August 17, 2021

The Honorable Anna G. Eshoo
Chairwoman, Health Subcommittee
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Brett Guthrie
Ranking Member, Health Subcommittee
House Committee on Energy and Commerce
2322 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairwoman Eshoo and Ranking Member Guthrie,

On behalf of the Research!America Board of Directors and alliance members, thank you for your steadfast commitment to advancing the health of Americans and populations across the globe. As you determine which policy issues and legislation the subcommittee will explore when the House returns from recess, we respectfully request that you consider holding a hearing on the “valley of death” in biomedical R&D financing. Several avenues that could play a meaningful role in addressing the so-called value of death have been proposed, including ARPA-H and the Long-term Opportunities for Advancing New Studies (LOANS) for Biomedical Research Act (H.R.3437).

The phrase “valley of death” in the context of biomedical R&D financing generally refers to the challenge of securing financing for high-risk, high-reward translational research at an early stage in the R&D continuum. However, financing gaps also exist in the highly competitive arena of financing for the clinical trials needed to assure new product safety and efficacy. COVID-19 disruptions and delays have only widened this funding gap. It is particularly tragic to see potential advancements reach FDA review and then fall by the wayside, not because they will not help patients in significant ways, but because other investment options take precedence.

A hearing on the “valley of death” would offer an opportunity to highlight the President’s ARPA-H proposal, as the proposed entity would serve as a bridge over the valley between basic science and practical use by supporting high-risk, high-reward biomedical R&D efforts. As NIH Director Dr. Francis Collins so aptly explained in an interview with Federal News Network this past July:

“...there is this traditional phrase called the Valley of Death, which is actually a pretty accurate description of what happens to a lot of promising clinical
advances, where you get to a certain point where you could see the potential, but it’s not something that commercial sector is ready to invest in, it’s too high-risk or the market is too small. And so it just goes into the Valley of Death and dies. And people therefore are not benefited by it. If we had an entity, and ARPA-H could be a really good one, to pick up those that seem most promising and be willing to fail. Because that’s necessary. If you’re going to get work done, you’re going to have to accept the fact that isn’t always going to work.”

The hearing could also incorporate H.R.3437. The bill, introduced in late May by Reps. Bobby Rush (D-IL) and Brian Fitzpatrick (R-PA) and which has support from 27 health- and research-related organizations, acts to overcome the valley of death in another way. Specifically, it authorizes a loan program for clinical trials that have received FDA clearance, but that cannot move forward because further financing simply is not available. Like early stage, high-risk, high-reward research, these funding gaps often arise because other potential treatments with a larger patient base are competing for the funding. Yet the size of the patient population is just one of several variables bearing on the human and economic toll any given disease exacts. It is vastly in the public interest to ensure financing is available when advances in medical progress are within our sights.

As the ARPA-H proposal and H.R.3437 illustrate, the status quo in R&D financing need not circumscribe the pace of medical and public health progress. The federal government can partner with the private sector in new ways to advance the public good. Because lost potential in the R&D arena translates into tragic missed opportunities to protect, restore, and advance health, we respectfully request that the subcommittee hold a hearing on these proposals as soon as possible when Congress returns from the August recess.

Thank you for considering and thank you to you and your staff members for the hard work you are devoting to our nation.

Sincerely,

Mary Woolley
President & CEO
Research!America

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The Honorable Frank Pallone, Jr.
The Honorable Cathy McMorris Rodgers