

114TH CONGRESS
1ST SESSION

H. RES. 95

Recognizing the importance of transformative breakthroughs in biomedicine, biotechnology, and life sciences in the diagnosis, management, curing, and treatment of illness and the existence of a “Valley of Death” in biotechnology and life sciences funding that stifles innovation and impedes translational medical research.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 5, 2015

Mr. VARGAS submitted the following resolution; which was referred to the Committee on Energy and Commerce

RESOLUTION

Recognizing the importance of transformative breakthroughs in biomedicine, biotechnology, and life sciences in the diagnosis, management, curing, and treatment of illness and the existence of a “Valley of Death” in biotechnology and life sciences funding that stifles innovation and impedes translational medical research.

Whereas cancer, rare and orphan diseases, diabetes, and Alzheimer’s are just a few of a growing number of large-scale challenges confronting modern society that can be addressed only through the sustained collaboration of thousands of highly skilled, dedicated, and independent individuals over many years;

Whereas many promising breakthroughs have occurred in biomedicine in recent years, including gene therapies, molecularly targeted drugs, new modes of medical imaging and radiosurgery, biomarkers for drug response, human genome sequencing, and advances in bioinformatics that enabled many of these new applications;

Whereas biomedicine is far more advanced today than even a decade ago is indisputable, but breakthroughs require years of translational research at a cost of hundreds of millions of dollars and have a substantial likelihood of failure;

Whereas the drug development pipeline is laden with unfavorable probabilities;

Whereas for every 5,000 to 10,000 compounds that enter the drug discovery pipeline, just 250 progress to preclinical development, and only one will become an approved drug;

Whereas the aggregate research and development budget of the pharmaceutical industry has nearly doubled from \$68,000,000,000 in 2002 to \$127,000,000,000 in 2010, there has been little appreciable impact on the number of new drugs approved;

Whereas Congress must work in a bipartisan fashion to reform the Food and Drug Administration's (FDA) review process for drug development and biomedical innovation in order to facilitate expeditious approval of safe and effective new products, better outcomes for patients, and more efficient and effective uses of FDA's limited resources;

Whereas biomedical innovation has become much more challenging to finance with private and public equity;

Whereas there is a growing concern within and outside the industry that the process of translating biomedical research into effective treatments is obsolete;

Whereas biotech and life sciences traditional financing vehicles of private and public equity are becoming less effective funding sources because the needs and expectations of limited partners and shareholders are not consistent with the increasing complexity and risk of biomedical innovation;

Whereas the lengthy process of biomedical innovation is becoming increasingly complex, expensive, uncertain, and fraught with conflicting motivations and public-policy implications;

Whereas industry professionals frequently refer to the “Valley of Death”, a steadily widening funding and resource gap that currently exists between basic research and clinical development, effectively limiting the field of potential novel therapies, technologies, and treatments for patients;

Whereas the life sciences industry needs novel approaches to early-stage drug development that better manage risk, lower capital cost, improve research effectiveness, create diverse portfolios, leverage risk-tolerant capital, and access new capital sources; and

Whereas innovative financial structures can achieve the necessary grand scale of capital needed to support effective diversification of biotech investments and create stable and attractive investment opportunities along the development pipeline: Now, therefore, be it

1 *Resolved*, That the House of Representatives—

2 (1) recognizes the importance of transformative

3 breakthroughs in biomedicine, biotechnology, and life

1 sciences in the diagnosis, management, curing, and
2 treatment of illness;

3 (2) recognizes the need for bipartisan reform of
4 the Food and Drug Administration (FDA) in order
5 to facilitate expeditious approval of safe and effec-
6 tive new products, better outcomes for patients, and
7 more efficient and effective uses of FDA's limited
8 resources;

9 (3) recognizes the existence of a "Valley of
10 Death" in biomedicine, biotechnology, and life
11 sciences funding, a steadily widening funding and re-
12 source gap that currently exists between basic re-
13 search and clinical development, effectively limiting
14 the field of potential novel therapies and drugs for
15 patients; and

16 (4) recognizes innovative financial structures
17 can achieve the necessary grand scale of capital
18 needed to support translational research and devel-
19 opment in biomedicine, biotechnology, and life
20 sciences.

○