

October 26, 2011

Honorable Tom Harkin
Chairman
Committee on Health, Education, Labor
and Pensions
United States Senate
731 Senate Hart Office Building
Washington, DC 20510

Honorable Michael Enzi
Ranking Member
Committee on Health, Education, Labor
and Pensions
United States Senate
379A Senate Russell Office Building
Washington, DC 20510

Dear Chairman Harkin and Ranking Member Enzi:

The undersigned are deeply concerned about the issue of the current conflicts of interest statutory provisions and their impact on the appointment of experts, particularly researchers and patients, as Special Government Employees (SGE's) on Food and Drug Administration Advisory Committees and as otherwise needed. As a group, our organizations promote efforts to bring better treatments and cures to those struggling with diseases. Many of these conditions have no adequate treatments and, therefore, it is imperative that we challenge hurdles that impede the quality and efficiency of the treatment development process.

It is our belief that protections must be in place when persons are appointed to positions where their own financial interests might influence their service to the federal government. However, it is also our strong belief that the current conflicts of interest statutes that apply to the Food and Drug Administration (FDA) have resulted in a system that is out of balance to the point that conflict avoidance is the primary driver of who serves on Advisory Committees, regardless of the extent of the conflict, the uniqueness of their expertise, or the government's need for their services.

As you know, FDA SGE's are subject to an additional layer of statutory conflict of interest provisions beyond those that already govern SGE's for all other departments and agencies in the executive branch. Specifically, under current law, the FDA must analyze potential committee members pursuant to Section 712 of the Food, Drug, & Cosmetic Act (FDCA), in addition to the government-wide provisions found in the Federal Advisory Committee Act and the Ethics in Government Act of 1978. This additional FDA-specific provision appears to drive the FDA to look only for individuals to serve as SGE's who have virtually no financial ties to any issue that might be addressed by a given Advisory Committee. While that may sound wise at first glance, in fact those with expertise in a given area often have foreseeable and unavoidable ties to the community as a result of their expertise. Yet, under the current structure, the FDA is not allowing those individuals to serve as SGE's, despite the fact that by doing so the FDA is being deprived of expertise by those who are best qualified. Accordingly, we support any effort to eliminate the additional conflicts of interest restrictions that apply only to the FDA¹.

It is our belief that the existing provisions in the Federal Advisory Committee Act and the Ethics in Government Act of 1978 are adequate to safeguard against conflicts of interest, while still

¹ <http://www.accessdata.fda.gov/FDA/Track/track?program=advisory-committees&id=AdvComm-waivers&fy=all>. While FDCA does give the FDA authority to issue waivers for those with conflicts of interest (with an annual cap on the number) it frequently selects for SGE service those who need no waivers, often meaning they have little direct involvement in an issue or a field.

allowing those with the necessary expertise and perspective to serve on these very important committees. In fact, the specific standard for SGE's found in 18 U.S.C. 208(b)(3) recognizes that potential SGE's may have conflicts of interest, but allows for their service nevertheless when the need for their services outweighs the potential for a conflict of interest created the financial interest involved. That standard is clear, reasonable, and balanced and appropriately recognizes that some potential SGE's may come to the FDA with ties to the community that may pose some conflict of interest, but that the primary issue must be the government's need for their services. The main goal of these committees, after all, is to help the FDA to make the best decisions possible. The FDA can only do that if it has the best, most well-informed researchers, clinicians, and patients advising it.

Sincerely,

AACSA Foundation
Addi and Cassi Hempel Fund
Advocacy for Patients with Chronic Illness, Inc.
AIDS Action Baltimore
AIDS Treatment Activist Coalition
Alliance for Aging Research
Alzheimer's Association
American Autoimmune Related Diseases Association
American Brain Coalition
American Brain Tumor Association
American Gastroenterological Association
American Pain Foundation
American Psychiatric Association
American Society for Parenteral and Enteral Nutrition
American Society of Experimental Neurotherapeutics
Amyloidosis Support Groups
Association of Clinical Research Organizations
Association of Gastrointestinal Motility Disorders, Inc.
Asthma and Allergy Foundation of America
BayBio
Benign Essential Blepharospasm Research Foundation
CARES Foundation, Inc.
Celiac Disease Center at Columbia University
Chromosome Disorder Outreach, Inc.
Colon Cancer Alliance
Community Access National Network
Cooley's Anemia Foundation
Council for American Medical Innovation
CurePSP
Cutaneous Lymphoma Foundation
Detroit Medical Reserve Corps.
Digestive Disease National Coalition
Friedreich's Ataxia Research Alliance
Friends of Cancer Research
Gastroparesis Patient Association for Cures and Treatments, Inc.

Genetic Alliance
Genetics Policy Institute
Hannah's Hope Fund for GAN
Hereditary Disease Foundation
Immune Deficiency Foundation
Infectious Diseases Society of America
Institute for Basic Research in Developmental Disabilities
International Essential Tremor Foundation
Kidney Cancer Association
Lymphangiomatosis & Gorham's Disease Alliance
Maryland Hepatitis Coalition
Men's Health Network
MLD Foundation
Moebius Syndrome Foundation
National Alliance on Mental Illness
National Ataxia Foundation
National Blood Clot Alliance
National Foundation for Celiac Awareness
National Fragile X Foundation
National Gaucher Foundation
National MPS Society
National Organization of Rare Diseases
National Parkinson Foundation
National PKU Alliance
NBIA Disorders Association
Organic Acidemia Association
Pachyonychia Congenita Project
Parent Project Muscular Dystrophy
Parkinson's Action Network
Project Inform
PXE International
RARE Project
Research!America
Sarcoma Foundation of America
Sjögren's Syndrome Foundation
Society for Women's Health Research
The AIDS Institute
The Association for Frontotemporal Degeneration
The Foundation for Prader-Willi Research
The Parkinson Alliance
Treatment Education Network
Tremor Action Network

Cc: Hon. Barbara A. Mikulski
Hon. Jeff Bingaman
Hon. Patty Murray
Hon. Bernard Sanders
Hon. Robert P. Casey, Jr.
Hon. Kay R. Hagan

Hon. Jeff Merkley
Hon. Al Franken
Hon. Michael F. Bennet
Hon. Sheldon Whitehouse
Hon. Richard Blumenthal
Hon. Lamar Alexander
Hon. Richard Burr
Hon. Johnny Isakson
Hon. Rand Paul
Hon. Orrin G. Hatch
Hon. John McCain
Hon. Pat Roberts
Hon. Lisa Murkowski
Hon. Mark Kirk