



February 6, 2018

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
Washington, DC 20510

The Honorable Charles E. Schumer
Minority Leader
U.S. Senate
Washington, DC 20510

The Honorable Paul D. Ryan
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Nancy Pelosi
Democratic Leader
U.S. House of Representatives
Washington, DC 20515

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

On behalf of the March of Dimes, a unique collaboration of scientists, clinicians, parents, members of the business community, and other volunteers, affiliated with chapters representing every state, the District of Columbia and Puerto Rico, I am writing to express our concerns about the potential inclusion of S. 974/ H.R. 2212, the Creating and Restoring Equal Access To Equivalent Samples (CREATES) Act, in Fiscal Year 2018 spending legislation.

The March of Dimes is concerned that passage of the CREATES Act could lead to the effective elimination of current critical safety protocols surrounding certain high-risk drugs subject to Risk Evaluation Mitigation Strategies (REMS) procedures known as Elements to Assure Safe Use, or ETASU. These rules are only put in place when needed to alleviate the threat of potentially fatal complications, severe allergic reactions, birth defects, organ damage, and serious infections that may result from the inappropriate use or mishandling of drugs.

Under the CREATES Act, generic manufacturers would only be required to demonstrate that their precautionary procedures are “comparable” to those of the brand-name REMS drugmaker instead of the current requirement that they are “equivalent.” Additionally, the CREATES Act could jeopardize FDA’s ability to verify a generic manufacturer’s safety record and its ability to follow a rigorous risk system. Given the extremely serious nature of the health consequences that can be experienced if ETASU protocols are not followed



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rigorously, the March of Dimes is deeply concerned that this legislation, as currently written, would not provide adequate safety assurances.

We fully recognize the need for rapid development of generic drugs and appreciate the positive impact lower-cost treatments have had on the well-being of patients and their families. However, these improvements must not jeopardize these patient or worker safety. The current REMS protocols help to ensure that patients get the drugs they need without unnecessary risk and should not be weakened.

Thank you for your willingness to protect the safety of patients. For more information, please contact Jaimie Vickery, Director of Federal Affairs for the March of Dimes at jvickery@marchofdimes.org or 202-292-2752.

Sincerely,

A handwritten signature in black ink, appearing to read 'Stacey D. Stewart', with a long horizontal line extending to the right.

Stacey D. Stewart,
President