Addressing the "Valley of Death" in Biomedical R&D Investment

Pending Legislation in the 118th Congress:

Updated May 2024

The "valley of death" in biomedical R&D investment refers to situations in which factors like high risk of failure and low rate of potential return in the marketplace leave gaps in the funding needed to translate basic research into new preventative measures, diagnostics, treatments, and cures.

Most investment incentives fall under one of two broad categories: "push" or "pull" mechanisms. "Push" mechanisms are incentives that help offset the costs of conducting the needed R&D. This category includes such funding mechanisms as prize competitions, tax credits, subsidies, and grants.

"Pull" incentives guarantee or bolster the revenues generated from product development. This category typically takes the form of market entry rewards, which provide a guaranteed funding stream after a product enters the market. Advanced market agreements are a common subset of these awards and guarantee procurement at a pre-set price and quantity. Exclusivity contracts are another form of market entry reward that guarantees the purchaser will only buy from one seller. A third version, fully delinked market rewards, provides a stream of funding that is not tied to the price or quantity of a product. Other push mechanisms include faster regulatory review, and voucher programs, which currently span "faster regulatory review" vouchers and "market exclusivity" vouchers.

Several members of Congress have introduced legislation that would establish new mechanisms specifically targeting marketplace gaps – from new direct funding sources, to targeted tax credits, to bond funds, to expanded eligibility for existing incentives, to "subscription" payments. While Research!America has not taken a position on any specific piece of legislation, we applaud Congress for seeking creative ways to maximize the value of publicly funded basic research by fostering its translation into fast-paced medical and public health progress.

Following is a summary of current "valley of death"-relevant legislative proposals. Please let Savannah Sims ssims@researchamerica.org know if we have missed any! Note this list does not include proposals that would establish or modify grant programs at the National Institutes of Health:

Incentive Legislation Summaries:

S.1355: Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act of 2023
Sponsor: Sen. Michael Bennet (D-CO)
Cosponsors: (7)
Companion Bill: H.R.2940: PASTEUR Act of 2023
Companion Sponsor: Rep. Drew Ferguson (R-GA-03)
Companion Cosponsors: (60)

Summary: Official One Pager
The "PASTEUR Act of 2023" was re-introduced into Congress by Senators Michael Bennet (D-CO) and Todd Young (R-IN), alongside U.S. Representatives Drew Ferguson (R-GA-03); Scott Peters (D-CA-50); Jake LaTurner (R-KS-02); and Mike Levin (D-CA-49). Among its provisions, the legislation would establish a subscription-style "pull" mechanism. Under a subscription model, instead of receiving reimbursement for individual uses of a drug under Medicare, Medicaid, and other federal health programs, pharmaceutical manufacturers would receive upfront payments in exchange for providing those programs as much of the drug as needed.

S.3464: Finding Orphan-disease Remedies with Antifungal Research and Development (FORWARD) Act of 2023
Sponsor: Sen. Mark Kelly (D-AZ)
Cosponsors: (2)
Companion Bill: H.R.6731: FORWARD Act of 2023
Companion Sponsor: Rep. David Schweikert (R-AZ-01)
Companion Cosponsors: (7)

Summary:
Arizona Senators Mark Kelly (D-AZ) and Kyrsten Sinema (I-AZ), along with Congressman David Schweikert (R-AZ-01), introduced the "FORWARD Act of 2023", to support research initiatives to combat Valley fever. The FORWARD Act proposes several new strategies for elevating R&D against fungal infections. Among its provisions, it would expand the list of diseases eligible for the Food and Drug Administration's (FDA) neglected tropical disease priority review voucher to include the fungal infection Valley fever, streamline the approval process for new vaccines and treatments, and authorize $500,000,000 to support public-private partnerships to prevent and slow the spread of Valley fever infections.

H.R.3832: Disease X Act of 2023
Sponsor: Rep. Lori Trahan (D-MA-03)
Cosponsors: (3)

Summary:
The Disease X Act of 2023, **introduced** by Representatives Lori Trahan (D-MA-03), Michael Burgess (R-TX-26), Dan Crenshaw (R-TX-02), and Susie Lee (D-NV-03), would incentivize R&D focused on viruses of pandemic potential. As it stands, the Biomedical Advanced Research and Development Authority (BARDA) does not have explicit authority to use push and pull incentives to encourage private sector development of countermeasures for viruses with pandemic potential. This legislation would give BARDA that authority.

H.R.5821: Mental Health Research Accelerator Act of 2023
Sponsor: Rep. Mike Thompson (D-CA-04)
Cosponsors: (3)

Summary:
Introduced by Rep. Mike Thompson (D-CA-04) and Rep. Mike Kelly (R-PA-16), the Mental Health Research Accelerator Act focuses on incentivizing collaborative efforts to advance research on neurodegenerative diseases and mental health conditions. The legislation would establish tax credits for private companies who collaborate with nonprofit research institutions on neurological research.

H.R.6424: The Supporting Innovative Global Health Technologies (SIGHT) Act of 2023
Sponsor: Rep. Brian Fitzpatrick (R-PA-01)
Cosponsors: (7)

Summary:
Representatives Brian Fitzpatrick (R-PA-01), María Elvira Salazar (R-FL-27), and Chrissy Houlahan (D-PA-06) introduced the Supporting Innovative Global Health Technologies (SIGHT) Act of 2023 to empower the United States Agency for International Development (USAID) to boost its research and development capabilities for health care technologies in low-income countries. Among its provisions, the bill would authorize a new grant

fund at USAID designed to advance several critical objectives, including developing new health technologies for use in low-resource settings to improve global health.

H.R.7539 – The Long-term Opportunities for Advancing New Studies (LOANS) for Biomedical Research Act
Sponsor: Rep. Brian Fitzpatrick (R-PA-01)
Cosponsors: (3)

Summary:
In March 2024, Representatives Brian Fitzpatrick (R-PA-01) and Sanford D. Bishop, Jr. (D-GA-02) introduced the LOANS for Biomedical Research Act to fund medical research for treatments and cures for diseases with unmet medical needs. The legislation creates a federally backed "BioBond" loan program that provides funding to eligible biomedical companies and universities to conduct clinical trials approved by the FDA.

Additional Tax Incentive Legislation

Other pieces of legislation, including H.R.5206, H.R.5207, and H.R.6979 would build off the current R&D tax credit to incentivize research focused such public health challenges as the Opioid crisis and biosecurity threats.