



Save Babies Through Screening Foundation, Inc.

4 Manor View Circle
Malvern, PA 19355-1622
Toll Free: 1-888-454-3383
Fax: (610) 993-0545
www.savebabies.org

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--Formerly Tyler for Life Foundation, Inc.--

Newborn Screening Saves Babies One Foot At A Time®

Jill Levy- Fisch, President 205 Delhi Road, Scarsdale, NY 10583 jill@savebabies.org 914-588-1127 Ph.

March 5, 2007

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket #2006D-0336 and Docket #2006D-0347

To Whom It May Concern:

Save Babies Through Screening Foundation is a national nonprofit public charity run by volunteers. Our mission is to improve the lives of babies by working to prevent disabilities and early death resulting from disorders detectable through newborn screening. Without proper screening affected children will likely suffer mental retardation, physical disability or even death. Most affected children can lead normal, healthy lives when diagnosed and started on treatment early. In the interest of testing that can provide this early and accurate diagnosis, we ask you to reconsider the IVDMIA and ASR Draft Guidances.

The ASR and IVDMIA Draft Guidances may have a negative impact on innovation, especially for diseases with lower incidence, and on the development of molecular diagnostic tests because manufacturers will not be able to offer ASRs for molecular-based diagnostic tests. Requiring ASR manufacturers to reconfigure their ASRs to contain only one "moiety" could have a detrimental effect on quality in laboratories. Currently, if a laboratory purchases an ASR that contains three primers, it combines this ASR product with other ingredients, develops a test, and validates it. Separating a three-primer ASR into three separate products that each contains one primer would introduce more complexity in the development of laboratory tests and increase the risk for analytical error by the laboratory without any public health benefit.

Save Babies Through Screening Foundation supports, assists and advocates for disorders that are detectable through filter paper newborn screening; are unlikely to be clinically diagnosed without screening; and cause mental retardation, physical disability and/or death in childhood when left untreated. It is essential to allow new tests and testing agents to be used as effectively as possible. While oversight of medical testing is

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important and necessary, these two FDA Draft Guidances may not permit adequate testing to continue. We ask that you direct your efforts towards promoting testing and research for all diseases instead of introducing requirements that may hinder further development.

Thank you for your consideration,

Save Babies Through Screening Foundation

A handwritten signature in black ink, reading "Jill Leng-Ford". The signature is written in a cursive style with a large initial "J" and a long, sweeping underline.