May 14, 2020

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Dear Chairman Alexander,

Thank you for your consideration of the privacy issues concerning newborn screening and the issues surrounding state government storage, use and sharing of the newborn’s dried blood spots (DBS). We greatly appreciate that you have added language to the Newborn Screening Saves Lives Reauthorization Act of 2019 that will require parent consent for the use of DBS—newborn DNA—in federally funded research.

Most states conduct newborn (genetic) screening on every newborn within 48 hours of birth. After delivery, a few drops of blood from the baby’s heel are squeezed onto a card with special filter paper, sent to the state’s public health laboratory and tested for all or most of the 35 genetic conditions recommended by a national panel. While most parents who know about the program—many don’t—support newborn screening, most do not understand it is a government genetic testing program or that the newborn’s dried blood spots and test results can be used and shared without parental consent for purposes beyond newborn screening.

These blood spots contain the private genetic makeup of the baby and should not be shared or used, without parental consent, for research or other purposes. Yet today, California is selling newborn DNA to researchers for about $20 to $40 per blood spot. And the state of Indiana has given researchers access to 666 banker boxes of DBS (newborn DNA) collected from babies born over a 23-year period. Many of these children are now adults. No consent is required.

When parents discover that their child’s DNA has been stored by the state, shared and used by researchers, they often sue. To date, parents in Minnesota and Texas have filed lawsuits and won. Parents in Michigan are currently pursuing a case against the state’s biobank and have won a recent victory in federal court.

Newborns cannot protect themselves from genetic analysis and exploitation. Congress was right in 2014 to protect these newborn citizens by adding a parental consent requirement to the Newborn Screening Saves Lives Reauthorization Act of 2014 (plus language acknowledging the use of DBS as research on human subjects) with the understanding that these protections would be included in the final Common Rule, which governs federally-funded research. Unfortunately, the final Common Rule, issued on the last day of the previous administration, specifically eliminated the parental consent requirement.
Thus, we appreciate your support for making these privacy and parental consent protections a permanent part of federal law. The genetic privacy rights of the four million babies born in America each year are at stake.

Please consider the information attached to this letter as you work with members of your committee to finalize the Newborn Screening Saves Lives Reauthorization Act of 2019.

On behalf of the undersigned organizations, we thank you for your attention to this critical genetic privacy issue and your strong support for requiring parental consent for the use of newborn DNA by federally-funded researchers.

Sincerely,

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