



May 18, 2015

The Honorable Fred Upton, Chairman  
The House Committee on Energy & Commerce  
2125 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Frank Pallone, Ranking Member  
The House Committee on Energy & Commerce  
2322A Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Upton and Ranking Member Pallone:

On behalf of the 30 million men, women, and children affected by one of the nearly 7,000 known rare diseases, the National Organization for Rare Disorders (NORD) thanks you and the Energy and Commerce Committee for your continuing support of the rare disease community.

We are writing today to express our support for Sections 2082 and 2083 of the 21<sup>st</sup> Century Cures Act titled “Expanded Access Policy” and “Finalizing Draft Guidance on Expanded Access”.

NORD supports these expanded access provisions, and has worked with Congressman McCaul’s office to ensure that the needs of the patient community are met. We believe the provisions will provide greater transparency for patients and their doctors, and will provide companies with greater clarity on FDA’s current thinking on expanded access. We thank the Committee for including these provisions throughout the 21<sup>st</sup> Century Cures process, and we encourage its inclusion in the final 21<sup>st</sup> Century Cures Act.

Thank you again for the opportunity to engage in this exciting and much-needed initiative. We look forward to working with you and the entire Energy and Commerce Committee as the 21<sup>st</sup> Century Cures Initiative continues, and we are grateful for your recognition of these extremely important issues within the rare disease community.

For questions regarding NORD or these comments, please contact Paul Melmeyer, Associate Director of Public Policy, at [pmelmeyer@rarediseases.org](mailto:pmelmeyer@rarediseases.org) or (202) 588-5700 ext. 102.

Sincerely,

Peter L. Saltonstall  
NORD President and CEO