

**Letter to the Centers for Medicare and Medicaid Services (CMS) requesting a genetics specialty under the Clinical Laboratory Improvement Amendments (CLIA)**

October 11, 2006

Leslie V. Norwalk, Esq.  
Acting Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

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Dear Ms. Norwalk,

As members of the genetics consumer community, we are very concerned with the quality of laboratories performing genetics testing in the United States. For this reason, we are joining with Genetic Alliance, the Genetics and Public Policy Center, and Public Citizen's Health Research Group to encourage you to create a genetics specialty under the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

On September 26, 2006, the organizations listed above submitted a petition requesting CMS to initiate rulemaking to create a genetics specialty under CLIA. The petition laid out arguments supported by both qualitative and quantitative data in support of this policy.

We believe that the establishment of a genetic testing specialty under CLIA encourages new technology and ensures safety and accuracy when those technologies are implemented. Today, there are more than 1000 diseases for which genetic tests are clinically available, several hundred used in research, and even more in various stages of development. Without a genetic testing specialty, CLIA cannot adequately ensure that consumers receive genetic testing services that are safe, accurate, and clinically useful.

We urge CMS to act quickly by issuing proposed regulations for a genetic testing specialty under CLIA.

## **Organizations**

The Alpha Pack - Wisconsin's Alpha-1 Support Group  
APS Foundation of America, Inc.  
BCCNS Life Support Network  
Beckwith-Wiedemann Children's Foundation  
Birt Hogg Dube Family Alliance  
C3: Colorectal Cancer Coalition  
Cancer Information & Support Network  
CARES Foundation, Inc.  
Claire Altman Heine Foundation, Inc.  
The Chromosome 18 Registry & Research Society  
Coalition of Heritable Disorders of Connective Tissue  
Cornelia de Lange Syndrome Foundation  
Cystinosis Research Network (CRN)  
GeneDx, Inc.  
Genetic Alliance BioBank  
Genetics, Ethics, and Policy Consulting  
FRAXA Research Foundation  
Hadassah, the Womens Zionist Organization of America  
Hereditary Hemorrhagic Telangiectasia Foundation International  
Hypertrophic Cardiomyopathy Association (HCMA)  
International Rett Syndrome Association  
Kids With Heart National Assn for Children's Heart Disorders, Inc.  
Mathew Forbes Romer Foundation  
Moebius Syndrome Foundation  
National Tay-Sachs & Allied Diseases Association, Inc. (NTSAD)  
Neurofibromatosis, Inc.  
Parent Project Muscular Dystrophy (PPMD)  
Patient's Best Friend  
Personalized Medicine Coalition  
PXE International  
Spina Bifida Association of Greater Pennsylvania  
Trimethylaminuria Foundation  
VHL Family Alliance

## **Individuals**

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