Maryam Banikazemi, M.D.
Neurogenetics
New York University at Rivergate
403 East 34th Street
New York, NY 10016

Dear Dr. Banikazemi:

The Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) received your nomination form and all accompanying materials (nomination package) for Fabry Disease on January 7, 2008. The ACHDNC reviewed the nomination package and reported the results of that review on August 7, 2008. Based on a review of the nomination form and accompanying materials, the decision was made not to send the nomination package forward to the ACHDNC's evidence review group at this time.

Although Fabry Disease is technically detectable in a screening panel for lysosomal storage disorders, the Committee felt that there were several factors that limit its appropriateness for inclusion in the routine newborn screening panel at this time: a) variable and possible late onset (>10 years) of the disease; b) unclear if those at highest risk of serious symptoms can be discerned in newborns; c) the lack of published data of preventive treatment early in life; d) some risk of immunologic response to enzyme replacement therapy; and e) the need for a prospective study of screening and therapeutic intervention to demonstrate the benefit of newborn screening for Fabry Disease. The ACHDNC is available for further discussion of screening newborns for Fabry Disease. The next ACHDNC meeting is October 1-2, 2008. ACHDNC may be contacted at 301-443-1080 if you wish to make public comments at this meeting.

Thank you for your interest and support of newborn screening programs and the ACHDNC's activities.

Sincerely yours,

/s/

R. Rodney Howell, M.D.
Chairperson