Archived Policy Statement

Oversight of Advanced Diagnostic Tests and Proposed IVDMIA Guidance

February 2, 2010

The Honorable Margaret A. Hamburg, MD
Commissioner, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Oversight of advanced diagnostic tests and proposed IVDMIA guidance

Dear Commissioner Hamburg:

We are writing to support the need for an FDA-centered regulatory framework for advanced diagnostics that is risk-based and transparent and promotes public health by facilitating timely introduction of accurate and reliable advanced diagnostic tests and providing information to patients and healthcare providers.

We understand that adapting regulatory policies and procedures to the scientific challenges presented by genetic and genomic testing will require creative thinking. It is critically important that we move forward with a regulatory oversight framework that is clear and consistent and recognizes that there are a variety of technological approaches to advanced diagnostic tests. Ultimately, the most critical aspect of any test is risk to the patient. We recognize that it will take time to develop and implement a more comprehensive and effective regulatory oversight framework than is contemplated in the In Vitro Diagnostic Multivariate Index Assay (IVDMIA) draft guidance, but the community of stakeholders—patient organizations, academia, and industry—are all committed to working with you to move forward without delay.

We oppose the release of the IVDMIA guidance, which applies to a vaguely-defined set of test systems, as opposed to a more logical, risk-based approach for all laboratory-developed genomic tests. We recommend focus on a risk-based approach. We agree with authors from the Genetics and Public Policy Center that, “Establishing a registry is a critical first step in the development of a more transparent, quality-centered system of oversight that will better inform and protect the public.” (Javitt, Katsanis et al. 2009). We believe that this is the cornerstone for a strong regulatory foundation necessary to support personalized medicine. We also believe that such a registry would be an excellent crossagency effort, since it should involve the use of tools and capacity already available at NIH. Collaborating with NIH on this

effort and not releasing the guidance would be a signal of strong leadership from multiple agencies to secure a robust pathway for personalized medicine.

Sincerely yours,

Alpha-1 Association
Alpha-1 Foundation
Alström Syndrome International
APBD Research Foundation
Belgian Alliance of Eurordis
Belgian Organization for Metabolic Diseases
Breast Cancer Network Strength
BVVL International
Cadasil Together We Have Hope Non-Profit Org
CARES Foundation
Chicago Center for Jewish Genetic Disorders
Children's Rare Disease Network
Children's Tumor Foundation
Chordoma Foundation
Claire Altman Heine Foundation
Coalition for 21st Century Medicine
Coalition for Pulmonary Fibrosis
Coalition of Heritable Disorders of Connective Tissue
Costello Syndrome Family Network
Digestive Disease National Coalition
Dysautonomia Foundation
Fight ALD
Foye Myopathy Project
Genetic Alliance
Genomic Health
HHT Foundation International
International Fabry Network
International WAGR Syndrome Association
IPOFA
Jacob's Cure
Kleiner Perkins Caufield & Byers
Lymphangiomatosis & Gorham's Disease Alliance
Lymphanigiomatosis Foundation
MLD Foundation
Myotubular Myopathy Resource Group
National Alopecia Areata Foundation
National Association of Social Workers
National Eczema Association
National Foundation for Ectodermal Dysplasias
National Tay-Sachs & Allied Diseases Association, Inc.
NBIA Disorders Association

Olive Branch Fund
Oxalosis & Hyperoxaluria Foundation
Pachyonychia Congenita Project
PCD Foundation
Prader-Willi Syndrome Association
Pull-thru Network, Inc.
PXE International
R.A.R.E Project
Redpath Integrated Pathology
Research Advocacy Network
Sudden Arrhythmia Death Syndromes (SADS) Foundation
Technic Solutions, LLC
The Progeria Research Foundation, Inc.
Trimethylaminuria Foundation
Trisomy 18 Foundation
XDx- Expression Diagnostics

*Javitt, G., S. Katsanis, et al. (2009). "Developing the blueprint for a genetic testing registry." Public Health Genomics **13**(2): 95-105.*