

116TH CONGRESS  
1ST SESSION

# H. RES. 242

Affirming the importance of the Orphan Drug Act, celebrating the over 750 new orphan therapies approved since its creation, and recognizing the need to continue supporting research and development for rare diseases.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 18, 2019

Mr. BUTTERFIELD (for himself and Mr. BILIRAKIS) submitted the following resolution; which was referred to the Committee on Energy and Commerce

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## RESOLUTION

Affirming the importance of the Orphan Drug Act, celebrating the over 750 new orphan therapies approved since its creation, and recognizing the need to continue supporting research and development for rare diseases.

Whereas 30 million people in the United States, or nearly one out of every 10 individuals in the United States, lives with at least one of more than 7,000 known rare diseases;

Whereas the Orphan Drug Act (Public Law 97–414) was enacted to provide research and development incentives to encourage the development of new therapies for diseases affecting fewer than 200,000 people in the United States;

Whereas in the 10 years prior to enactment of such Act, only 10 therapies for rare diseases were developed by private industry and approved by the Food and Drug Administration;

Whereas since enactment of such Act, research and development of therapies addressing rare diseases has resulted in more than 750 new therapies for rare diseases;

Whereas experts estimate that without the tax credit under section 45C of the Internal Revenue Code (relating to a tax credit for clinical testing expenses for certain drugs for rare diseases or conditions), one of the incentives for innovation established in the Orphan Drug Act (Public Law 97–414), at least one-third of such new therapies would likely not have been developed;

Whereas the Orphan Drug Act (Public Law 97–414) continues to lead to increased research and successful therapeutic development along the full range of rare diseases;

Whereas people with rare diseases benefit from new orphan drugs by having a longer life and a higher quality of life;

Whereas society benefits from new orphan drugs through increased productivity from individuals affected by rare diseases as well as a potential decline in the resources devoted to health care, disability, caregiving, and related spending with respect to those individuals;

Whereas despite the success of the Orphan Drug Act (Public Law 97–414), fewer than 10 percent of the more than 7,000 identified rare diseases have at least one treatment option that is approved by the Food and Drug Administration; and

Whereas the significant, lifesaving accomplishments of such Act over the course of the 36 years since its enactment should be recognized: Now, therefore, be it

1       *Resolved*, That the House of Representatives—

2               (1) applauds the tremendous growth in research  
3               and development into new therapies for rare diseases  
4               and the resulting number of therapies for people liv-  
5               ing with rare diseases approved by the Food and  
6               Drug Administration;

7               (2) recognizes that significant research and de-  
8               velopment efforts and related investments are need-  
9               ed to develop therapies to treat and cure the thou-  
10              sands of rare diseases for which no treatment op-  
11              tions are currently available; and

12              (3) affirms the need to continue supporting  
13              public investment and encouraging private invest-  
14              ment in research and development of new treatments  
15              for rare diseases.

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