

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
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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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Brandeis University

John Twomey, RN, PhD

Joan O. Weiss, MSW
Founder of Genetic Alliance

Marion Yanovsky
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