Advanced Research Projects Agency for Health (ARPA-H) Fact Sheet

We will see more technological change in the next 10 years – than we saw in the last 50 years. And we're falling behind in that competition. … The National Institutes of Health, the NIH – should create an … Advanced Research Projects Agency for health. To develop breakthroughs – to prevent, detect, and treat diseases like Alzheimer's, diabetes and cancer. … I can think of no more worthy investment. And I know of nothing more bipartisan. (President Biden's Joint Address to Congress April 28th 2021).

We stand at an unprecedented moment of scientific promise. The creation of a new entity, the Advanced Research Projects Agency for Health (ARPA-H), seizes this opportunity and challenge.

I. Concept for ARPA-H
The mission of ARPA-H will be:

> **to make pivotal investments in break-through technologies and broadly applicable platforms, capabilities, resources, and solutions that have the potential to transform important areas of medicine and health for the benefit of all patients and that cannot readily be accomplished through traditional research or commercial activity.**

ARPA-H will:
- Revolutionize how we prevent, treat, or cure a range of diseases, including cancer, infectious diseases, Alzheimer's disease, and other diseases that have a significant impact on Americans' health and quality of life.
- Embrace "use-driven" ideas focused on solving practical problems that advance equity and transform breakthroughs in biomedicine into tangible solutions for all patients more rapidly than was previously thought possible.
- Foster breakthroughs to serve patients equitably—at levels ranging from the molecular to the societal—and drive them to the point that they will be adopted by medicine and commercialized by industry.
- Examples of projects that ARPA-H might undertake: developing mRNA vaccines to prevent most cancers; creating molecular "zip codes" that target drugs only to specific tissues and cell types, to eliminate serious side effects; highly accurate, inexpensive, non-intrusive, wearable monitors for blood pressure and blood sugar that provide real-time data to patients and providers; and holistic systems that eliminate racial disparities in maternal morbidity and mortality rates and premature births.
- Many more areas are ripe for major transformation with the right support and collaboration.

II. Structure of ARPA-H
- ARPA-H will be a distinct division within the NIH, with a unique culture and organization.
  - Creating ARPA-H within the NIH, rather than as a stand-alone entity, makes sense because the ARPA-H mission falls squarely within the overall NIH mission ("to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability") and because it is important that ARPA-H be closely coupled to the vast range of biomedical and health knowledge, expertise, and activities within NIH.

- ARPA-H will focus on time-limited projects with goals, benchmarks, and accountability.
- ARPA-H Director will be selected based on extraordinary technical and leadership skills, such as proven innovation and partnership-building track-records, and will be responsible for setting the culture, including injecting the principles of risk-tolerance, urgency, equity, and innovation into every decision.
- A diverse cohort of ARPA-H program managers will be recruited from industry, academia, or other sectors based on demonstrated scientific vision, judgment and management skills, and they will have broad autonomy to drive transformational change.
- ARPA-H will establish partnerships and collaborations with key stakeholders from industry, government, non-profits, and academia to leverage critical skills and expertise in tackling the systemic challenges that the current systems were not designed to address.

III. Authorities needed by ARPA-H

To accomplish its mission, ARPA-H will need many of the same authorities and flexibilities employed by DARPA and ARPA-E.

- Like DARPA and the similarly-modeled ARPA-E, ARPA-H will need to hire individuals rapidly based on a unique skill set outside the typical civil service hiring system and pay those individuals a competitive wage, including those in administrative or management positions for the agency. [42 U.S.C. 16538(g)(3)(A), (C), and (D); 10 U.S.C. 1599h (b)]
- Like DARPA, ARPA-H will need to recruit expert program managers from industry, academia, and think tanks to lend their skills and knowledge to the government for 3-5 years, with adequate protections for both the government and the individual. [10 U.S.C. 1599g]
- Like DARPA, ARPA-H will need broad, flexible funding authorities that make it possible to mix and match from the best ideas within different applications with minimal bureaucracy [42 U.S.C. 282(n)], that allow for projects that don't fit neatly into one-year intervals [41 U.S.C. 3903], that allow for funding distribution over multiple years [42 USC 16538(o)], and that provide a mechanism to challenge scientific teams and industry players to compete. [10 U.S.C. 2374a]
- ARPA-H will need exemptions from traditional proposal review processes, which work well for much of the biomedical research ecosystem, but can take 18 months or more to get from idea to workshop to concept clearance to funding announcement to application to first, and second level scientific review before the actual work even begins. [42 U.S.C. 289a and 42 U.S.C. 284a]

IV. Resources needed by ARPA-H

ARPA-H will require adequate resources to support transformative projects:

- The President's Budget for fiscal year 2022 requests $6.5 billion that can be spent over three years.

Conclusion

The potential opportunity is extraordinary: ARPA-H can help shape the future of health and medicine in the U.S. by transforming the (currently) impossible into reality.