Good morning, Chairwoman Eshoo, Ranking Member Guthrie, and Members of the Subcommittee. Thank you for the opportunity to speak before you today and for your consideration of a new federal entity, the Advanced Research Projects Agency for Health or ARPA-H. This is a concept that my colleague, Dr. Michael Stebbins, and I have been working on since 2016. We are delighted to see it gaining momentum with President Biden and the bipartisan support it has received from Congress. I want to acknowledge Mr. Bob Wright and Ms. Liz Feld of the Suzanne Wright Foundation, who have been instrumental in the development and promotion of this momentous initiative.

ARPA-H holds the potential to transform health care and improve health for all Americans and people around the world through the creation of new diagnostics, treatments, and cures. The Committee is well informed of the breadth of support for the creation of ARPA-H. I do wish to point out that Dr. Stebbins and I made the case for ARPA-H (HARPA) in 2019 for the Day One Project and I have provided your staff with a copy of that paper for reference. A cornerstone of our thesis is ARPA-H should be modeled identically on the Defense Advanced Projects Agency (DARPA), the gold standard for innovation.

In order for ARPA-H to revolutionize the discovery and delivery of medical capabilities it needs a revolutionary apparatus. Nothing is more critical to the success of this new agency than getting it right from Day 1, starting with the leadership, authorities, resources, culture, and independence. Retrofitting an existing agency within the government to include ARPA-H will send a message that this approach is merely more of the same, with a different name and some new funding.

While an active-duty Army colonel and after, I served at DARPA for 11 years and was the founding Director of the Biological Technologies Office, a Defense Sciences Office Program Manager, and was named “DARPA Program Manager of the Year” in 2009. DARPA’s success developing transformational technological capabilities for national security and everyday life are well known and result directly from its organizational structure and culture. Notable DARPA innovations include the Internet (aka ARPANet), Saturn rocket engine, GPS, night optical vision, portable ultrasound, stealth, robotics, self-driving car, Siri and mRNA genomic vaccines. The “DARPA model” provides an ideal template for ARPA-H.

I would like to focus your attention on one essential aspect of DARPA critical to its success: its independence from larger more established research funding entities in the Dept of Defense. During its inception in 1957, there were efforts by the Army, Navy, and Air Force to fold DARPA into their respective organizations. The Army, Navy, and Air Force were already conducting research and development so certain organizational structures were in place. The rationale was that existing administrative functions such as contracting, legal, and human resource offices could be used to support this new agency. Fortunately, President Eisenhower recognized that if DARPA were to be placed into an existing organization it would be subsumed into an existing culture and thus, nothing would change.

We have an opportunity today, like we have never had before, to build an engine of innovation with the potential to save and improve millions of lives. Industry is on the sidelines waiting for a green light that signals the kind of urgency, accountability, and culture around our health investments that they have seen for DARPA projects.

ARPA-H must be an independent agency within HHS. It must have a reporting structure separate and distinct from the NIH and other agencies. It must have a budget clearly identified and codified into law as separate and distinct from the NIH and the other agencies. Oversight of ARPA-H should come from Congress and not the NIH or any of the other agencies. ARPA-H leadership should hold Director status, with the same rank as the FDA, CDC, CMS, and NIH leaders. Importantly, the ARPA-H Director and senior staff must be term limited to ensure fresh ideas and perspectives are always flowing into the agency.

DARPA’s culture is distinct from the other DoD research and development agencies. ARPA-H must have the same innovative culture. The philosophy is to create capability as quickly and efficiently as possible. To do this, it will be a culture of looking for ways to say “yes.” It will be a culture of urgency.
It will be a culture of solving problems. How does DARPA do this? DARPA program managers are recruited from everywhere – universities, government, and industry, including start-ups. They serve for pre-determined tenures, at will, which imbues them with urgency and personal responsibility. Risk is rewarded so long as that risk is mitigated by detailed planning, close oversight, and setting clear expectations that involve rewarding success and termination of funding for not meeting performance goals. Program managers must have authority and flexibility in managing their programs to include moving funds from one team to another, terminating contracts for inadequate performance, and bringing in new performers to optimize success. These are core processes that enable DARPA to function as well as it does. An analogy to the DARPA model is professional baseball teams. They will make roster changes during the season, and the teams who made the correct changes will be the ones in the World Series. The accountability for the poor program performance rests with the Program Manager. The accountability of Program Manager performance rests with the Director.

ARPA-H will create new capabilities that cannot be created through other funding mechanisms because they require intense project management approaches that are unique to the DARPA model. These capabilities should be foundational and thus able to solve numerous problems. However, the program itself will be focused on a “use case” to achieve the objective of creating and delivering the capability. An example of an unmet serious problem is the lack of a reliable U.S. solution to the PPE shortage. A DARPA program was created to develop a robot that makes garments such as uniforms. This robot could just as easily make PPE. Another example is ensuring U.S. military’s independence from overseas medicine manufacturing. In 2009, DARPA created a program to develop point-of-care medicine manufacturing to streamline the military’s logistics chain and to alleviate its dependence on a potential peer adversary for any aspect of medicine procurement, including chemical precursors, active pharmaceutical ingredients, or final formulated drugs. This program will result in a “3-D printer” for final formulated medicines that will fit into the back of a Humvee or onto a Blackhawk helicopter to go where the troops go, wherever they are called to serve. DARPA was created to serve DoD. It has stepped in to meet vulnerabilities pertinent to servicemember health. ARPA-H will be created to serve HHS and thus the health of all Americans.

ARPA-H needs to be separate and distinct for fairness. The other agencies do their intended functions well. It is both unfair and unreasonable to expect another agency to change or adapt its culture to enable ARPA-H’s. Every HHS agency should be allowed to do what it does in the manner and with the culture most suitable for their purpose.

ARPA-H has the potential to be another U.S. contribution to the world, and another example of visionary U.S. leadership resulting in improved health and quality of life. However, if ARPA-H is to realize this future, it must be allowed to become what it must, do what it must, and do what is needed. The only way it can accomplish this is by being unencumbered by existing structure, organization, and bureaucracy. It must be separate, distinct and independent.

Thank you.