

WRITTEN TESTIMONY

OF

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SUBCOMMITTEE ON HEALTH

**ARPA-H: THE NEXT FRONTIER OF BIOMEDICAL
RESEARCH**

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Chairwoman Eshoo, Ranking Member Guthrie, Members of the Subcommittee, thank you for the opportunity to speak with you today about what I believe is an historic and transformational moment in American biomedical research and American history– the creation of ARPA-H – a moment that is both long overdue and desperately needed.

Most of you know me as Admiral Giroir, former Assistant Secretary for Health and Acting FDA Commissioner, and the “Testing Czar” in the Trump Administration. But long before that, in 1998 while faculty at UT Southwestern Medical Center, I became a member of a small technical assessment group sponsored by DARPA. Our group spent months each year probing the frontiers of science, and then providing recommendations for new programs and initiatives to the agency. One of our initial studies led to the development of chlorine dioxide as the first operationally viable gaseous decontamination agent for biological warfare agents – it was later used to decontaminate the Hart Senate Office Building and numerous other facilities after the 2001 Amerithrax anthrax attacks.

Five years later, in late October 2003, I received a call from the DARPA Director, Tony Tether, that the country needed me to leave my tenured university faculty position, my practice of pediatric ICU medicine, and my home, to come to DARPA as the Deputy Director, and eventually the Director, of the Defense Sciences Office. I would have no career there, an uncertain future when my tour was over, a dramatic drop in compensation, family disruption, and the most onerous national security investigation and clearances imaginable; but I would have the chance to serve our nation in a truly unique role, and perhaps change the world in the process. On January 2, I was in Arlington Virginia, at DARPA, for the opportunity of a lifetime. I later became the first physician to lead an office at DARPA in its 50-year history.

During my 4½ years at DARPA, and many times since, I have been involved in assessing and recommending concepts for organizations loosely modeled on DARPA – within the United States government, and also among our global allies. Almost always, these organizations have failed to live up to the achievements of DARPA

because they were created with fatal flaws that condemned them to mediocrity from their inception. America cannot afford to make these mistakes in the creation of ARPA-H.

I am enthusiastic about being here before this subcommittee, because the legislation proposed by Chairwoman Eshoo evidences deep insight into what is critically needed to enable ARPA-H to achieve our nation's extraordinary expectations - to transform public health and medicine, and end centuries of unacceptable health disparities.

Before commenting on a few specific issues, I want to detail several overall principals that must be the foundation of the agency and its operation:

1. At all costs, ARPA-H must nurture and protect a *culture of innovation*, where the Director and program managers seek transformational change, not incremental change; where there is no disincentive for failure, only for not being bold enough; where conventional wisdom and ideas are acknowledged, but almost always rejected in favor of novel hypotheses and orthogonal approaches; where the power of ideas are always more important than a proposer's institutional brand or national influence; where leaders *orchestrate* instead of *manage*; where leaders protect program managers from bureaucratic intrusion and administrative distraction; and where the goal is to create an interactive collaboration among diverse performers around a common goal, rather than stove-piped competition among performers working in their own individual siloes.

2. The ARPA-H Director must have the ability to motivate, attract, hire, and enable diverse program managers from the government, academia, non-profits, and industry. Program managers must be exceptional not only in their scientific expertise in a single field (which may or may not be medicine), but for their ability to work "out of the box" and out of their specific field of expertise. Program managers must be entrepreneurial leaders who spend most of their time roaming the country in search of new ideas and approaches, and building empowered teams who share unbridled passion to achieve the objectives of the program.

DARPA program managers do not look for a reason to reject a proposal, as is the case for many other federal funding organizations; rather, they look for even one key insight or novel approach that could be catalytic for success, and then work collaboratively with the performer to emphasize the strengths and minimize the weaknesses of the proposal. As one DARPA internal quip goes: “An NIH program officer approaches a barn, opens the door, sees that the barn is 6 feet deep in horse manure, is horrified by the smell, screams in disgust, and runs away from the barn. A DARPA program manager opens the same door, sees and smells the same manure, but immediately asks the question, where is the pony?”

Program managers will make or break ARPA-H. They cannot fear failure, only failure to swing for the fences. Program managers at ARPA-H must understand, as I did at DARPA, that if you don’t invent the next Internet, at best you get a “B” on your report card.

