

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 FDA<sup>1</sup>.

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

---

<sup>1</sup> <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