

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
Cicatrical 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