

115TH CONGRESS
2D SESSION

S. RES. 690

Affirming the importance of the Orphan Drug Act, applauding the life-saving accomplishments of the Act during its 35-year history, and recognizing the need to continue support for research and development of new therapies for rare diseases.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 15, 2018

Mr. HATCH submitted the following resolution; which was referred to the
Committee on Health, Education, Labor, and Pensions

RESOLUTION

Affirming the importance of the Orphan Drug Act, applauding the life-saving accomplishments of the Act during its 35-year history, and recognizing the need to continue support for research and development of new therapies for rare diseases.

Whereas 30,000,000 people in the United States, or nearly 1 out of every 10 individuals in the United States, live with at least 1 of more than 7,000 known rare diseases;

Whereas, in 1983, the Orphan Drug Act (Public Law 97–414; 96 Stat. 2049) was enacted to provide research and development incentives to encourage the development of new therapies for diseases affecting less than 200,000 people in the United States;

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

Whereas, since the enactment of the Orphan Drug Act, research and development of therapies for rare diseases has resulted in more than 650 new therapies for rare diseases;

Whereas experts estimate that without the tax credit for testing expenses for drugs for rare diseases, known as the “Orphan Drug Tax Credit”, one of the incentives of the Orphan Drug Act, at least $\frac{1}{3}$ of those new therapies would likely not have been developed;

Whereas the Orphan Drug Act continues to lead to increased research and successful therapeutic development along the full range of rare diseases, including the rarest diseases;

Whereas new therapies for rare diseases benefit the individuals affected by such diseases through increased life expectancy and improved quality of life;

Whereas new therapies for rare diseases benefit society through increased productivity of the individuals affected by such diseases and a potential decline in the resources devoted to health care, disability, caregiving, and related spending; and

Whereas, despite the success of the Orphan Drug Act, only approximately 5 percent of the more than 7,000 identified rare diseases have at least one treatment option approved by the Food and Drug Administration: Now, therefore, be it

1 *Resolved*, That the Senate—

1 (1) affirms the importance of the Orphan Drug
2 Act;

3 (2) applauds the significant, life-saving accom-
4 plishments of the Orphan Drug Act during the
5 course of the 35-year history of the Act, including
6 the tremendous growth in research and development
7 of new therapies for rare diseases and the resulting
8 number of therapies approved by the Food and Drug
9 Administration for people living with rare diseases;

10 (3) recognizes that significant research and de-
11 velopment efforts and related investments are need-
12 ed to develop therapies to treat and cure thousands
13 of rare diseases for which no treatment options are
14 currently available; and

15 (4) recognizes the need to continue supporting
16 public investment, and encouraging private invest-
17 ment, in research and development of new therapies
18 for rare diseases.

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