



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Advisory Committee on Heritable
Disorders in Newborns and Children
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<http://www.hrsa.gov/heritabledisorderscommittee>

October 13, 2010

Thomas R. Frieden, MD, MPH
Director, Centers for Disease Control and Prevention
Administrator, Agency for Toxic Substances and Disease Registry
1600 Clifton Rd
Atlanta, GA 30333

Margaret Hamburg, M.D.
Commissioner, Food and Drug Administration
WO Bldg. 1, Rm. 2217
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Donald Berwick, M.D.
Administrator, Centers for Medicare & Medicaid Services,
7500 Security Boulevard
Baltimore, MD 21244

Dear Drs. Frieden, Hamburg and Berwick:

For its September 2010 the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) meeting, the SACHDNC requested a presentation on the Clinical Laboratory Improvement Advisory Committee (CLIAC) recommendations for good laboratory practices in biochemical genetic testing and newborn screening for inherited metabolic disorders, which were developed in February, 2010. In preparation for this presentation, the SACHDNC received the enclosed request from Roberta B. Carey, Ph.D., Acting Director of the Center for Disease Control and Prevention's (CDC) Division of Laboratory Science and Standards.

The CDC reported to the Committee, at the SACHDNC September 2010 meeting, that while the CLIAC recommendations are final, the recommendations will not be developed into regulations at this time. Rather, CDC requested input from the SACHDNC for the purpose of developing a Morbidity and Mortality Weekly Report (MMWR) guideline on the CLIAC recommendations for a document to be published in 2011.

The SACHDNC would be glad to assist in the development of a guideline on the CLIA recommendations. In addition, the Committee offers the following comments. The SACHDNC supports CLIA's efforts to better define and develop best laboratory practices as they relate to newborn screening, and is particularly interested in supporting CLIA's efforts towards quality improvement of newborn screening programs. The CLIA report and recommendations provide a very comprehensive document that serves as a useful starting point to develop a MMWR publication.

However, the SACHDNC has several areas of concern about the final CLIA recommendations, including concern that the report and recommendations exceed the scope of laboratory practice, in particular those recommendations dealing with informed consent. In addition, the Committee cautions for careful differentiation between the newborn screening and biochemical diagnostic testing requirements.

The SACHDNC also is concerned that there was no collaborative process established by CLIA to receive input from the SACHDNC in the preparation of the recommendations in those areas where the committees' charges overlap. Please note that the authorizing legislation for the SACHDNC charges the Committee to advise the Secretary of the Department of Health and Human Services in areas relevant to heritable conditions in children, especially childhood and newborn screening. The Committee reviews and reports regularly on newborn and childhood screening practices, and recommends improvements in the national newborn and childhood screening programs to the Secretary.

The SACHDNC therefore is concerned that regulations will be developed for the CLIA report and recommendations without Committee consultation. The SACHDNC points to the need for substantial SACHDNC involvement in the development of regulations as they apply to state newborn screening laboratories and programs and where there is overlap in programmatic charge.

Again, please know that the SACHDNC appreciates the opportunity to be involved in the manuscript preparation of the MMWR publication and welcomes the opportunity to provide assistance to you and your agencies in advancing ongoing projects pertaining to genetics in general and newborn screening specifically.

Sincerely yours,

R. Rodney Howell, M.D.
Chairperson

Enclosure:

[August 25, 2010 Letter from Acting Director, Center for Disease Control and Prevention's \(CDC\) Division of Laboratory Science and Standards](#)