



May 15, 2019

The Honorable Nancy Pelosi, Speaker  
United States House of Representatives  
Washington, D.C. 20515

The Honorable Kevin McCarthy, Minority Leader  
United States House of Representatives  
Washington, D.C. 20515

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

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

Dear Speaker Pelosi, Leader McCarthy, 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 *Strengthening Health Care and Lowering Prescription Drug Costs Act (H.R. 987)*.

NORD is a unique federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases and assisting the over 270 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.

H.R. 987 includes provisions that will help the rare disease community in two significant ways. First, it will increase access to safe and effective generic and biosimilar medicines. Second, it will increase access to affordable, accessible, and adequate health insurance.

NORD appreciates in particular the inclusion of Subtitle C of H.R. 987 that would enact the CREATES legislation (H.R. 965) introduced by Representatives Cicilline and Sensenbrenner. Rare disease patients rely on safe and effective generic and biosimilar medicines to increase access to innovative, potentially lifesaving therapies. NORD supports this common-sense legislation because it will remove one of the barriers that delays and sometimes prevents the development of generics and biosimilars.

This legislation would give generic and biosimilar manufacturers a clear and efficient pathway to obtaining brand samples, ultimately allowing for earlier approvals. It would simultaneously ensure patient safety by requiring that the Food and Drug Administration (FDA) only authorize qualified manufacturers to receive these samples when the brand is subject to REMS requirements.

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NORD is also supportive of provisions within the legislation that aim to bolster and protect affordable, accessible, and adequate health care coverage. Section 202 of this legislation, which would enact H.R. 1386, sponsored by Representative Castor, would augment funding and strengthen the requirements for the navigator program within the Affordable Care Act. Navigators help consumers enroll in Qualified Health Plans (QHPs) and provide them with the information necessary to make better health care decisions. Rare disease patients rely on navigators to ensure they obtain the best plan possible for their unique situation.

Additionally, Section 203 would enact proposals put forward by Representative Blunt Rochester. Namely, this legislation would increase funding for the Department of Health and Human Services to carry out outreach and education programs surrounding health care coverage on the federal exchange. These programs would help consumers better understand QHPs and their ability to secure financial assistance.

Finally, Section 204 of this legislation, which would enact H.R. 1010, also sponsored by Representative Castor, would prevent the Administration from implementing the 2018 guidance pertaining to short-term, limited-duration health plans. Short-term, limited-duration health plans were intended to act as a plan of last resort for consumers in periods of transition, which is why they were originally intended to be effective for no longer than three months with no opportunity to renew. Allowing these plans, which are not required to comply with pre-existing conditions protections, to remain in effect for 364 days and to also be renewed threatens the stability of the marketplace and endangers consumers. NORD supports this legislation, which would prevent implementation of this guidance.

H.R. 987 would benefit the rare disease community, and NORD appreciates your efforts to advance this legislation. We look forward to working with you to ensure its successful passage.

Sincerely,

A handwritten signature in black ink, appearing to read "Peter L. Saltonstall". The signature is fluid and cursive, written on a light-colored background.

Peter L. Saltonstall  
President and CEO