

Overview of Litigation Regarding the Retention and Use of Residual Newborn Screening Dried Blood Samples

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Why We Need to Pay Attention

- Issue has not gone away
- Overview of Legal Issues
- Additional Parental Concerns

Science Translational Medicine Article

- *“The public debate about this issue has included little discussion about the destruction of a potentially valuable public resource that can be used for research that may yield improvements in public health. The research community must advocate for policies and infrastructure that promote retention of residual dried blood samples and their use in biomedical research.”*

Blogosphere

- **“System Announces It Will Use DNA Stolen From Babies (www.beapatriot.wordpress.com)”**
- **Written by Dave, retired Air Force**
- “After years of denying that blood samples were taken at birth, bioethicists are arguing for the State’s right to seize newborns’ blood samples for a global database.”
- “For years, the system denied that blood samples from newborns were being taken at birth and databased into DNA ‘warehouses.’ Now, that period of denial is over, and the same system is instead declaring its right to do so.”

Hostile Email

- 12/23/12 Email to Michelle Lewis
- Subject: Stop it
- Email text: “Could you please stop thinking my children's blood is yours? Leave me alone. Leave my kids alone. Keep your hands to yourself and get out of my life. Thank you.”

Overview of Litigation Re DBS Retention and Use-Texas

- Five families brought a class action lawsuit against state DOH on behalf of all infants born in state
- Claimed that the practice of retaining and using de-identified DBS w/o explicit parental consent violated constitutional right to privacy and right to be free from search and seizure
- When lawsuit was initiated, no consent req'd and parents not given option to refuse
- New law passed to implement opt-out procedures

Texas Litigation

- Parties settled-part of settlement agreement was to destroy 5 million DBS
- Then it was reported that DOH had given samples to U.S. Armed Forces Pathology Lab
- Plaintiffs claimed that this information had been withheld from them during settlement negotiations
- A second lawsuit was filed-held to be moot b/c law had changed and the plaintiff's children's DBS had never been released to other entities & had been destroyed
- Tx policies changed again, now requires consent to release DBS for "external public health research"
- Legal issues never adjudicated (constitutionality of opt-out)

Minnesota Litigation

- *Bearder v. State of Minnesota*
- 9 families sued state alleging multiple claims
- Plaintiffs initially lost at District Court level and on appeal
- Minnesota Supreme Court held that state practice of retaining DBS and using them for secondary research w/o explicit parental consent violated genetic privacy provisions of state government data practices act (opt-out mechanism was not ok)

Government Data Practices Act

Definitions 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. . . (emphasis added)

“Genetic Information” Defined

- 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. Sec. 13.386, subd. 1. (2006). (emphasis added)

Minnesota Supreme Court Decision

- GPA restricts the collection, use, storage and dissemination of blood samples collected pursuant to nbs statutes
- Ct held that “an individual’s blood samples are biological information subject to protection” under the GPA
- DNA w/l sample that brings sample w/l protection
- Genetic info includes the biological info itself, not just the analysis of the info

Impact of Decision

- QA: Commissioner's power to conduct health studies does not include unlimited authority to use genetic info obtained fr 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 informed consent."
can't perform qa activities w/o consent
- Only dissemination permitted is reporting of results

Current Minnesota Law

Minnesota Statute 144.125 (2012)

Subd. 5. **Newborn screening program operations.** (a) "Newborn screening program operations" means actions, testing, and procedures directly related to the operation of the newborn screening program, limited to the following:

- (1) confirmatory testing;
- (2) laboratory quality control assurance and improvement;
- (3) calibration of equipment;
- (4) evaluating and improving the accuracy of newborn screening tests for conditions approved for screening in Minnesota;
- (5) validation of equipment and screening methods; and
- (6) continuity of operations to ensure testing can continue as required by Minnesota law in the event of an emergency.

(b) No research, public health studies, or development of new newborn screening tests shall be conducted under this subdivision.

- Boundary between “program operations” and research?