3. ARPA-H must have rapid, streamlined, and non-burdensome processes to award grants, contracts, cooperative agreements, and “other transactions” within weeks, not months or years. DARPA uses contracting officers and their technical representatives from throughout the government, from diverse departments, based on their ability to effectively interact with and enable performers. During my tenure, DARPA’s in house contracting shop was only used for the most challenging programs or atypical government performers, and represented only about 10% of total funds expended by the agency.

There are other important principals, but in my experience, these are the most crucial; and the specific legislative authorities and procedures bestowed on ARPA-H by Congress must reflect and operationalize these principals.

Next, let me comment on a few specific issues directly related to pending legislation:

1. In my opinion, it would be a fatal mistake to organize ARPA-H within NIH. To a great degree, we need ARPA-H because the NIH has not, and cannot, create the

culture of innovation, the disciplined execution and managed accountability, and streamlined processes that are required for a DARPA-like agency. This is not to say that the NIH is not outstanding and necessary for what it does – it is. But the NIH will never be DARPA or ARPA-H. As such, I am strongly supportive of Chairwoman’s Eshoo’s legislation that ARPA-H be independent of NIH and that the Director should report directly to the Secretary of HHS. ARPA-H should not be housed on the NIH campus, and perhaps not even in DC. It must be in a place where program managers and their families want to temporarily locate for 4-6 years, near a convenient airport, and in an open environment where performers from academia, non-profits, government, and commercial entities can easily gather and interact with ARPA-H staff and each other.

2. There is a rumor that DARPA does not utilize peer review as part of its selection processes. That rumor is false. DARPA does indeed utilize expert reviewers to evaluate proposals, but unlike NIH, DARPA engages in *peer review* but not *peer decision*. For the most part at NIH, academics from within the specific field form peer review committees. Members on the review committees know the proposers at least professionally if not personally, tend to be highly risk-averse, and essentially rank the proposals by specific *quantitative* scores. With rare exception, a cutoff score is established by available resources; proposals scoring above the line are funded, and those below the line are not.

In contrast, the review process for ARPA-H should look more like the DARPA process. In general, reviewers are technical experts within DARPA and other governmental agencies, not academic peers who work in the field and subject to personal and professional bias and self-interest. At DARPA, proposals were ranked *qualitatively* along several general parameters, not ordered in a regimented rank by specific quantitative scores. Most importantly, the program manager together with the director must be able to select performers based on the overall likelihood of the program achieving its objectives. As such, it is critical to pick a variety of technical approaches and performers with an array of different risks and relative assets, not just the “top five scoring proposals” that may all look

the same, and had been carefully submitted by historically advantaged institutions that have mastered grantsmanship.

3. With the exception of core business and legal staff, ARPA-H staff should have a limited term, and my suggestion is 4 years with an option to renew for another 2 years. When program managers are time-limited, they don't worry about their careers because they don't have a career to begin with. Term limits also create a "hair-on-fire" culture in which program managers know they have a limited time to achieve their dreams, create their legacies, and to change the world. At ARPA-H, there should be no limitations on creativity, no bureaucratic barriers, and essentially no limitations on resources – the only limitation is personal performance during a defined period of time. That is extraordinarily motivating and a "secret sauce" for success.
4. Proposers from academia, industry, and non-profits are, in general, equally eligible to propose to DARPA, and the same should be so for ARPA-H. In my experience, hybrid teams that bring together the best of these diverse sectors are the most successful in achieving aspirational goals. *Teams* should be encouraged by ARPA-H, if not outright required for a majority of programs.

DARPA often leverages informal white papers by proposers in response to a Broad Agency Announcement (BAA). These white papers, written simply and following "Heilmeier's Catechism" (see attachment), serve as the basis for initial discussions and interactions from program managers. They also serve as the basis for teaming; indeed, we frequently had "speed dating" events where potential proposers were brought together in a single room to self-assemble into teams – and sometimes even for DARPA "forced marriages."

White papers can also serve as the basis for seedling funding, which is generally a few hundred thousand dollars available within weeks to jumpstart an idea. The results of seedlings can serve as the basis for advancing an idea or group of ideas into a major program. Once an idea or approach gains traction, then a formal

RFP or BAA is posted and traditional rules for competitive selection are followed.

Once a proposal is selected, unlike for NIH grants, performance of contractors and grantees is frequently reviewed by program managers (weekly), office directors (quarterly) and the director (annually). There are milestones and timelines, and if these are not met, the entire weight of the agency tries to address the root cause and remedy it. ARPA-H can only be successful if the performers are successful. On the other hand, if a project is irretrievably unsuccessful, funding can be stopped and reallocated to alternate approaches.

