

May 5, 2017

The Honorable Mitch McConnell, Majority Leader  
United States Senate  
Washington, DC 20510

The Honorable Paul Ryan, Speaker  
United States House of Representatives  
Washington, DC 20515

The Honorable Charles Schumer, Minority Leader  
United States Senate  
Washington, DC 20510

The Honorable Nancy Pelosi, Minority Leader  
United States House of Representatives  
Washington, DC 20515

Dear Majority Leader McConnell, Speaker Ryan, and Minority Leaders Schumer and Pelosi:

On behalf of the millions of men, women, and children in the United States living with chronic or rare diseases and disabilities, the undersigned organizations urge you to quickly reauthorize the Food and Drug Administration (FDA) user fee agreements.

The current FDA user fee agreements are the culmination of months of negotiation between FDA and the medical product industry, with significant input from the patient advocacy community. We stand behind these agreements and ask that they are reauthorized as quickly as possible.

The FDA largely relies on user fees authorized by Congress to operate. Without the user fees, a majority of drug, biologic, and device reviewers would be laid off, and the necessary review of innovative therapies would be substantially impaired, if not halted all together. Further delay, such as a one year extension of the current agreement, will impact FDA's ability to carry out its vital mission and delay many of the much welcomed improvements included in the Commitment Goals Letters.

The Prescription Drug User Fee Act (PDUFA) Commitment Goals Letter includes many important improvements and advancements to FDA processes and initiatives. These include the continuance of the Patient-Focused Drug Development program, requiring guidance for industry; the strengthening of the Breakthrough expedited review pathway; and the expansion of the Rare Diseases program, among others.

Other provisions included in the agreement, such as increased emphasis on biomarkers and surrogate endpoints, streamlining combination product reviews, studying the feasibility of incorporating real-world evidence (RWE) provided from clinical settings, and improving FDA hiring and retention practices, will lead to a more efficient FDA that is better equipped to review 21st Century treatments in a timely fashion.

The Medical Device User Fee Amendments (MDUFA) Commitment Goals letter also contains several crucial reforms including the further inclusion of patient preference information and patient-reported outcomes in device development and review, as well as the creation of the National Evaluation System for health Technology (NEST).

Additionally, the Generic Drug User Fee Amendments (GDUFA) and Biosimilars User Fee Act (BsUFA) are designed to bring lower-cost alternative prescription medicines to market as quickly as possible. These alternatives represent one of the best ways to lower the cost of care.

We request the Committees of jurisdiction and Congress as a whole keep the user fee reauthorization process timely, bipartisan, uncontentious, and focused on the patients FDA serves every day.

The chronic and rare disease and disability patient communities rely on FDA to ensure that innovative, safe, and effective treatments reach those in need. We thank Congress for moving forward with these critical funding mechanisms, and look forward to their swift and unimpeded passage.

Sincerely,

Abby Grace Foundation  
Abigail Alliance for Better Access to Developmental Drugs  
Acromegaly Community  
ADNP Kids Research Foundation  
Allergy & Asthma Network  
Alpha-1 Foundation  
Alport Syndrome Foundation  
Alzheimer's Association  
Alzheimer's Impact Movement  
American Autoimmune Related Diseases Association (AARDA)  
American Cancer Society Cancer Action Network  
American Kidney Fund  
American Partnership for Eosinophilic Disorders  
Amyloidosis Foundation  
Amyloidosis Support Groups  
Angioma Alliance  
APBD Research Foundation  
Aplastic Anemia and MDS International Foundation  
Arthritis Foundation  
Asian & Pacific Islander American Health Forum  
Association for Creatine Deficiencies  
Autism Speaks  
Bcureful  
Bridge The Gap - SYNGAP Education and Research Foundation  
Caregiver Action Network  
Central Pain Nerve Center  
Children's Cardiomyopathy Foundation  
Children's PKU Network  
Chloe's Fight Rare Disease Foundation  
Cicatricial Alopecia Research Foundation  
CJD Aware!  
Coalition Duchenne  
Coalition for Clinical Trials Awareness  
Colon Cancer Alliance  
Congenital Adrenal Hyperplasia Research, Education & Support Foundation (CARES Foundation, Inc.)  
Congenital Hyperinsulinism International  
Consortium of Multiple Sclerosis Centers  
COPD Foundation  
Cure HHT  
CureCADASIL Association  
CureCMT4J/Talia Duff Foundation  
CureDuchenne  
Cutaneous Lymphoma Foundation  
DADA2 Foundation  
Debra of America

Degos Disease Support Network  
Dementia Alliance International  
Dysautonomia International  
Epilepsy Foundation  
Fabry Support & Information Group  
Florida State Hispanic Chamber of Commerce  
FOD (Fatty Oxidation Disorders) Family Support Group  
Foundation for Prader-Willi Research  
Friends of Cancer Research  
Garrett the Grand -Batten Fighter  
Global Healthy Living Foundation  
Guardian Hands Foundation  
HealthHIV  
Hemophilia Federation of America  
Heterotaxy Connection  
Huntington's Disease Society of America  
Indian Organization for Rare Diseases  
International Medical Angels Network Inc.  
International Myeloma Foundation  
International Organization of MS Nurses  
International Pemphigus and Pemphigoid Foundation  
Kids with Heart National Association for Children's Heart Disorders, Inc.  
Lung Cancer Alliance  
Lupus and Allied Diseases Association, Inc.  
Lupus Foundation of America  
Lupus Research Alliance  
March of Dimes  
Mended Hearts  
Miracle For Madison SMA Research at OSU  
MitoAction  
Mobeius Syndrome Foundation  
Myasthenia Gravis Foundation of America  
Narcolepsy Support Group of Iowa  
National Ataxia Foundation  
National Eczema Association  
National Eosinophilia Myalgia Syndrome Network  
National Foundation for Ectodermal Dysplasias  
National Health Council  
National Hemophilia Foundation  
National Lymphedema Network  
National MPS Society  
National Multiple Sclerosis Society  
National Organization for Rare Disorders  
National PKU Alliance  
Neuroendocrine Cancer Awareness Network  
Organic Acidemia Association  
Pakistan Down Syndrome Association  
Parent Project Muscular Dystrophy  
PKD Foundation  
Planning Health

PMG Awareness Organization  
Polycystic Kidney Disease Foundation  
Prader-Willi Syndrome Association (USA)  
Prevent Cancer Foundation  
Pulmonary Fibrosis Advocates  
Pulmonary Hypertension Association  
Rare and Undiagnosed Network (RUN)  
Relapsing Polychondritis Awareness and Support Foundation  
RetireSafe  
Sickle Cell Disease Association of America, Inc.  
Spina Bifida Association  
SSADH Association  
Tarlov Cyst Disease Foundation  
The Association for Frontotemporal Degeneration  
The Chronically Awesome Foundation  
The Cluster Headache Support Group  
The Erik Metzler Foundation, Inc.  
The Guthy-Jackson Charitable Foundation  
The Michael J. Fox Foundation  
Tuberous Sclerosis Alliance  
United Leukodystrophy Foundation  
Usher 1F Collaborative  
U.S. Pain Foundation  
Veterans & Americans United for Equality in Medical Care  
Washington State UW JHS/hEDS Support Group

CC: The Honorable Donald Trump, President of the United States;  
The Honorable Thomas Price, MD, Secretary, Department of Health and Human Services