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GO2 FOUNDATION FOR LUNG CANCER

July 16, 2021

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representative DeGette and Representative Upton:

I am writing on behalf of GO2 Foundation for Lung Cancer (GO2 Foundation) to thank you for your continued leadership and commitment to advance the policy process with input from the patient community and stakeholders on health research and patient care. To build upon our previous comments to the 21st Century Cures 2.0 concept, we are pleased to respond to your questions requesting specific information on Cures 2.0 Discussion Draft: Sec. 501. Advanced Research Projects Agency for Health (ARPA-H) Proposal.

Question: In calling for the creation of ARPA-H, President Biden has cited the success of the Defense Advanced Research Projects Agency (DARPA) and expressed his belief that ARPA-H should be similar.

GO2 Foundation supports the President's idea inspired by DARPA, which follows a flexible and nimble strategy, undeterred by the possibility of failure, which has driven breakthrough advances for the Department of Defense (DOD) for more than 60 years. We support the National Health Council's (NHC) recommendation that ARPA-H should adopt a focus on high-risk, high-reward research. ARPA-H should emulate the DARPA model of soliciting creative thinkers from the private sector who can offer an innovative approach independent from government scientists and traditional academic researchers. This will allow ARPA-H to stand apart from the traditional National Institute of Health (NIH) research and help infuse new ideas and accelerate the speed of actual research translation. With that said, we also agree with the Personalized Medicine Coalition (PMC) that diligently investing in research at the NIH is equally key to bringing us closer to a future in which every patient benefits from an individualized approach to health care. We agree that forming priorities for ARPA-H that are distinct from NIH's existing centers and institutes will avoid duplication and further our progress in research.

Question: To ensure it has the biggest impact, on what activities or areas should ARPA-H focus and what activities or areas should ARPA-H avoid?

In order to realize the most outstanding potential for ARPA-H, GO2 Foundation strongly recommends significantly impacting human disease through a broad portfolio of projects focused on the following core principles:

- **Improving early detection of disease**—The majority of diseases that afflict Americans offer opportunity for more prevention and/or intervention when detected early in pre-disease or early-disease settings. Cancer and heart disease are two key areas where early detection can lead to a significant improvement in outcomes. Investment in new platforms and models of risk and early disease detection could have significant impacts on the overall health of the population, across many disease areas.

- **Further advancing precision medicine**—Precision medicine utilizes a person's genetics, environment, and lifestyle to help determine the best approach to prevent or treat disease. In disease areas such as cancer, precision medicine has already improved how we diagnose and treat certain segments of the patient population. However, there is more work to be done. This is an area where broad, risk-taking innovative approaches could dramatically impact health care. Innovative clinical trial designs and infrastructure that reach and enroll more members of disease communities will be critical in advancing this goal. There is a need to streamline clinical trial regulatory processes to make them less burdensome and to accelerate community accrual through incorporation of newer concepts such as just-in-time designs and increased telehealth utilization. Notably, equity in precision medicine is a huge issue. We do not yet understand how factors such as race and ethnicity affect the best approaches to prevent and treat disease across most disease areas, and current clinical trials are not designed to enroll equitably across many different demographic areas.

- **Increasing community engagement & access to care**—Research innovations do not improve lives unless implemented correctly in all communities throughout this country. We saw this clearly with the urgent need to roll out COVID-19 vaccines efficiently into diverse communities of different racial, ethnic, religious, socioeconomic, and subgroups across the United States. Innovations across all disease areas are facing the same challenges; current technologies that we know are lifesaving are not equitably available in all communities. There are barriers at many levels of implementation. New platforms and models are urgently needed to engage patients early on in research and innovation, and the barriers to access need to be addressed appropriately. In addition, secure but flexible data sharing that allows all stakeholders, including patients, to access the medical data that they need remains a key priority.

- **Improving quality of life**—As we improve treatments for diseases such as Alzheimer's, heart disease, diabetes, and cancer, new issues arise for patients who are living with these conditions as more chronic, long-term diseases. Both physical side effects and emotional issues such as anxiety and depression can reduce quality of life and even work productivity. The time for significant focus on broad innovation in this space has arrived. Examples could include improving supportive care agents and mechanisms or technologies and platforms for simplified disease/recurrence monitoring. New, bold advances would ensure optimal patient experience

and support health-related quality of life along with physical, cognitive, and emotional functioning.

