DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington DC 20201

OCT 30 2015

Joseph A. Bocchini Jr., MD
Chairperson, Advisory Committee on Heritable
Disorders in Newborns and Children
5600 Fishers Lane, Room 18W68
Rockville, Maryland 20857

Dear Dr. Bocchini:

Thank you for your letter to U.S. Department of Health and Human Services (HHS) Secretary, Sylvia M. Burwell, regarding the recommendations of the Advisory Committee on Heritable Disorders in Newborns and Children (Committee). Secretary Burwell asked that I respond to you on her behalf.

HHS appreciates the presentation of information and discussion at the Committee's May 2015 meeting, which provided helpful information on implementing Section 12 of the Newborn Screening Saves Lives Reauthorization Act of 2014. We understand the need for greater clarity on issues relating to informed consent for federally-funded research using residual newborn dried bloodspots and are grateful for your efforts to understand state challenges and relay them to HHS.

After careful review, the Secretary accepts the Committee's recommendation number five to create and distribute targeted materials on the importance of newborn screening and on options for parents to participate in newborn screening research. She has asked the Centers for Disease Control and Prevention to work with states, the Health Resources and Services Administration, the U.S. Food and Drug Administration, and the Assistant Secretary for Health's Office for Human Research Protections (OHRP). These HHS organizations will work together with states to develop guidance and educational materials on these issues.

After careful consideration, the Secretary does not accept the Committee's recommendation number one to adopt the Secretary's Advisory Committee on Human Research Protections' recommendations, as this matter remains under review by OHRP. In addition, the Secretary does not accept the Committee's recommendation numbers two through four to partner with states on developing guidance for institutional review boards. OHRP has responsibility within HHS for development of federal policy for the protection of human subjects, including the type of guidance referenced in the recommendations. To ensure fairness and appropriate feedback from all stakeholders, OHRP is not partnering directly with states or other stakeholders. However, the Secretary will ask OHRP to consult with states, as necessary, to develop guidance in the areas specified in the recommendations. Lastly, the Secretary does not accept the Committee's recommendation number six to fund states for translational research activities, but she will encourage HHS divisions to take opportunities to use discretionary funding for such research as they are able.

I understand that the overall goal of the Committee's recommendations was to urge HHS to clarify information referenced in Section 12 of the Newborn Screening Saves Lives Act – specifically what laboratory activities are considered research and what routine quality assurance activities are required by federal regulations. I believe the recently issued Federal Policy for the Protection of Human Subjects Notice of Proposed Rule Making (NPRM) demonstrates HHS' strong commitment to updating its informed consent policies.

Secretary Burwell and I value the Committee's thoughtful review and consideration of issues related to informed consent for use of residual newborn dried bloodspots. We share the Committee's desire for families to have ample opportunity to consider such consent, while minimizing negative impacts on vital research and on overall newborn screening rates.

Thank you for your continued dedication to the health and welfare of America's children.

Sincerely,

Mary K. Wakefield
Acting Deputy Secretary