Concerns of Plaintiffs in *Bearder*

- 1st line of Bearder memorandum: “Defendants violated the public’s trust and violated the public’s right to privacy and bodily integrity.”
- “MDH will do whatever it wishes to effect what it assumes is best for the public.”
- “Plaintiffs fear the use of their blood specimens and test results by government and private entities for unknown purposes.”
- Bearder: objected to Mayo being allowed to keep DBS and perform its own tests on them
- Objected to Mayo being able to keep results-so DBS AND results
- “This lawsuit is not about ending newborn screening.”

Bearder Concerns

- Plaintiffs did not distinguish between QA and research—include QA in research activities that state had undertaken with DBS
- De-identification of samples—Did not matter that DBS were de-identified, argued that the law does not require that the information be about an identifiable individual—need consent even if de-identified
- Plaintiffs said not clear what state means when it says samples have been de-identified—de-identification process and standards not defined
- Concerned that state kept the link, concerned about possible re-identification, did not want state at Honest Broker

Bearder Concerns

- Impression that DBS were being sold to private 3d parties
- Argued that plaintiffs had a property right in their genetic material-but conceded no precedent in Minnesota

Beleno Concerns

- Samples stored “for purposes of undisclosed research unrelated to the purposes for which the infants’ blood was originally drawn, without the knowledge or consent of the infants’ parents.”
- Defendants “never disclosed specifically the purposes or methodologies of such research other than that they are unrelated to the purpose for which the infants’ blood was originally drawn.”

Beleno continued

- “Plaintiffs are concerned about the potential for misuse of that information and fear the possibility of discrimination against their children and perhaps even relatives through the use of such blood samples and research activities thereon.”
- Under current policy, state can use DBS for “cancer research, lab equipment calibration, and other undisclosed matters indefinitely, without the knowledge or consent of their parents.”

Beleno Pleadings

- Violates “standard, mandatory medical research protocols of first obtaining informed consent from subjects before they are studied.” —but de-identified samples are not considered human subjects research & federal human subjects research protections that require informed consent (as for identifiable subjects) do not apply
- “Nor have they disclosed what kind of financial interests or transactions are involved, such as taxpayer expense or whether the samples are sold.”

Beleno Pleadings

- Asked court to compel state to disclose for what purpose they used the DBS of plaintiffs' children and of the class and disclose all financial transactions.
- Wanted to know what happened to their children's DBS
- "Plaintiffs do not object to the state's mandatory newborn screening program so long as safeguards are in place to destroy an infant's samples within a reasonable period of time.

From Press Release of *Bearder* Attorneys

- “Discovery also revealed that a number of proposed contracts for testing of the retained newborn blood samples would potentially benefit third-parties through the right to benefit from commercial applications of their research.”
- “Insisting on written, informed consent for storage and research on newborn blood and DNA continues to be a paramount concern in this day and age where the medical industry is willing to put profits ahead of privacy.”
- “Once the government has control of blood and DNA, there is no telling what may ultimately happen to it.”

Minnesota Class Action Suits

- *Anderson v. State of Minnesota*
- *Skaja v. State of Minnesota*
- Suing for injunctive relief (to require “enforcement of the prohibition on the storage, use, and dissemination of genetic information, w/o informed consent”) and recovery of damages incurred as a result of DOH’s unlawful conduct

Minnesota Class Action Suits

- Allege that the state “conducted tests and other research on the Plaintiffs’ genetic information after the initial screening of the blood samples for diseases without obtaining Plaintiff’s written consent.”
- --this could include pilot studies
- Allege damages greater than \$50,000
- Exemplary damage of \$1,000-\$15,000 for each violation of the GPA.

Concluding Thoughts

- These activists have been extremely successful-at persuading courts and legislatures. Their voices have been the loudest.
- Activities have been harmful to nbs programs, diverted resources, negative attention.
- These issues are not going away.
- States need to take their concerns seriously.
- Many instances, reflect lack of understanding, but this points to greater need for transparency and education about QA and research enterprise to educate reasonable people/legislators/judges.