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House Passes Newborn Screening Bill with Informed Consent Amendment; Heads to President’s Desk for Signature

Citizens’ Council for Health Freedom’s Twila Brase Says Parents Will Now Be Informed about Research on Their Newborn Baby’s DNA

ST. PAUL, Minn.—The U.S. House of Representatives last night passed by unanimous consent the “Newborn Screening Saves Lives Reauthorization Act of 2014” (H.R. 1281), with the inclusion of an amendment that requires that parents give informed consent before their babies’ DNA can be used for federally funded research. Now, the last step for the measure to become law is a signature from the President.

Citizens’ Council for Health Freedom (CCHF, www.cchfreedom.org), a Minnesota-based national organization dedicated to preserving patient-centered health care and protecting patient and privacy rights, led by president and co-founder Twila Brase, has been advocating on both the state and national levels for parental consent requirements for the storage and use of newborn blood samples.

“This is a critical victory for privacy rights for newborn babies,” Brase said. “It’s important to note, however, that this new law stipulates that parents must be informed about only federally funded research and there is still no consent required for government storage of DNA. Furthermore, the measure is good only until the National Institutes of Health issues the final language of the Common Rule, which governs human-subject research. This final wording has not yet been completed; therefore, parents must still keep abreast of their rights when they enter the hospital to welcome a new member to the family.”

Furthermore, Brase added, newborn blood spots will be protected under the measure beginning 90 days after the enactment of the law. For three months after enactment, therefore, newborn blood spots will still be subject to research, and parents will not legally have to be informed about how their baby’s DNA is used.

She added that states can also pass their own laws that are more protective than this federal law, and she believes states should do so.
Nevertheless,” she said, “the federal law sets the standard. This is the first time newborn dried blood spots are mentioned in federal law, and it connects them directly to human beings because it requires that they be considered human research subjects without exception.”

Brase says it is a step in the right direction, as many parents are unaware that their baby’s private genetic information is stored indefinitely and possibly used for research without their consent.

The U.S. Senate passed the bill on Monday evening, and the new Amendment, sponsored by Sen. Rand Paul (R.-Ky.), added language that will require informed consent for federally funded newborn screening research, specifically, “Research on newborn dried blood spots shall be considered research carried out on human subjects meeting the definition of section 46.102(f) (2) of title 45, Code of Federal Regulations, for purposes of Federally funded research conducted pursuant to the Public Health Service Act until such time as updates to the Federal Policy for the Protection of Human Subjects (the Common Rule) are promulgated pursuant to subsection (c). For purposes of this subsection, sections 46.116(c) and 46.116(d) of title 45, Code of Federal Regulations, shall not apply.”

The Amendment goes on, “Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed regulations related to the updating of the Federal Policy for the Protection of Human Subjects (the Common Rule), particularly with respect to informed consent. Not later than 2 years after such date of enactment, the Secretary shall promulgate final regulations based on such proposed regulations.”

CCHF first discovered state warehousing and use of newborn DNA without parental consent in 2003, and has worked the past 11 years to secure parental consent requirements. Earlier this month, Brase alerted the public about the issue, urging lawmakers in this lame duck session to say no to bypassing parental rights and allowing the government to have access to the genetic blueprint of America’s tiniest citizens.

Celebrating its 20th year, Citizens’ Council for Health Freedom is a patient-centered national health freedom organization based in St. Paul, Minn. CCHF exists to protect health care choices and patient privacy. CCHF sponsors the daily, 60-second radio feature, Health Freedom Minute, which airs on more than 150 stations nationwide on the American Family Radio Network and 90-plus stations on the Bott Radio Network. Listeners can learn more about the agenda behind proposed health care initiatives and steps they can take to protect their health care choices, rights and privacy.

CCHF president and co-founder Twila Brase, R.N., has been called one of the “100 Most Powerful People in Health Care” and one of “Minnesota’s 100 Most Influential Health Care Leaders.” Brase, a public health nurse, has been interviewed by CNN, Fox News, Minnesota Public Radio, NBC Nightly News, NBC’s Today Show, NPR, New York Public Radio, the Associated Press, Modern Healthcare, TIME, The Wall Street Journal, The Washington Post and The Washington Times, among others. She is at the forefront of informing the public of crucial health issues, such as intrusive wellness and prevention initiatives in Obamacare, patient
privacy, informed consent, the dangers of “evidence-based medicine” and the implications of state and federal health care reform.

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For more information or to interview Twila Brase, president and co-founder of Citizens’ Council for Health Freedom, contact Deborah Hamilton, Hamilton Strategies, 215.815.7716, 610.584.1096, DHamilton@HamiltonStrategies.com.