



# Citizens' Council on Health Care

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**DUPLICATE**

July 12, 2007

Commissioner Dianne Mandernach  
Minnesota Department of Health  
625 N. Robert St.  
St. Paul, MN 55155-2538

**RE: Chief ALJ Krause's Reconsideration Order on Newborn Screening, July 3, 2007**

Dear Commissioner Mandernach,

On July 3, 2007, Chief Administrative Law Judge Raymond R. Krause denied your request for reconsideration of Finding 67 of Judge Barbara Neilsen's ALJ Report on Newborn Screening, dated March 27, 2007. He agreed that the MDH newborn genetic testing program is not exempt from the state's genetic privacy law (M.S. 13.386).

Judge Neilsen's Finding 67 states in part:

“There is no express authorization in the newborn screening statute for the Department's current practice of retaining the information indefinitely without consent and permitting the information to be used without consent for purposes other than the detection, treatment, and follow-up of heritable and congenital disorders as contemplated by the newborn screening statute.”

“[T]he newborn screening statute does not expressly authorize the Department to store genetic information indefinitely or disseminate that information to researchers without written informed consent provided by parents. As a result, Minn. Stat. § 13.386 does apply to the proposed rules and the failure to incorporate its requirements into parts 4615.0550 and 4615.0600 constitutes a defect in the rules.”

In his Reconsideration Order, Chief ALJ Krause wrote in part:

“There is no express provision in law that exempts the blood spots from the coverage of Minn. Stat. § 13.386.”

“[R]econsideration of Finding 67 of the ALJ Report is denied.”

Thus, the health department's executive decision 10 years ago to claim ownership to the DNA of every Minnesota-born baby had no legal standing. The retention and dissemination of baby blood has been done outside the laws of Minnesota. It should never have been permitted.

The Department's recent attempt to use policy arguments to convince Chief Krause to rule outside the parameters of state law in favor of the Department (June 27, 2007 reconsideration request) was a sign of bad faith to the Minnesota public— and specifically to all parents and children whose blood and DNA are being held by the Department without legal authority, and in most cases, without their knowledge or consent. We are therefore pleased that Chief Krause informed you in his Order that policy judgments are not the role of administrative law judges:

“The role of the administrative law judge is not to make policy judgments nor is that a relevant factor for reconsideration.”

Thus far, MDH has laid claim to the blood and DNA of at least 670,000 babies according to the *St. Paul Pioneer Press* (4/11/07). By its own admission, your department has also provided baby blood and DNA to genetic researchers without parent knowledge or consent.

**CCHC now calls on you, as Commissioner of Health, to immediately do the following to bring the Department into compliance with state law:**

- 1) Destroy all newborn blood specimens held and retained by MDH without the written informed consent of parents.
- 2) Demand immediate recall of all newborn blood specimens that were disseminated to the Mayo Clinic, the University of Minnesota, and other researchers without the written informed consent of parents.
- 3) Destroy all recalled newborn blood specimens immediately upon receipt from Mayo, the University of Minnesota and other researchers.
- 4) By August 9, 2007, issue a press release affirming to the public that all retained and disseminated newborn blood specimens have been destroyed, and are no longer property of the State of Minnesota.

As your staff said in testimony before this year's Minnesota Senate, without an exemption from the state's genetic privacy law, the Department would be required to destroy the newborn blood specimens. That exemption has been denied.

In addition, we call on you to immediately address the serious defects found by Judge Neilsen in the proposed newborn screening rule, and to incorporate each of her corrective actions into the final newborn screening rule.

No parent should be in the dark about newborn genetic testing.

The public expects transparency from the Minnesota Department of Health. Unfortunately, as we have learned with the recent discovery of the Department's delay in release of cancer data on miners, your department is willing to purposely withhold public data from the public—and to chide public health staff for open communications. If the Department is serious about garnering the public's trust, it must be transparent about all its activities, including newborn genetic testing.

We are gratified that Judge Neilsen and Chief Administrative Law Judge Krause ruled that the Minnesota Department of Health is not outside state law. Minnesota citizens expect that their government will obey the law.

It is now time for you and your department to begin obeying Minnesota's newborn screening and genetic privacy laws.

By Thursday, July 19, 2007 we expect a letter from you confirming your intent to carry out numbers 1 - 4 above and your schedule to destroy all newborn blood samples.

Sincerely,

A handwritten signature in black ink, appearing to read "Twila Brase". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Twila Brase  
President