Question: Some assert ARPA-H's ability to operate independently and transparently will be essential to its success. Do you agree? If so, what is the best way to design ARPA-H in order to accomplish this?

GO2 Foundation strongly agrees with many in the community that ARPA-H's ability to operate independently and transparently will be essential to its success. To ensure ARPA-H has a mission, culture, organizational leadership, mode of operation, expectations, and success metrics that are different from the status quo, we endorse the One Voice Against Cancer's (OVAC) recommendation to have ARPA-H adopt a culture and operational processes that is driven by an urgency to improve patient outcomes and based on the following OVAC Principles:

- The agency must be empowered to, and embrace, collaborations with all stakeholders including patients, other federal agencies and public-private partnerships, and/or industry partners who can help to advance breakthroughs.
- The agency's projects should include a focus on addressing existing health disparities, ensure funded clinical trials are inclusive, and foster diversity in the research workforce. ARPA-H must incorporate the perspectives of stakeholders from underserved and under-represented communities, in order to build patient trust in any medical breakthroughs. APRA-H must have an appointed leader who will ensure issues of equity are considered and implemented in all aspects of the agency's work.
- Identification of unmet needs within disease areas should be conducted through a formal multi-stakeholder process that includes patients and advocacy groups representing the disease areas, with an emphasis on transparency to ensure the agency improves patient's health care in meaningful ways.
- The agency should have full transactional authority, as well as the ability to conduct all phases of research, product development and regulatory approval.

Question: How should ARPA-H relate to, and coordinate with, existing federal entities involved in health care-related research and regulation?

GO2 Foundation agrees with PMC that despite advances to promote personalized medicine and the efforts to modernize the regulatory and reimbursement systems, challenges remain to implement personalized medicine across health care delivery settings. We support the recommendation that ARPA-H could help address clinical integration challenges by prioritizing implementation research on personalized medicine. This concept is echoed in our proposed core principal above of "Increasing community engagement and access to care."

We also suggest that ARPA-H could focus on streamlining regulatory processes across federal agencies to accelerate clinical trial accrual and make trials more efficient to conduct. The system should not make running a phase II or phase III clinical trial as difficult, resource-intensive, or burdensome as it is today. ARPA-H should fund innovations—such as point-of-care, just-in-time

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study designs, and authorizations for remote research procedures by video—and implement them in the clinical trial arena.

In addition, we strongly support the specific recommendation of NHC that ARPA-H should coordinate with the Centers for Medicare and Medicaid (CMS). ARPA-H activities should be carefully coordinated with payers and CMS to assure they are prepared to leverage the information and technology provided to ensure that coverage is not a barrier to bringing innovative therapies to a patient. As we have commented previously to Cures 2.0 on modernizing CMS, we must streamline and expedite the federal structure and the process responsible for review and implementation of new patient services, particularly regarding preventive services to ensure benefits reach people more rapidly and efficiently. The system must become more adaptive and agile to transition from scientific breakthrough to a national public health implementation plan. We also agree that the Food and Drug Administration (FDA) must be a critical partner working with ARPA-H to continue to speed the translation to approved, licensed, or clear therapies.

Question: What is the appropriate funding level for ARPA-H? How do we ensure ARPA-H funding does not come at the expense of traditional funding for the National Institutes of Health?

The GO2 Foundation advocates annually for robust and sustainable funding for all research agencies, including the NIH, FDA and DOD's Congressionally Directed Medical Research Programs (CDMRP). We therefore would advocate for ARPA-H as a separate line item with a robust, predictable, and sustainable budget at a level consistent with its mission and what is requested for its success. We support the President's proposed FY 2022 request of $6.5 billion for APRA-H.

In conclusion, we would like to thank you for the opportunity to review the draft discussion on Cures 2.0 and for your consideration of our responses to your thoughtful engaging questions on the development of ARPA-H. We encourage Congress and the Administration to provide additional opportunities to review the authorizing bill and policies that will establish ARPA-H. Please consider GO2 Foundation for Lung Cancer for future input. We look forward to working with you on next steps.

Your staff may contact Elridge Proctor, Senior Director, Government Affairs at 202-669-5547 (Eproctor@go2foundation.org) with any questions or updates.

With Sincere Regards,

Laurie Fenton Ambrose
Co-Founder, President and CEO