacy Law

- Passed in 2006
- Defines “genetic information” as:
  - Information about an identifiable individual derived from an alteration of a gene 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
  - Also means medical or biological information collected from an individual about a particular genetic condition used to provide medical care
- Restricts collection, storage, use, and dissemination
  - Only with informed consent unless otherwise expressly provided by law



# MN Statutes, 144.125: MN's Newborn Screening Law

- Newborn Screening includes:
  - Allows testing for heritable and congenital disorders
  - Determination of tests to be administered
  - Allows parents to refuse screening or testing to be completed but the dried blood spot and all tests destroyed after testing has been completed
  - Silent on collection and storage of dried blood spots
  - Silent on QA/QC/QI



# Rule Making Observation

- 2006-2007
  - Rule Making process reveals potential conflict with 13.386
  - MDH tries to resolve apparent conflict between statutes
  - Bill vetoed by then-Governor



# 2009 Lawsuit

Lawsuit filed *Bearder v State of Minnesota*

- Alleges MDH in violation of 13.386 by storing dried blood spots and using them for purposes other than newborn screening

MDH's Motion to Dismiss

- Granted in the District Court
- Upheld in the Court of Appeals



# MN Supreme Court Decision

November 16, 2011

- Reversal of decision; ruled NBS did not have express authority to store samples beyond testing

## Ruling

- The Court held that blood samples are genetic information.
- The Court also treated NBS test results as genetic information.
- Supreme Court remanded the case to the District Court for determination of remedies.
- Prohibited use of bloods spots for QA/QC/QI



# 2012 Legislation

- Sought to reverse the worst effects of the MN Supreme Court Decision
- Passed unanimously in House and Senate
- Specimen Destruction
  - Blood Spots with Negative Test Results at 71 Days
  - Blood Spots with Positive Test Results at 24 Months
  - All Test Results 24 Months After Report Date
- Required Prenatal Educations/Discussion
- Option to consent specimens for long-term storage and use





# 2012 Legislation Continued

- Program Operations Reinstated
  - All laboratory quality control and quality assurance activities
  - Calibration and testing of equipment
  - Evaluating and improving the accuracy of newborn screening tests for conditions approved for screening by MDH
  - Validation of equipment and screening methods
  - Continuity of operation drills to ensure testing can continue in the event of an emergency



# Litigation

- Remained ongoing after Supreme Court Decision as plaintiffs sought damages
  - 3 lawsuits filed in total:
    - *Bearder v State; Skaja v State* (consolidated); *Anderson v State*
    - NBS Advocates tried to intervene, but were denied
- Set-up pre-Supreme Court and post-Supreme Court specimens and pre-legislation and post-legislation specimens:
  - Specimens and test results treated differently
  - Very difficult to educate public and providers
  - Even more difficult to keep straight!



# Lawsuit Settlement

- December 30, 2013
- Portion of attorney fees were paid, but NO remedies to the plaintiffs were awarded and NO liability determined.
- All blood specimen cards of the minor Plaintiffs were transferred to the parents within 14 days
- Court lifted litigation hold, so in order to comply with Supreme Court decision, MDH:
  - Destroyed ~**1 million** blood spots received prior to 11/16/2011
  - Destroyed **9,782,333** blood spot test results from any specimen older than 2 years



# 2014 Legislation

## Legislation driven by MNAAP

- Restoration bill for retention of blood spots AND test results
  - Sets retention periods to indefinite
  - Holds new test development to Program Operations
  - Opt-in model for non-newborn screening related research

The screenshot shows the website for the American Academy of Pediatrics (AAP) Minnesota Chapter. The page is titled "Restoring Minnesota's Newborn Screening Program" and is dated "Updated 7/31/14". The main content area includes a "Quick Links" sidebar with options for "Videos, Webinars and Podcasts", "Helpful Tools and Resources", and "Home: Newborn Screening". The main text discusses the "2014 Newborn Screening Law" signed by Governor Mark Dayton on May 6, 2014, which allows the Minnesota Department of Health (MDH) to retain blood spots and test results indefinitely unless parents request their destruction. It also addresses "What changes went into effect on August 1?" and "What about babies born before August 1?".



# Public Health Impact- Negatives

## Loss of Dried Blood Spots

- Destruction of 1 million + dried blood spots
- False negatives
- Fulfilling parental request to retrieve specimens for extended storage and use before the 71 day destruction

## Loss of Data

- Destroyed 9 million + test results- hard copy and electronic
- False negatives
- False positives
- Trend analysis
- Refining cut-off values
- Less accountability
- Redaction of validation and verification data



# Public Health Impact- Negatives

## Long Term Follow-Up

- Loss of data
- Building forward with new legislation

## MDH Public Health Laboratories

- Update statute language to include explicit authority

## Staff Time

- Lawsuit Discovery
- Destruction of dried blood spots and test results
- Suspended program operations
- Delayed SCID implementation
- Consents management



# Public Health Impact- Positives

## Education

- Prenatal education
- Birth Facility requirements for giving information to parents about newborn screening and the process
- Community communication about the program

## Clearly Defined State Statute

- Defined program operations
- Defined consent process for research use only

## Data Practices and Records Retention

- Updated and clarified records retention schedule for the program
- Not keeping data for the sake of keeping data



# Challenges

“I expected times like this-but I never thought they’d be so bad, so long, and so frequent.”

*Unknown*





“In times of great stress or adversity, it's always best to keep busy, to plow your anger and your energy into something positive.”

[Lee Iacocca](#)



