August 6, 2021

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

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

Reference: Lupus Research Alliance Input on Issues and Questions Raised by Sec. 501. Advanced Research Projects Agency for Health

Dear Congressman Upton and Congresswoman DeGette:

The Lupus Research Alliance (LRA) applauds your inclusion in Sec. 501 of the "Cures 2.0 Act" Discussion Draft of President Biden's proposal to establish an Advanced Research Projects Agency for Health (ARPA-H). As an organization committed to supporting and driving research innovation and breakthroughs in lupus research and translation, the LRA enthusiastically welcomes the creation of a much-needed engine of modernization and rapid implementation of health breakthroughs.

Lupus is a chronic and complex autoimmune disease that can affect the joints, skin, brain, lungs, kidneys, and blood vessels, causing widespread inflammation and tissue damage in the affected organs. Lupus primarily targets women and disproportionately impacts Blacks, Native Americans, Latinas, and Asian Americans. As the largest nongovernmental, nonprofit funder of lupus research worldwide, the LRA aims to transform treatment while advancing toward a cure by funding the most innovative lupus research; fostering diverse scientific talent; stimulating collaborations; and driving discovery toward better diagnostics, improved treatments and, ultimately, a cure for lupus.

We commend the plans to model ARPA-H on the highly successful Defense Advanced Research Projects Agency (DARPA). Successfully supporting bold innovative approaches to disease challenges requires an original and daring approach to complement, build upon, and synergize with the robust existing biomedical ecosystem in the United States. The ARPA-H concept envisions numerous essential aspects of this Agency that should be pursued aggressively, including its substantial budget, autonomy, flat and nimble structure, near-term yet highly ambitious mandates, contract-based funding and collaborative approaches, and large-scale undertakings. Also critical will be visionary leadership that champions equity as well as innovation, highly creative and entrepreneurial staff and a laser-sharp focus on disease detection, treatment, and prevention.

We offer the following points for consideration in refining the plans for ARPA-H:

- While the Biden-Harris Administration's ARPA-H Concept Paper is understandably general and not targeted to any specific disease area, we strongly encourage you to ensure that its eventual priorities include research into curing, preventing, and treating autoimmune diseases that affect tens of millions of Americans and disproportionately impact women, and in the case of lupus, women of color. To date, there are few therapies targeting this class of chronic illness. Signaling Congressional intent and

commitment to tackling this area of unmet medical need would be a powerful acknowledgement that this major spectrum of diseases is in desperate need of rapid medical solutions, chiefly advancing ways to detect and prevent autoimmune diseases before they strike and impose their devastating lifestyle and financial burdens on individuals and the health care system.

- We support the proposed funding level of $6.5B to establish ARPA-H. We believe that to be successful, ARPA-H must benefit from robust and sustained funding, but strongly recommend taking all necessary steps to ensure that ARPA-H's budget will not cannibalize the budgets of the National Institutes of Health (NIH) or other federal research funding agencies.

- To ensure the biggest impact, ARPA-H should focus on large-scale, collaborative projects with significant and near-term health impact with special focus on diseases that disproportionately impact underserved populations. It should avoid duplication with other ongoing efforts, as well as a strong emphasis on disease areas already significantly and consistently funded.

- We agree that ARPA-H's ability to operate independently and transparently will be critical to its success. Visionary leadership, entrepreneurial culture, and an operational approach that balances innovation and risk with clear metrics and deliverables will be key to achieve ARPA-H's goals. We also feel that it will be critical for ARPA-H to have close and effective working relationships with the NIH, the Food and Drug Administration, and the Centers for Medicare and Medicaid services to ensure seamless integration of foundational discoveries with translatable breakthroughs, clear regulatory pathways, and healthcare delivery and access.

- It will be vital for ARPA-H to coordinate activities effectively and seamlessly with other federal agencies while maintaining transparency, independence and ensuring the highest ethical standards from the onset. For ARPA-H to replicate the success of DARPA, it will be important for there to be links to DARPA to ensure implementation of best practices and synergies within areas of related activities.

- ARPA-H would benefit from close collaboration with the non-governmental entities as well as with other federal research agencies. Public Private Partnerships may be appropriate vehicles for such interactions for some initiatives. For others, however, more creative and proprietary arrangements may need to be established while still avoiding any issues of conflict or other ethical challenges.

- Finally, and perhaps most critically, ARPA-H must have a clear mandate to work closely with disease-focused organizations to bring the patient voice to the core of its activities and ensure that the mission of ARPA-H is continually driven by the patients' needs.

We are grateful for the opportunity to provide the above input and welcome additional occasions to engage in the planning and implementation of this transformative enterprise.

Sincerely,

Kenneth M. Farber
President & CEO

Teodora Staeva, PhD
Chief Scientific Officer