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

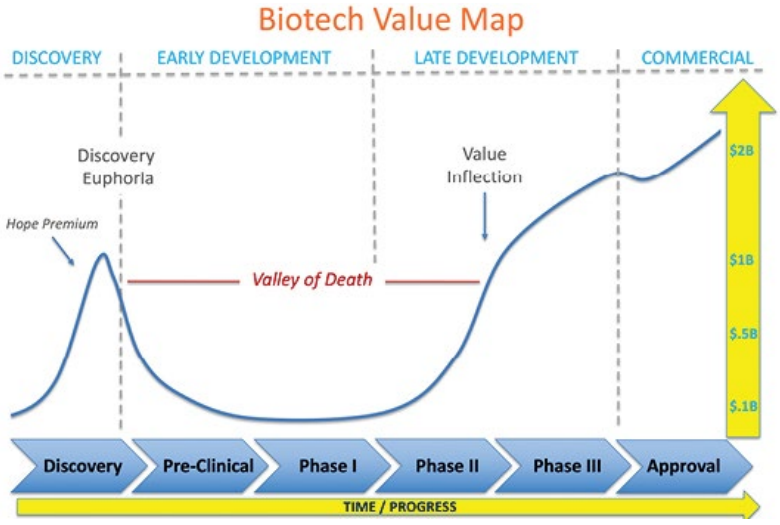
Introduction

Across the United States, patients need biomedical research and innovation. We often hear about groundbreaking discoveries from independent investigators in major disease areas such as cancer, vision restoration, mental health, and physical mobility. However, the structural issues facing biomedical research prohibit the necessary investment in early-stage research that could well advance treatments and cures far more quickly and surely with additional financial resources.

To see the impact of funding on research, one need look no further than the way the federal government mobilized resources to address the urgent, unmet medical need that was COVID-19: Operation Warp Speed (OWS). At the same time, we must consider proposals that maximize the efficient use of federal dollars to speed treatments and cures that might otherwise take years to realize. **In short, a new financial instrument is needed to accelerate biomedical progress and spur funding for innovative treatments.**

Government agencies, such as the National Institutes of Health (NIH), fund research that paves the way for human studies, but stop before the clinicial trials essential to develop successful therapies. Although private capital also funds biomedical research, it generally does so only at the point at which a drug or device shows clear signs of success, targets large patient populations, and/or garners high prices. Many of the therapies addressing the disease areas mentioned earlier are being driven by small biotechnology companies. These companies often have the same burdens as other small businesses, while additionally facing the steep costs that accompany drug development. For biotechnology companies, initial pre-clinical work to final approval is an estimated $2.6 billion.[i]

These factors have led the biomedical industry to refer 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, or through, human studies. The novel financial instrument proposed in the LOANS Act bridges the funding between early stage and clinical research, while providing a lifeline to these startup companies.[ii]



What is the LOANS Act?

The bipartisan Long-term Opportunities for Advancing New Studies (LOANS) for Biomedical Research Act authorizes 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. The bill creates funding for under-funded biomedical research – that is, for private capital investment to bridge the gap between direct government spending for basic research and high-return, short-term biomedical-funding sources such as venture capital (VC) firms and large biopharmaceutical companies.

The LOANS Act follows a time-tested financial model that led to the flow of trillions of private-sector funds for sustainable-energy and climate-risk projects deemed outside the reach of private-sector finance only a decade ago – "Green bonds." Green bonds were the world's first sustainable financial instrument, launched in 2008 with the help of a World Bank guarantee.[iii]

The LOANS Act, as currently drafted, includes several "guardrails" to ensure a diverse portfolio and successful marketplace:

A Maximum Loan of $25 Million Per Company Per Year

The maximum loan amount for a given company would be $25 million per year to ensure broad access to the loans as well as diversity in the bond portfolio. This figure will provide for a robust portfolio of companies at an amount that will make a material impact on individual organizations. Many small loans in one BioBonds instrument also significantly reduces taxpayer risk.

The Federal Government as a Guarantor – Not a Lender

It is important to note that the Federal Government is **not** issuing loans to companies. Rather, an organization applies for a loan from a bank or other lender willing to extend credit in accordance with LOANS Act regulation. As with all other loans, eligibility is determined by **ability to repay. In other words, it is not based on the likelihood of success of any one company's clinical trial. Again, this reduces taxpayer risk even as it lowers the cost of funding for small biomedical companies and allows them to retain control over critical development decisions that increases the odds of medical success.**

Assurances of Repayment

Another important protection in the bill ensures that fiscal agents only authorize purchase loans where a borrower has demonstrated an ability to repay. If a company is unable to repay the loan from cash flow, then there are several mechanisms to increase the likelihood that the borrower still "makes good" on its obligation to repay. For example, companies may choose to liquidate their physical holdings (e.g., a building) or sell their intellectual property (IP).

