



August [], 2013

The Honorable [Insert Name]
[] House Office Building
Washington, DC 20515

Dear Mr./Ms. [Name] :

Thank you for your continued leadership as a member of the House Committee on the Budget and your commitment to assuring that the 30 million Americans who have rare diseases, two-thirds of whom are children, continue to have access to appropriate and often life-saving treatments. The National Organization for Rare Disorders (NORD) respectfully asks that you consider the *Food and Drug Administration Safety Over Sequestration Act, H.R. 2725*, sponsored by Congressman Leonard Lance.

This legislation, if enacted, would exempt user fees collected under the Food and Drug Safety and Innovation Act (FDASIA) from sequestration. These fees support a substantial portion of the FDA staff that reviews and approves new therapies. Sequestration of these funds inevitably will lead to delays in the availability of many new drugs and devices that patients with rare diseases need.

Fees collected from the drug and medical device industries are essential in providing FDA with the resources it needs to promptly and efficiently review applications for new therapies, many of which are intended to treat patients with rare diseases. Regulated companies have been required to pay fees since 1992 so that FDA can have enough resources to provide efficient product reviews.

FDA has been successful thus far in meeting most of its deadlines in product reviews but continued sequestration of user fee funds will undermine FDA's future ability to provide the kind of efficient reviews that will enable the marketing of new therapies.

NORD is a unique federation of patient organizations dedicated to helping people with rare or "orphan" diseases. We are committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and service. NORD supports a social, political, and financial culture of innovation that supports the basic and translational research necessary to create diagnostic tests and therapies for all rare disorders.

This legislation has NORD's support and we look forward to working with you to ensure passage of this important legislation.

Sincerely,

Peter L. Saltonstall
President and CEO