



Rockville, Maryland 20857

OCT 21 2008

R. Rodney Howell, M.D.
Chairperson
Advisory Committee on Heritable Disorders
In Newborns and Children
5600 Fishers Lane, Room 18A-19
Rockville, MD 20857

Dear Dr. Howell:

Thank you for your service to the Nation as the chair of the Advisory Committee on Heritable Disorders in Newborns and Children. We deeply appreciate the contributions that the Committee is making to advance newborn screening programs based on a thoughtful approach to national health policy and the best available scientific evidence. Secretary Leavitt asked me to respond on his behalf to the Committee's formal recommendations as expressed in your letters to the Secretary dated April 21, 2005, September 9, 2005, and April 4, 2007.

Your first two letters made several recommendations about how the Secretary could facilitate the advance of State-based newborn screening programs. I am pleased to say that we have either completed or made excellent progress on those recommendations.

Specifically, the Health Resources and Services Administration (HRSA) accomplished the following activities recommended by the Committee:

- We sent to the Secretary the report from the American College of Medical Genetics (ACMG) entitled "*Newborn Screening: Toward a Uniform Screening Panel and System*," which proposed a uniform panel of conditions to include in State newborn screening programs.
- We also released the ACMG report to the public for review and comment through the Federal Register.

The Advisory Committee had an opportunity to review and provide advice to the Secretary on the public comments. You advised the Secretary that the Committee strongly and unanimously recom-

mended that the Secretary initiate appropriate action to facilitate adoption of the ACMG recommended screening panel by every State newborn screening program. 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's Council on Bio-Ethics related to ethical issues in the current expansion of newborn screening. Therefore, the Secretary will defer making a determination pending further information.

In the interest of identifying and addressing the needs of newborns and children affected by heritable disorders, HRSA has completed many actions appropriate to facilitating the States' adoption of the ACMG recommendations, including the following:

- We established seven Regional Genetic and Newborn Screening Service Collaboratives and a National Coordinating Center to enhance, improve or expand the ability of State and local public health agencies to provide quality care for screening, counseling or healthcare services to newborns and children having, or at risk for, heritable disorders.

Activities by the Regional Collaboratives and the Coordinating Center are expected to improve access to newborn screening and genetic services and the quality of those services.

- We developed and disseminated educational resources for implementation of a quality newborn screening program.
- We created and published Action Sheets and algorithms as clinical resources for physicians to help them provide on-the-spot quality diagnostic and treatment services. These have been adopted by the ACMG, the American Academy of Pediatrics, and state newborn screening programs.
(<http://www.acmg.net/resources/policies/ACT/condition-analyte-links.htm>)
- We developed resources for pediatric care providers in order to 1) delineate responsibilities of pediatricians and pediatric medical subspecialists within the newborn screening system, and 2) outline resources that will provide support for the pediatric care professional.

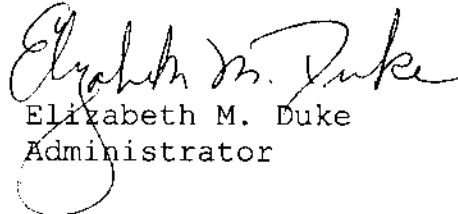
(*Pediatrics* 2008, 121: 192-217, "Newborn Screening: Expanded Recommendations.")

- We established a monitoring mechanism within the National Newborn Screening and Genetics Resource Center (NNSGRC). According to NNSGRC's update of September 16, 2008, 39 States are implementing the ACMG-recommended core screening panel.

In your third and most recent letter, you conveyed the Committee's recommendation that the Secretary develop and fund a mechanism to study the distribution of existing newborn screening educational material and acquisition of knowledge about newborn screening by expectant parents in the context of the healthcare provider-patient relationship. We will ask the newly authorized Secretary's Newborn and Child Screening Interagency Coordinating Committee to assess the feasibility of and possible approaches to conducting these studies so that we can develop a cost estimate for conducting the studies if and when funding becomes available.

Again, thank you for your leadership of the Committee and for the Committee's recommendations. Secretary Leavitt and I appreciate the Committee's valuable contributions and look forward to working with you on these important issues.

Sincerely,


Elizabeth M. Duke
Administrator