What is the Exact Role of the Federal Government?
The LOANS Act tasks the Department of Health and Human Services (HHS) with establishing a "BioBonds Program" to govern the way private financial institutions make eligible loans and then turn them into BioBonds. Once the program is authorized, HHS, in consultation with the Treasury, will issue governing rules that establish the process for setting contracts with financial institutions to carry out the program in the marketplace. Fiscal agents would purchase loans that are made to borrowers by financial institutions and sell bonds that are comprised of the loans. In consultation with Treasury, HHS would be responsible for issuing rules to ensure diversification across all medical conditions and ensure taxpayer protection.

How a "BioBond" Works in the Financial Market and for Taxpayers
1. A biomedical venture (university lab, foundation, company) receives FDA clearance for the human trials essential to establish treatment safety and efficacy.

2. The borrowing entity determines that debt financing is an attractive funding source – entities are of course free to pursue venture capital or other investment funding.

3. The biomedical entity applies for a loan from a bank or other lender willing to extend credit in accordance with BioBond regulation. The company need not demonstrate the likelihood of scientific success – no lender could judge this beyond the factors considered by the FDA. Instead, the borrower needs to demonstrate ability to repay under the terms of a loan. The loan is structured to enhance affordability thanks to the lender's ability to sell the loan into a BioBond and thus take virtually no risk.

4. Borrower ability to repay may be based on factors such as the likely value of its intellectual property, revenue streams from other sources, and/or a guarantee from a university, foundation, or even just one well-heeled philanthropist.

5. Rules ensure that a wide spectrum of diseases and disabilities are funded, with no borrower allowed to receive more than one loan of no more than $25 million each year on demonstration of continuing ability to repay. Clinical trials funded by BioBond loans are encouraged to ensure access and inclusion. A financial institution manages this process, purchasing loans eligible for the BioBond guarantee and structuring them into BioBonds in accordance with applicable rules.

6. In the initial three-year period authorized in the bill, up to $10 billion a year in BioBonds could be issued backed by a 90% federal guarantee for principal (not interest).

7. BioBonds might have a maturity of ten or more years with no interest due to the investor until the maturity date (i.e., "zero-coupon bonds" common in financial markets). The bond does earn interest at a preset rate (e.g., five percent), but interest payments accrue over many years after which bonds are payable to the investor.

8. As a loan is gradually repaid, a trust established for each BioBond must invest the proceeds in U.S. Treasury obligations and approved securities until the bond comes due. This income further reduces taxpayer risk. The trust also addresses any failure to repay, pursuing collateral and otherwise seeking to make the loan whole and thus protect the taxpayer.

9. All cash proceeds received from the repayment of a BioBond are first used to reduce the amount of principal guaranteed by the government and the government has a senior claim on all assets and collateral to the extent the guarantee has not been extinguished.

Federal Deficit Implications

The LOANS Act is designed to protect the interest of American taxpayers. The federal deficit impact is likely to be limited: a third-party score using Congressional Budget Office (CBO) methodology indicates that, assuming a 90 percent Federal guarantee rate, $30 billion of loans could be provided to fund clinical trial research in the United States under the BioBond program at an estimated taxpayer cost of $800 million.

Because the amount of each loan is relatively small and each BioBond would be relatively large (at least $250 million), longstanding principles of risk reduction via portfolio diversification provide a significant amount of taxpayer protection atop all the interest payments and investment income held in trust. Most loans will be repaid, investment income will be substantial, and the government guarantee will thus be called upon in only rare circumstances, if at all.

Conclusions

Research funding for cures in the U.S. is broken. The LOANS Act offers a novel mechanism whereby the private sector can work to empower the Federal Government and speed the next generation of cures for diseases and disabilities affecting millions of Americans without creating significant taxpayer risk and deficit cost. The LOANS Act will meet the needs of the American people and serve as a global model for American biomedical innovation.

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

[iii] World Bank, "10 years of Green Bonds: Creating the Blueprint for Sustainability Across Capital Markets," (March 18, 2019), available at https://www.worldbank.org/en/news/immersive-story/2019/03/18/10-years-ofgreen-bonds-creating-the-blueprint-for-sustainability-across-capital-markets