



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Secretary's Advisory Committee on Heritable  
Disorders in Newborns and Children  
5600 Fishers Lane, Room 18A19  
Rockville, Maryland 20857  
(301) 443-1080 – Phone  
(301) 480-1312 – Fax  
<http://www.hrsa.gov/heritabledisorderscommittee>

October 13, 2010

The Honorable Kathleen Sebelius  
Secretary of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Secretary Sebelius:

The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) is charged with advising the Secretary of the Department of Health and Human Services in areas relevant to heritable conditions in newborns and children such as newborn and child screening, counseling, or health care services for newborns and children having or at risk for heritable disorders.

In September 2009, I wrote to update you on various SACHDNC activities, including the status of a draft briefing paper titled "*Considerations and Recommendations for a National Policy Regarding the Retention and Use of Dried Blood Spot Specimens After Newborn Screening.*" The Health Resources and Services Administration (HRSA) sought public comments on the draft and its recommendations through publication of a Notice in the *Federal Register*. The notice included a 60-day public comment period. Public comments were received from approximately 550 individuals as well as the following organizations: American College of Medical Genetics, American Health Insurance Plan; Association of Public Health Laboratories, Association of State and Territorial Health Officials, Center for Biomedical Ethics and Society, Vanderbilt University School of Medicine; Citizen's Council of Health Care; Genetic Alliance; March of Dimes; Michigan Department of Community Health; Secretary's Advisory Committee on Genetics, Health, and Society; Society for Inherited Metabolic Disabilities; Texas Department of State Health Services; University of Minnesota: Epidemiology Steering Committee of the Children's Oncology Group; University of Washington School of Medicine; Wadsworth Center - State of New York Department of Health. Additionally, comments were received from the Department of Health and Human Services' Office of Human Research Protections (OHRP), Office of Civil Rights (OCR), Agency for Healthcare Research and Quality (AHRQ), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and National Institutes of Health (NIH).

Committee staff and the work-group writing the paper reviewed and analyzed all comments and revised the draft to address the concerns raised – particularly in the following areas:

interpretation that the recommendations for the storage and use of newborn DNA do not acknowledge the consent, privacy, parent and DNA property rights of the individual; the belief that the Committee is advocating for the expansion of government power over the individual's most intimate property; the opinion that the recommendations advocate for the reduction of Constitutional rights of individual citizens and as proposed do not comply with the legal individual rights and informed written consent requirements as secured by the 4th Amendment privacy and property protection; and lastly, the perception that the Committee seeks to establish and support government banking and ownership of citizen DNA at birth through the creation of 50 state government DNA warehouses for nationwide genetic research on the American public without the informed written consent of citizens. Additionally, issues and suggestions raised by AHRQ, CDC, NIH and FDA – such as model policies for consent/dissent, mechanisms to ensure privacy and confidentiality and the utility and feasibility of establishing a voluntary national repository – were also incorporated in the final draft. Committee review of this draft is now complete and the final briefing paper is submitted for your information, review and consideration.

This briefing paper has two principal purposes. The first purpose is to review the ethical, legal and social issues facing state newborn screening programs related to the retention and use of residual dried blood spot specimens; education, awareness and ensuring the public trust; and financial considerations for the use and storage of residual biological samples remaining after the newborn is screened. The second purpose is to lay the foundation for developing national guidance to states in this area.

SACHDNC encourages an approach to guidance that maintains the standard uses of the residual blood specimens by newborn screening programs and upholds the core principles of benefiting infants, families and society, protecting privacy and confidentiality, and ensuring the public's trust while recognizing the research value of residual newborn screening specimens and their potential for advancing science and clinical care. The SACHDNC believes that national guidance on the retention and use of residual newborn screening specimens would help states to navigate these complex issues. The recommendations related to the retention and use of residual dried blood spot specimens are intended to work in concert with – and not to weaken – longstanding and highly effective state newborn screening programs.

To address the potential to advance science and clinical care for newborns, children, their families and society through the use of residual newborn screening blood specimens and protect this valuable resource for the public good, the SACHDNC makes the following recommendations to the Secretary of the Department of Health and Human Services and requests action by the Secretary where applicable

- 1) *All state newborn screening programs should have a policy in place that has been reviewed by the state attorney general or other appropriate legal authority that specifies who may access and use dried blood specimens once they arrive at the state-designated newborn screening laboratory, including further access after newborn screening tests are completed.*

- 2) *All state newborn screening programs should have a policy in place that has been reviewed by the state attorney general or other appropriate legal authority addressing the disposition of dried blood specimens remaining after newborn screening. Policymakers should consider the value of the specimens as a promising resource for research, the protection of the privacy and confidentiality of families and the necessity of ensuring the public's trust.*
- 3) *All state newborn screening programs should develop a well-defined strategy to educate health care professionals who provide patients with prenatal and postnatal care about newborn screening and the potential uses of residual dried blood specimens.*
- 4) *All state newborn screening programs should create policies that are in compliance with federal research regulations, assure that parents are aware of these activities, and consider whether documentation of parents' wishes and willingness to participate are required.<sup>3</sup>*
- 5) *All state newborn screening programs should work proactively to ensure that all families of newborns are educated about newborn screening as a part of prenatal and postnatal care.*
- 6) *The Secretary of Health and Human Services should help improve efforts to educate the public and health care providers about newborn screening and the retention and use of specimens.*
- 7) *The Secretary of Health and Human Services should facilitate a national dialogue among federal and state stakeholders about policies for the retention and use of residual newborn screening specimens, including model consent and dissent processes.*
- 8) *The Secretary of Health and Human Services should explore the utility and feasibility of establishing a voluntary national repository of residual dried blood specimens, in which families may choose to participate.*

In conclusion, please know that the Committee stands ready to be of service to you to help strengthen newborn screening programs. Effective newborn screening programs play an important role in improving the health of our children.

Sincerely yours,

R. Rodney Howell, M.D.  
Chairperson

Enclosure:

Tab A: Briefing Paper - *Considerations and Recommendations for National Guidance Regarding the Retention and Use of Residual Dried Blood Spot Specimens after Newborn Screening*