

April 29, 2019

The Honorable Donald J. Trump
President
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

The Honorable Mick Mulvaney
Acting Chief of Staff
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Russell Vought
Acting Director
Office of Management and Budget
725 17th Street, N.W.
Washington, D.C. 20503

Dear Mr. President, Secretary Azar, Mr. Mulvaney and Mr. Vought;

The undersigned organizations, representing millions of patients, advocates, caregivers, and health care professionals strongly urge the administration to reconsider the enactment of the memorandum issued on April 11, 2019 regarding “Guidance on Compliance with the Congressional Review Act”.

We strongly believe that if applied to the U.S. Food and Drug Administration (FDA), the public health, safety, and future well-being of the American people will be put at risk.

The FDA is unique from most all other agencies regarding the guidance process. The agency currently has a vigorous process for issuing and reviewing potential guidance, including a robust public vetting of draft guidance that are noticed and open for public comment and input long before they are finalized. For decades, through this process, the FDA has put forth some of its most innovative and important pathways for how new therapies will be reviewed and how they can most safely and efficiently reach patients.

With the current pace of scientific discovery unfolding at an unprecedented pace, the FDA needs to be able to effectively communicate with the biomedical research community without delay. We respectfully ask that the Administration exempt the FDA to avoid the serious unintended consequences that delaying or impeding science would have on millions of patients and their families.

We welcome a future productive dialogue with the Administration surrounding the importance and rigor of the FDA guidance process and any other policy proposals that impact patients' lives.

Sincerely,

Alliance for Aging Research
American Academy of Pediatrics
American Society of Hematology
Association of Clinical Research Organizations
CancerCare
Fight Colorectal Cancer
Friends of Cancer Research
GO2 Foundation for Lung Cancer
LUNGevity Foundation
Melanoma Research Foundation (MRF)
National Alliance on Mental Illness
National Organization for Rare Disorders (NORD)
National Osteoporosis Foundation
National Patient Advocate Foundation
Research!America
St. Baldrick's Foundation
The Leukemia & Lymphoma Society