The Problem: A “valley of death” has long separated promising early biomedical research from the clinical trials needed to speed treatments and cures to patients. Pandemic disruptions have greatly exacerbated this challenge, diverting resources, forcing the indefinite suspension or end to ongoing trials, and threatening the financial viability of small biomed companies, thus slowing ongoing and new biomedical research into the next possible pandemic, cancer, Alzheimer’s, arthritis, diabetes, blindness, rare diseases, and much more.

Financial market chaos due to the pandemic makes these disruptions still worse, reducing already-scarce philanthropic and private capital funding for biomedical treatments and thereby deepening the valley of death. Patients waiting longer for urgently-needed therapies suffer needlessly and families experience even more distress.

The FDA has an established system for judging which clinical trials protect patients and have strong prospects for success. A targeted federal guarantee akin to that in H.R. 2620 speeding an end to blindness should be enacted to fund urgently-needed, FDA-approved clinical trials for treatments and cures across the spectrum of disease and disability, including those targeted at viruses and other pathogens that could cause future pandemics. Doing so would bridge the translational valley of death.

Bonds comprised of loans to new clinical trials would create a new class of investment suitable for the multi-trillion-dollar private-capital market seeking “ESG” obligations that not only provide a reasonable rate of return, but also benefit society as a whole.

Overview: A $150 billion BioBond Fund would be established under the authority of the Departments of Health and Human Services (HHS) and Treasury to set the terms and conditions for BioBond issuance. BioBonds would be comprised of loans or other financial obligations to eligible biomedical companies and universities receiving FDA approval for clinical trials. Investors in BioBonds would be those with patient, risk-adverse capital (e.g., pension funds, insurers), and borrowers must be able to repay these extensions of credit regardless of a research project’s success. A 90% federal guarantee would back the principal of bonds offered to private-sector investors.

How the bonds would work:

• Under regulations required no later than ninety days after enactment, a program would be established to solicit applications from biomedical companies and universities not otherwise able to find funding for FDA-approved trials and to convert these loans into BioBonds sold to institutional investors such as pension funds and insurance companies.
• BioBonds would include significant taxpayer protections, including assurance that funds received from loan repayments are used first to reduce taxpayer risk under the federal guarantee. Clinical-trial eligibility would be based on FDA approval and credit worthiness.
• The $150 billion authorized for BioBonds would be disbursed over the next three fiscal years in $50 billion tranches. Each $50 billion would fund any losses the taxpayers may incur on the 90% guarantee budgeted under the Federal Credit Reform Act (FCRA). FCRA scoring
would permit a considerably larger program that reaches far more diseases and disabilities based on the risks projected to taxpayers.

- Any excess bond issuances made possible by FCRA scoring would back future BioBonds after the initial three-year authorization.
- HHS would issue rules stipulating that each $50 billion of BioBond issuance would provide guaranteed loans or other specified investments in eligible companies advancing FDA-approved clinical trials in a manner ensuring that no single disease or group of related diseases or disabilities receives more than fifteen percent of the principal amount of each BioBond.
- All individual loans and related financial instruments covered by this federal guarantee would be in amounts of no more than $25 million in any single year.
- HHS in consultation with the Treasury Department would establish the size of each BioBond issuance within annual caps to ensure market acceptance, portfolio diversification and taxpayer protection.
- Entities receiving loans must demonstrate an ability to repay the loans received under this program to the satisfaction of the regulated financial institutions selected as fiscal agent(s).
- Repayment capacity would be judged by borrower collateral and financial capabilities, not the prospects for project success.
- Treasury’s financial agents would also be required to ensure compliance with all terms and conditions, including that guarantees support a diverse range of biomedical projects that do not favor one disease or disability other than as directed by Congress.
- These financial agents would also act as BioBond issuers, with compensation provided from bond proceeds in an amount determined by Treasury regulation.
- Loan terms would be based on applicable Treasury rates for obligations of comparable maturity plus a rate to be determined by Treasury regulation to reflect prevailing market conditions, taxpayer protection, and the need to ensure ample funding for FDA-approved clinical trials.

When the authorization expires, private lenders and investors would be better able to price and absorb the financial risks associated with translational biomedical research, creating a new asset class rivaling “green bonds,” which started with a small World Bank guarantee over a decade ago. Due in part to that guarantee, there would now be a market of over $500 billion a year in private capital for sustainable energy. BioBonds would do the same for urgently-needed treatments and cures.