



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Advisory Committee on Heritable
Disorders in Newborns and Children
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November 22, 2009

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

Dear Secretary Sebelius:

The 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 including newborn and child screening, counseling, and health care services for newborns and children having or at risk for heritable disorders. Amending legislation under the Newborn Screening Saves Lives Act 2008 indicates the Committee is to:

1. Provide recommendations, advice, or information on certain diagnostic and screening activities;
2. Provide such recommendations, advice or information as may be necessary to enhance, expand or improve the ability of the Secretary to reduce the mortality or morbidity in newborns and children from heritable disorders;
3. Make systematic evidence-based and peer-reviewed recommendations that include the heritable disorders that have the potential to significantly impact public health for which all newborns should be screened, including secondary conditions that may be identified as a result of the laboratory methods used for screening;

Moreover, one of the central purposes of the Newborn Screening Saves Lives Act is to provide federal guidance to help states voluntarily bring their programs into alignment with the most current, evidence based, scientific and clinical standards. Because each state designs and operates its own newborn screening program there is great variation between states in the number and conditions for which newborn are screened.

On July 22, 2005, the SACHDNC voted to adopt the American College of Medical Genetics (ACMG) panel as its recommended uniform screening panel and agreed to so advise the Secretary. In a letter of September 9, 2005, the SACHDNC strongly and unanimously recommended to former Secretary Leavitt that he initiate appropriate action to facilitate adoption of the ACMG recommended screening panel by every State newborn screening program.

In regard to this recommendation, on October 21, 2008, Dr. Elizabeth Duke responded as follows for Secretary Leavitt, "...based on the information available now, we are considering adopting the conditions recommended in the ACMG report as a national standard for newborn screening programs. Before making this determination, the Secretary would like to consider further information including the findings and recommendations of the President Bush's Council on Bioethics related to ethical issues in the current expansion of newborn screening. Therefore, the Secretary will defer making a determination pending further information." This council, which President Obama disbanded in June 2009, set out to explore possible ethical challenges that might have accompanied the expansion of newborn screening.

The SACHDNC has many reservations about the final report from President Bush's Council on Bioethics and the Committee now inquires if the Secretary has made a determination about whether or not to accept the SACHDNC's recommendation. The SACHDNC reaffirms its recommendation that the Secretary facilitate adoption by all state newborn screening programs of the ACMG recommended uniform screening panel (now the SACHDNC's recommended uniform screening panel) which will provide the federal guidance necessary to help states voluntarily bring their programs into alignment with the most current standards. Action by the Secretary would set the stage for dramatic improvement in the identification, diagnosis, treatment of rare genetic disorders in newborns and children

Sincerely yours,

R. Rodney Howell, M.D.
Chairperson