

***A Critical Analysis of the Implications for Genetic
Privacy and Consent Rights in Congress' Proposed
'Newborn Screening Saves Lives Act of 2007' ****

S.1858 & H.R. 3825

*Proposed federal legislation to establish a national system for government
genetic testing, surveillance and research on citizens using blood taken at birth*

If enacted, H.R. 3825, and its companion bill S.1858—which was passed by the U.S. Senate in December 2007—will nationalize the genetic testing of all newborn children—and their families.

FIVE KEY CONCERNS

No Consent: Expanded Testing

Newborn screening is “the first program of populationwide genetic testing.”¹ H.R. 3825 will expand government genetic testing of newborn citizens. It calls for the expansion of genetic conditions for which all newborns are to be tested, and identification of “secondary conditions.” While the Institute of Medicine recommends that all genetic screening be voluntary—including PKU testing and other newborn screening—parent consent is not required by the legislation.

Nationalized Government Databases and Registries

H.R. 3825 will nationalize current state newborn (genetic) screening programs, registries, and data systems. Infants and families will be placed into testing databases and tracking registries as part of the newborn screening program. H.R. 3825 requires the U.S. Department of Health and Human Services to coordinate with state programs to “collect and analyze data on the incidence and prevalence of genetic and heritable disorders” and to operate regional centers for research. The HIPAA Rule currently allows government access to private patient data without consent.

Tracking Individuals with “Disorders”

Once newborns are screened, federal grants can be used to track and assess the child and “coordinate ongoing followup treatment.” As the list of trackable disorders and “at risk” genes expands—perhaps to include obesity, diabetes, alcoholism, and violence—more children and families will be entered into genetic tracking registries for monitoring and assessment.

Research on Citizens without Consent

H.R. 3825 exposes every newborn and their family to government-funded research. Grantees are encouraged to analyze data collected from newborn screenings to “*identify populations at risk* for disorders affecting newborns and to examine and recognize and address relevant *environmental, behavioral, socioeconomic, demographic, and other relevant risk factors.*” [my emphasis]

¹ “Newborn Screening: Complexities in Universal Genetic Testing” Nancy S. Green M.D. [March of Dimes Birth Defects Foundation] et al. American Journal of Public Health. Nov. 2006 (96) No. 11.

The Centers for Disease Control and Prevention (CDC) contemplates building a national databank of newborn dried blood spots (DBS) for genetic research, seemingly without parent consent. A 2003 survey found 13 state health department laboratories using newborn DBS for research, 34 using newborn DBS to evaluate existing or new screening tests, and 20 states willing to contribute newborn DBS to multi-state research projects. (*see CCHC-created table in full report*)

Coercive Funding

The millions of dollars in federal appropriations (*see below*) are tied to compliance with Advisory Committee recommendations. State health department staff and advocates of newborn screening will likely use the new federal grant dollars to push for expansion of the program—and to argue against parent consent for genetic testing, surveillance and research.

CONSIDER THIS

While the American College of Medical Genetics recommends screening children for 29 conditions, states like Minnesota and Indiana test for more than 50 conditions. The vision of the 8-state Heartland Genetics and Newborn Screening Collaborative goes even farther:

Do you see...every Heartland newborn screened for 200 conditions where early recognition makes a difference in their life and health?...Do you see...every new student in the Heartland with an individual program for education based on confidential interpretation of their family medical history, their brain imaging, their genetic predictors of best learning methods?²[my emphasis]

There are serious legal, ethical and self-determination implications to government-imposed genetic testing:

- The parent/patient right of consent for medical testing is a long-established legal right.
- Genetic tests are only predictive, but many erroneously consider them presumptive.
- Results are entered in child's medical record which could enable future discrimination.
- Studies find false positives cause long-term anxiety in parents.
- Blood and test results held by the State are considered *government property*, available for whatever purposes future legislatures might choose.
- Not everyone wants to know about their health future—or let others know about it.

CONCLUSION

H.R. 3825 will expand newborn genetic testing, initiate identification of secondary conditions, place more individuals into government tracking systems, build intrusive government treatment monitoring and follow-up programs, strengthen claims of government ownership to the DNA and genetic information of citizens, make research subjects of citizens, and violate the citizens' right to "not know/not tell" their genetic predispositions. The proposed legislation does not acknowledge or uphold the rights of citizens to be free from government genetic testing, government surveillance and government-conducted or government-supported genetic research.

PROPOSED APPROPRIATIONS 2008 – 2012 (detailed funding chart in Appendix B of full CCHC report):

S. 1858 - \$228,062,500 (plus NIH funding)

H.R. 3825 - \$58,500,000 (plus NIH funding) – *for 2008; "such sums as may be necessary" for 2009-2012.*

² Heartland Genetics and Newborn Screening Collaborative: Strategic Plan 2006-2009. Heartland Regional Collaborative. <http://heartland.ouhsc.edu>. Accessed February 5, 2008.