

February 7, 2022

Dear Chairwoman Eshoo, Ranking Member Guthrie, and Members of the Health Subcommittee,

I am writing to applaud your bipartisan efforts to create a new Advanced Research Projects Agency for Health (ARPA-H). As the leading biotech platform innovation firm, Flagship Pioneering prides itself on asking bold and provocative questions that drive our innovative science forward, often in unprecedented ways. So as we consider the ambitious remit of a proposed new ARPA-H, we would like to pose this question to the Subcommittee -- What if we could create a future largely free from disease?

Over the past two years, the world has experienced the devastating collision of the “fast” pandemic of COVID-19 with the “slow” pandemics of obesity, diabetes, cancer, neurodegeneration, and other chronic disease. The non-elderly with such underlying health issues were most likely to suffer serious illness or death from COVID-19. Our communities, particularly the underserved, have been hit so hard not only because we were unprepared for pandemic threats, but also because we suffer from insufficient health resilience. Too many people were too vulnerable because of their poor health — but it does not have to be this way.

One lesson? We have been too complacent about disease. Our healthcare and medical product innovation systems are actually *sick care* systems: they are almost entirely focused on the diagnosis and treatment of disease rather than on protecting, maintaining or improving health. By waiting for disease to manifest, outcomes are worse and costs are higher – for both society and afflicted patients.

We believe that an alternative, proactive paradigm can be built, so that people live disease-free for longer: adding years to life and life to years. By focusing on the period before sickness manifests, when people are seemingly healthy, we can preempt disease. During these periods of pre-disease (before we are patients), we know that underlying physiological changes have begun that indicate that a trajectory toward disease has commenced. By proactively identifying disease precursors and the novel biomarkers of a pre-disease state, we can find new ways to intervene earlier to reverse, prevent or postpone disease. We at Flagship call this preemptive health: the application of leading-edge biological sciences and digital technology to traditional population-level health goals. This is an urgent problem and requires innovative approaches that expedite the clinical development and regulatory pathways.

We believe ARPA-H can aid this revolutionary paradigm shift from our current sick care system to a true healthcare system by spurring development of truly transformational technologies that preempt progression of disease at much earlier stages. By marshalling its resources, access to large research and biological datasets, advanced technologies such as AI and machine learning, partnerships with industry, and risk-taking culture, ARPA-H can help us tackle our most scientifically challenging diseases in novel, use-driven ways aimed at developing targets and technological strategies for early disease intervention.

Moreover, multidisciplinary efforts could be aimed at creating the scientific foundations for a new regulatory framework that should be created – one that would provide a transparent roadmap for facilitating efficient innovation for pre-disease detection and intervention, something the current FDA regulatory paradigm is not designed to do. This is the type of breakthrough R&D which it is challenging

for any single company to effectively pursue, but which would be essential to fulfill ARPA-H's overall mission to dramatically accelerate the development of game-changing technologies and medicines for patients.

We do not believe this approach would duplicate or intrude upon the broader basic research function of the National Institutes of Health. Rather, we believe ARPA-H can and should focus on leveraging this massive federal investment in basic research to identify and support mechanisms for transformational change aligned with its ambitious mission.

As the Subcommittee develops authorizing language for ARPA-H, we would encourage you to consider ways to incorporate this critical concept of preemptive health into the mission of this new agency, and Flagship stands ready to assist you in any way.

Sincerely,



Noubar Afeyan, PhD.
Founder & Chief Executive Officer
Flagship Pioneering