HR 7539, The LOANS Act:
Accelerating the Development of Treatments and Cures for All Americans

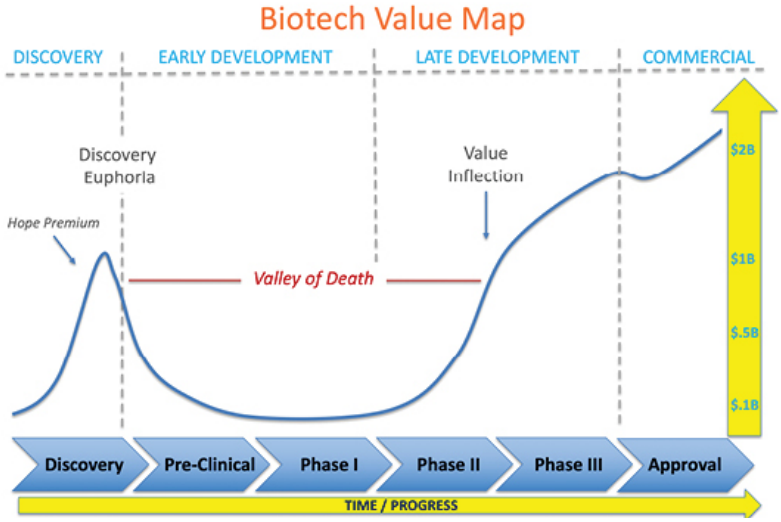
Background

The development of treatments and cures for devastating medical conditions is limited by a lack of investment in clinical biomedical research. Although government agencies like the National Institutes of Health (NIH) fund research that paves the way for human studies, private markets do not provide the stable, long-term financing that's necessary to advance critically needed medications and devices through early-stage clinical trials. **HR 7539 is a novel solution to aid the development of livesaving treatments by addressing a major gap in funding for the U.S. research community.**

The Issue

Research funding for innovative cures in the U.S. is broken. Potential remedies for diseases which affect millions of Americans, such as cancer, eye diseases, Alzheimer's Disease, and Parkinson's, fail to advance to early-stage clinical trials due to a lack of consistent private investment. Private capital does fund biomedical research, but generally only at the point at which a drug or device shows clear signs of likely success and holds out the prospect of large patient populations or high prices. Further, the existing market dynamics for new therapies also effect the availibility of capital during development.

- Drug development is expensive: from initial pre-clinical work to final approval on average costs $2.6 billion.[i] Small biotechnology companies need outside investment throughout the development process to bring their products to market.
- Private investors, namely venture capital firms and large pharmaceutical and biotechnology companies, primarily focus their investments on the later stages of drug development after there is compelling evidence of a therapeutic effect in human studies.
- Many promising treatments are unable to secure early clinical-stage private investment due to unproven market opportunity. Such products could provide lifesaving or lifechanging treatments, but stall in development due to extraneous market forces such as preferences for late-stage development and interest rates.[ii]
- The biomedical industry refers to the development period between promising lab research and clinical trial launch as the "valley of death" because so many drug candidates don't receive the needed funding to move into human studies. [iii]



HR 7539, The LOANS Act – Bridging the "Valley of Death"

The bipartisan Long-term Opportunities for Advancing New Studies (LOANS) for Biomedical Research Act will provide a lifeline to startup and small biotech companies which have received authorization from the FDA to launch early-stage clinical trials for their promising treatments and cures.

- The bill would authorize a limited federal guarantee for low-interest, long-term loans to small drug or medical-device developers. The loans would be packaged into investment instruments known as "BioBonds" and sold on the open market to long-term investors such as insurance companies and pension funds.
- These BioBond issuances would total no more than $10 billion per year for three years, backed by federal guarantees to encourage private investors to enter a field essential to public welfare. The maximum loan amount for a given company would be $25 million to ensure broad access to the loans and diversity in the portfolio.
- The loans made must be repaid, therefore minimizing the legislation's burden on taxpayers.
- A third-party economic analysis indicates that $30 billion in guarantees for new loans for biomedical research would cost the taxpayer no more than $800 million — far less than any equivalent amount of direct federal spending.
- Statutory language ensures that no single disease group or researcher is favored, and prioritization will be given to clinical trials for underserved diseases as well as for those conducted by women and minority researchers.

[i] Thomas Sullivan, "A Tough Road: Cost to Develop One New Drug is $2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less than 12%," Policy & Medicine, May 6, 2018.

[ii] Walter Isaacson, The Code Breaker: Jennifer Doudna, Gene Editing, and the Future of the Human Race, (New York: Simon & Schuster, 2021).

[iii] Sourced from https://www.pharmexec.com/view/escaping-the-valley-of-death-the-funding-process-for-biotechnology-companies