



April 2, 2019

The Honorable Frank Pallone, Chairman
U.S. House Committee on Energy & Commerce
2107 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Greg Walden, Ranking Member
U.S. House Committee on Energy & Commerce
2185 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Pallone and Ranking Member Walden:

On behalf of the 25 to 30 million Americans with one of the approximately 7,000 known rare diseases, the National Organization for Rare Disorders (NORD) writes to express support for the *Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019* (H.R.965), introduced by Representatives Cicilline (D-RI), Sensenbrenner (R-WI), Nadler (D-NY), Collins (R-GA), Welch (D-VT), and McKinley (R-WV), and to thank you for advancing this important legislation to markup in the House Committee on Energy and Commerce on April 3, 2019.

NORD is a unique federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services.

Rare disease patients rely on safe and effective generic and biosimilar medicines approved by the Food and Drug Administration (FDA) to increase access to critical, potentially lifesaving therapies. NORD supports this common-sense legislation because it will remove one of the barriers that prevents the development of generics and biosimilars.

Since it was created in 2007, FDA's Risk Evaluation and Mitigation Strategies (REMS) program has been an important tool for patient safety by ensuring that the benefits of a drug or biological product outweigh its safety risk. However, this well-intentioned program has been used by some pharmaceutical companies to prevent competition for products with, and without, required REMS programs. These companies have used the REMS requirements (or voluntarily imposed restricted distribution programs) as an excuse to deny generic and biosimilar manufacturers the brand samples necessary for development, resulting in delays in submission of, or an inability to submit, applications for approval. Consequently, generic and biosimilar approvals are blocked or delayed, and patients are left without access to these more affordable versions of the medicines they need.

The CREATES Act would give generic and biosimilar manufacturers a clear and efficient pathway to obtaining brand samples, ultimately allowing for earlier approvals. The bill would

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simultaneously ensure patient safety by requiring that FDA only authorize qualified manufacturers to receive these samples when the brand is subject to REMS requirements.

The CREATES Act would also address another practice that delays generic and biosimilar competition—specifically, when brand companies deny generic and biosimilar access to a FDA-approved single, shared REMS program. This is an important provision of the legislation and should be retained.

By preventing such abuses of the REMS program, the CREATES Act will further patient access to safe, effective, and affordable medications. NORD appreciates your efforts to advance this important legislation, and we look forward to working with you to ensure its successful passage.

Sincerely,

A handwritten signature in cursive script, appearing to read "Peter L. Saltonstall".

Peter L. Saltonstall
President and CEO

CC: The Honorable David Cicilline
The Honorable Jim Sensenbrenner
The Honorable Jerry Nadler
The Honorable Doug Collins