5. The choice of the ARPA-H Director, especially the inaugural one, will set the tone for the agency; and thus, the choice is a critical one. The Director must have deep technical knowledge in *a* field, but by definition, cannot be expert in everything that ARPA-H will address. The Director must be strategic, visionary, and able to recruit the best and brightest program managers and convince them to completely disrupt their lives for a once-in-a-lifetime opportunity. The ability to communicate up the chain, down the chain, and especially to potential performers across the country is paramount. The Director does not need to be the smartest person in the room, but must be able to discern opportunities and risks, and mentor and enable the creativity of program managers and staff.

An option for the President and Congress might be to place a former DARPA Director, Office Director, or highly successful Program Manager as ARPA-H *Acting Director*, in order to establish the appropriate culture and processes for a limited time until a “permanent Director” can be appointed by the President and/or Congress. There are many individuals with bioscience expertise who were highly successful at DARPA who could potentially fill such a role.

6. The programs and initiatives at ARPA-H must be informed by national priorities, and thus it is vital for the Director and program managers to receive diverse input from federal, state, and local stakeholders – just as we did at DARPA from all

segments of the Armed Forces and Intelligence Community. I do believe the ARPA-H mission should be broad, and approaches to achieving the objectives should be unencumbered by traditional norms.

But national priorities must also intersect with scientific opportunities. It may not be possible to “cure late-stage pancreatic cancer” next year, although it is clearly a national priority; but it may be possible to develop technologies for extraordinary early diagnosis of multiple cancers at home, on a rapid test, and then provide early and curative treatment. I believe it is highly possible to create distributed and equitably accessed technologies to monitor health in the home, prevent falls, diagnose and treat early kidney disease and prevent the need for dialysis, and prevent pregnancy complications that lead to maternal mortality especially among racial and ethnic minorities. These types of initiatives are in the sweet spot for the DARPA process, and can be early wins for the new ARPA-H within its first few years.

7. It is critical to understand what ARPA-H can and should do, and what it cannot. The role of ARPA-H should *not* be to implement and bring to the market preventions or cures. ARPA-H’s role is to develop and prove the *viability* of novel technologies and transformational approaches – to create and sponsor the performance of very high-risk, high-reward research and development – but not to implement it nationally. That is why transition of programs for advanced development is so important. For example, DARPA proved that the prototype F-117 stealth fighter, code-named “Have Blue,” was undetectable by radar. But it looked more like a refrigerator than a fighter jet and indeed could barely fly. Nonetheless, the technical challenge of creating a radar-invisible aircraft was solved. The Air Force took it from there, developed the complex flight controls required, and ultimately made it a formidable and revolutionary combat aircraft. By analogy, once ARPA-H solves the technical barriers for a revolutionary cure, diagnostic, sociological approach, or solution to disparities, the program should be transitioned to other parts of the federal government, for example BARDA or CMS, or for private sector investment to bring it ultimately to the American

people. That type of implementation requires a different skill set and a more management-minded, efficient operation than could ever be done at ARPA-H. After successful program transition, ARPA-H can then refocus on what it is intended to do, and that is, high-risk transformational R&D for another disease or public health challenge.

In conclusion, when the Soviet Union launched Sputnik, the United States channeled our surprise, concern, and technical defeat into action – and thus DARPA was created with a one-page document. DARPA’s history of world changing innovation, including the Internet, GPS, Stealth, NASA, microelectronics, autonomous vehicles, the entire field of materials science, mRNA vaccines, and the bionic arm, stemmed from that simple action and its resultant culture of innovation. Much like our nation’s Sputnik moment, it is time for America to admit that the health of our nation is intolerably poor, that health disparities have generally worsened for racial and ethnic minorities, the poor, and rural populations, and that we spend far too much to get so little in return. While ARPA-H is not a panacea, it has the realistic opportunity to catalyze revolutionary technologies and approaches that will enable a healthier future for America, and for the entire world.

Thank you for the opportunity to testify today and I look forward to your questions.

Attachment



Heilmeier's Catechism



George Heilmeier
DARPA Director
1975-1977

- **What are you trying to do?**
 - *Articulate your objectives using no jargon*
- **How is it done today?**
 - *What are the limitations of the current practice*
- **What is new in your approach?**
 - *Why do you think it will be successful*
- **Who cares?**
 - *If you are successful, what difference will it make*
- **What are the risks and payoffs?**
- **How much will it cost? How long will it take?**
- **What are the midterm and final “exams” to check for success?**