Immunocompromised Collaborative

March 4, 2022

Chair Rosa DeLauro
2413 Rayburn House Office Building
Washington, DC 20515

Ranking Member Kay Granger
1026 Longworth HOB
Washington, DC 20515

Chair Patrick Leahy
437 Russell Senate Building
Washington, DC 20510

Ranking Member Richard Shelby
304 Russell Senate Office Building
Washington, DC 20510

Re: COVID-19 Therapeutics Inclusion in the Supplement Package

Dear Congressional Appropriations Leaders,

We write as representatives of the Immunocompromised Collaborative, which consists of patient organizations representing the approximately 9 million Americans who are immunocompromised across the country and who continue to face serious challenges living with, treating, and responding to the COVID-19 virus**.** On their behalf, we urge your support of supplemental funding to ensure access to sufficient supplies of essential medications that enable both prevention and treatment for COVID-19 patients.

The population of the immunocompromised account for at least 2.7% of U.S. citizens across all age, gender, race and ethnicities. It includes individuals with one of the over 450 types of primary immunodeficiencies (PI) in which a person's immune system fails to function properly because of genetic or intrinsic defects and those with secondary immunodeficiencies where other factors lead or contribute to a diminished immune system. These include people living with human immunodeficiency virus (HIV), those with cancer, recipients of bone marrow and organ transplants, and individuals with other conditions being treated with medications that suppress the immune system. Also included are individuals with autoimmune conditions such as lupus, rheumatoid arthritis, psoriasis, type 1 diabetes, and Sjogren's syndrome. These and other autoimmune conditions, as well as the treatment for such conditions, can result in suppressed and malfunctioning immune systems.

Medical innovation and government investment is largely responsible for our successful response to the COVID-19 pandemic thus far by developing the tools needed to fight the pandemic. Over the last two years Congress has invested in the development and procurement of vaccines, therapeutics, and diagnostics. But further investments are needed if our nation is going to continue to combat both the current and potential impact of COVID and new variants. Funding is desperately needed at HHS for further procurement of existing COVID-19 medical countermeasures (MCMs) as well as investment in second generation therapeutics. The proposed COVID-19 Supplemental package includes important funds for procurement of existing MCMs and funds for R&D in next generation vaccines. We strongly support the inclusion of these funds and their allocation to BARDA. We also strongly recommend that funds at matching levels be allocated to BARDA for the research and development of second-generation therapeutics as well as an explicit line item in the supplemental.

Hospitalization rates, while declining after the Omicron spike, are still higher than they were a year ago today when access to vaccines was still very limited. Authorized COVID-19 therapeutic antibodies and antivirals have been lifesaving. Therapeutics in the pipeline and optimized formulations of currently authorized products feature different modalities, mechanisms of action and/or routes of administration

and may offer broader protection against arising variants. These new therapeutics could meet important unmet clinical and access needs by decreasing hospitalizations, death and period of infectivity and ultimately contribute to bringing this pandemic to an end. They can also help facilitate access and lead to better health outcomes for the nearly 9 million immunocompromised patients across the country who struggle to amount an immune response. We believe that there is great utility in having a broad array of products to treat COVID-19 as the pandemic continues, variants arise, and COVID-19 eventually becomes an endemic disease.

Due to the complexity of administration of current therapeutics and variability in access to healthcare, there have been disparities in access to these products. Continued investment in additional therapeutics is critical for ensuring equity across populations in terms of access to treatments. Continuous investment in a broader portfolio of COVID-19 therapeutics will facilitate access to new medical countermeasures through easier routes of administration, fewer potential doses, or more specific impact on clinical outcomes, especially for those at highest risk of severe disease, such as the immunocompromised populations. Achieving these goals will require increased investment in products at all stages of development, for novel mechanisms in early development to strategic modifications to currently authorized MCMs.

With nearly a third of the nation still unvaccinated and the threat of new variants, the risk of further health and economic impact still looms over the American population. As important as developing next generation COVID vaccines are, new therapeutics need to be a part of the future solution to the pandemic, especially for those with autoimmune conditions that put them at a higher risk for serious illness from COVID increasing the possibility of hospitalization and death.

During the two years of the pandemic, we have seen at least 3 major surges that have stretched many of our nation's hospitals and health care providers to a breaking point. It is important to point out that development and manufacture of COVID therapeutics is not a just-in-time operation where a new formula can be altered in weeks. Most manufacturing requires six-month lead time. Response will never be quick enough to prevent hospitalization and loss of life, which is why investing now in preparedness for the next variant and having a full armamentarium of treatments available is essential. As we work towards second generation products in the coming months and years, there is also a need today for additional government procurement of currently authorized therapies.

We urge the Appropriations Committee leaders to support the allocation of funds directly to BARDA for procurement of existing and new COVID-19 vaccines, therapeutics and diagnostics. We also urge the Committee to allocate funds for new BARDA partnerships for the research and development of not just second-generation vaccines but also novel therapeutics. We welcome the opportunity to discuss this issue in more detail with you and your staff.

Sincerely,

Immune Deficiency Foundation
Lupus Foundation of America
Autoimmune Association
The AIDS Institute