THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

December 16, 2013

Joseph A. Bocchini, Jr., MD
Committee Chairperson
Discretionary Advisory Committee on Heritable Disorders
in Newborns and Children
Professor and Chairperson
Department of Pediatrics
Louisiana State University
1501 Kings Highway
Shreveport, LA 71130

Dear Dr. Bocchini:

As I indicated in my letter to your predecessor, Dr. R. Rodney Howell, I referred the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's (Committee) recommendations regarding the retention and use of dried blood spot specimens after newborn screening to the Interagency Coordinating Committee on Screening in Newborns and Children (ICC) for additional input regarding implementation. I charged the ICC to review the Committee's recommendations and subsequently submit a report to me with responses regarding possible future implementation of the recommendations. I took the Committee's recommendations into account, as I reviewed the ICC's report, and I found both documents provided keen insight into the difficult issues surrounding the retention and use of residual newborn screening blood specimens.

In addition, the U.S. Department of Health and Human Services (HHS) is currently involved in activities to revise the Federal Policy for the Protection of Human Subjects (the Common Rule), which necessarily impact my consideration of the Committee's recommendations. The Common Rule establishes baseline ethical and regulatory requirements for most federally funded human subjects research and much academic human subjects research, regardless of the source of funding. Currently, de-identified specimens and de-identified data collected for purposes other than the proposed research can be used for research without any requirement for review by an institutional review board or consideration of whether informed consent must be obtained. However, as HHS indicated in an Advance Notice of Proposed Rulemaking, published in July, 2011, we are considering whether to modify the Common Rule such that, in the future, informed consent would become the general rule for any research use of a biospecimen, even if de-identified.

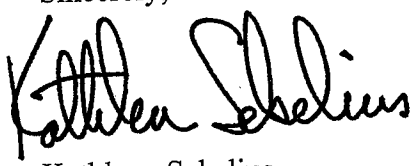
Taking into consideration the ongoing review and possible revision of the Common Rule, along with the Committee's recommendations and the ICC report, I decline to adopt the Committee's recommendations that all state newborn screening programs should have policies in place to: (1) specify who may access and use dried blood specimens once they arrive at the newborn screening laboratory; (2) address the disposition of dried blood specimens remaining after

newborn screening; and (3) ensure that parents are aware of these activities and consider whether documentation of parents' wishes and willingness to participate are required. I also decline, at this time, to adopt the Committee's recommendation to explore the utility and feasibility of establishing a national repository of residual dried blood specimens, but am willing to reconsider this issue in the future, if re-submitted by the Committee after completion of any revisions to the Common Rule.

Recognizing state sovereignty over newborn screening programs, I accept the remaining four Committee recommendations addressing state and federal initiatives to educate newborn screening stakeholders and facilitate a national dialogue among stakeholders. Federal agencies can provide opportunities for states and other newborn screening stakeholders to engage in discussions and to share practices and experiences. I encourage representatives from the relevant federal agencies to provide an update on these activities to the Committee at a future meeting.

I would like to commend the Committee on their review and analysis of issues related to the research and use of residual newborn screening blood specimens to advance science and clinical care for newborns and children.

Sincerely,



Kathleen Sebelius