Newborn Screening Saves Lives Reauthorization Act

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Newborn Screening Translational Research Network
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Newborn Screening Saves Lives Act

- **P.L. 110-204**, signed 4/20/2008
  - State NBS grants and pilots
  - Authorization of SACHD and expansion of its duties
  - NBS clearinghouses
  - Hunter Kelly research program at NIH

- **S. 1417/H.R. 1281 the NBS Saves Lives Reauthorization Act**
  - Various program refinements
  - As few changes as possible
  - Very little new funding
S. 1417/H.R. 1281 the NBS Saves Lives Reauthorization Act

3/2013: Introduced in the House
8/2013: Introduced in the Senate
12/19/2013: Senate committee reports favorably
1/29/2014: Senate passes by unanimous consent
6/19/2014: House committee reports favorably
6/24/2014: House passes on suspension
“I do share concerns on this bill as well, as well intentioned as this is, and let me just list what my concerns are.

“Number one, the Federal Government will have the ability to collect and automatically store the blood sample of every baby in the United States. There won’t be any allowance for parental consent to be required before the storage of these blood samples are made. Every baby’s DNA, which is the entire genetic code of that baby, will be under the control of the government.

“I have data privacy concerns. Why should anyone, especially our government, have everyone’s identity at their disposal?

“Third, there is no provision for any parent to opt out, so this legislation presumes that every parent of every newborn in the United States of America pre-agrees that the government can have their baby’s blood sample, which contains their DNA code, and that the government can indefinitely store that data.

“What limitations will there be on our government and what they can do with this information and how they will handle this data?

“Now, Mr. Speaker, knowing that our government has the potential to control every American’s health care under ObamaCare, how could government’s control of a baby’s DNA information impact the full access to health care or education opportunities or job opportunities for a child who is predetermined, by their DNA, to potentially have a problem later in life?”
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- Objecting Senators were eventually identified as Rand Paul (KY), Ted Cruz (TX), Mike Lee (UT), Pat Toomey (PA) and possibly Tom Coburn (OK)
- Negotiations persisted for many weeks, often with minimal communication
- Actively considered letting the bill go indefinitely
Compromise amendment

12/8/2014: Passed by the Senate
12/10/2014: Passed by the House
12/12/2014: Sent to the White House
12/18/2014: Signed into law.
Section 12

- Paul amendment supporters were not interested in further compromise.
- End of session loomed
- Prospective application would protect access to existing samples
- Purposeful ambiguity
Administration reticence

- Lack of clarity as to lead agency
- Hesitance to take lead role
- No consensus as to questions requiring clarification
- No consensus as to how to answer the questions
- Wariness to act before proposed Common Rule revisions released
Next steps

• Proposed Common Rule revisions
  - Published Sept 8 in the Federal Register
  - Analysis under way

• Potential guidance from HHS

• Possible further input from Capitol Hill

• Impact of other factors
  - 21st Century Cures Act
  - Rules around lab-developed tests
  - State laws