Congress of the United States
Washington, DC 20515

July 14, 2016

Dr. Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue Hillandale Building, 4th Floor
Silver Spring, MD 20993

Dear Dr. Woodcock,

We write to you to express our frustration with the inability of the Food and Drug Administration (FDA) to complete its review of a New Drug Application (NDA) for a potential new therapy for Duchenne muscular dystrophy (DMD).

On February 17, 2016, 109 Members of Congress sent you a letter encouraging the FDA to utilize all available tools to expedite the process of delivering safe and effective treatments for DMD. In the agency's response, it assured members that the FDA is "committed to providing timely access to potentially useful medical treatments for seriously ill patients as well as to working for speedy approval of new drug products while maintaining high, scientifically based, safety and efficacy standards."

Despite this promise and the fact that DMD is a rare disease without an approved treatment, the FDA has failed to act in an expeditious manner. The agency recently notified the manufacturer that it would be unable to finish its review of the NDA by the goal date of May 26, 2016. This is the second time the goal date has been extended, after the FDA initially delayed the decision by three months in February of this year.

The FDA's failure to make a timely decision on the NDA is unacceptable. Tens of thousands of boys with DMD have been waiting for years for a safe and effective treatment. We have heard from patients, family members, and providers that these treatments work, giving young boys hope that they can slow the progression of their fatal disease and one day have access to a cure.

While we recognize the FDA must balance safety and effectiveness with patient access to life-saving treatments, FDA's foot-dragging is denying patients the chance to delay certain death. We strongly encourage the FDA to listen to the stakeholders and make a judicious and prompt decision regarding cures for DMD.

Sincerely,

Erik Paulsen
Member of Congress

John Conyers Jr.
Member of Congress

Ralph Abraham, M.D.
Member of Congress

André Carson
Member of Congress

Lou Barletta
Member of Congress

Theodore E. Deutch
Member of Congress

Andy Barr
Member of Congress

Alcee L. Hastings
Member of Congress

Rod Blum
Member of Congress

Collin C. Peterson
Member of Congress

Mo Brooks
Member of Congress

Adam Smith
Member of Congress

Bradley Byrne
Member of Congress

Ryan Costello
Member of Congress

Michael G. Fitzpatrick
Member of Congress

Scott Garrett
Member of Congress

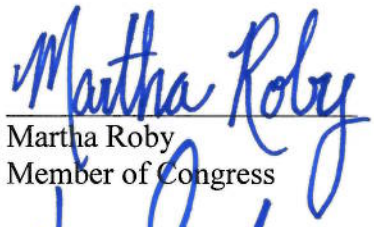
H. Morgan Griffith
Member of Congress

Gregg Harper
Member of Congress

Lynn Jenkins, C.P.A.
Member of Congress

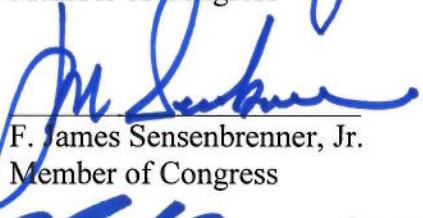
Peter King
Member of Congress

Gary Palmer
Member of Congress

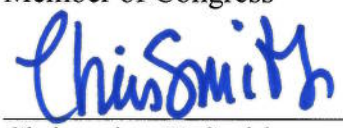


Martha Roby
Member of Congress

Matt Salmon
Member of Congress



F. James Sensenbrenner, Jr.
Member of Congress



Christopher H. Smith
Member of Congress

Marlin Stutzman
Member of Congress