Congress of the United States
Washington, DC 20515

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

The Honorable Gary L. Disbrow, Ph.D.
Acting Director
Biomedical Advanced Research and Development Authority
200 Independence Avenue, S.W.
Washington, D.C. 20201

July 21, 2020

Dear Secretary Azar and Acting Director Disbrow,

We write to you concerning the lack of investment by the Department of Health and Human Services (HHS) and the Biomedical Advanced Research and Development Authority (BARDA) into clinical trials and research of potentially preventative COVID-19 immune globulin (COVID-IG) injections for individuals not yet exposed to COVID-19, or with Post-Exposure Prophylaxis (PEP). Immune globulin injections have been used for many other viral diseases – including influenza, measles, hepatitis B, polio, and Ebola – proving to be safe and effective before a vaccine became readily available.[1][2] HHS and BARDA must take the lead on the allocation of federal funds to encourage public-private investments to explore the effectiveness of preventative COVID-IG injection clinical trials and its possible use as a pre-vaccine solution to preventing the spread of COVID-19.

According to infectious disease and supply chain experts, the shortage of private sector entities filing for clinical trial programs with the Food and Drug Administration (FDA) is largely due to a deficiency of investment in public-private partnerships. The possibility of a vaccine being made available before companies can make a profit on COVID-IG injections creates a financial disincentive to strong investments in research on this treatment without federal support.[3] We have been made aware of

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[1] Casadevall, A, and Pirofski, L. "The convalescent sera option for containing COVID-19." *The Journal of Clinical Investigation*. https://www.jci.org/articles/view/138003/pdf (March 13, 2020)
[2] Bloch, EM, et al. "Deployment of convalescent plasma for the prevention and treatment of COVID-19." *The Journal of Clinical Investigation*. https://www.jci.org/articles/view/138745 (April 7, 2020) .
[3] Baumgartner, Emily. "A plasma shot could prevent coronavirus. But feds and makers won't act, scientists say." *The Los Angeles Times*. https://www.latimes.com/science/story/2020-07-10/injection-prevent-coronavirus-feds-manufacturers-fail-to-act (July 10, 2020)

preventative COVID-IG injection proposals that were rejected by BARDA in early March. We ask that the agency reconsider these and future proposals.[4]

The largest amount of federal funding allocated for preventative COVID-IG clinical trials is through the Department of Defense, which has provided $34.6 million for a clinical trial with frontline healthcare workers with Post-Exposure Prophylaxis (PEP) in New York State. This project is operated by the Mount Sinai Health System, Emergent Biosolutions, and ImmunoTek Biocenters.[5] The DOD will use the research from this trial to consider possible preventative treatments for military personnel, but there has been little discussion of this treatment being available to everyday Americans if proven successful, despite it being the result of an investment of their tax dollars. In comparison to the vaccine development program Operation Warp Speed, which has at least $10 billion appropriated for the program,[6] the level of federal investment in preventative COVID-IG injections is not nearly enough to help determine the viability of these procedures or to achieve the scale needed for a nationally operated program.

Two senior public health officials from the Trump Administration recently recognized the potential efficacy and safety of convalescent plasma and COVID-IG injections in a Senate Health, Education, Labor, and Pensions Committee hearing. Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, stated that an upper-arm injection with the functionality of a vaccine "is a very attractive concept." At the same hearing, Food and Drug Administration Commissioner Stephen Hahn discussed the Mayo Clinic trials with convalescent plasma for individuals who are already infected with COVID-19, stating that, "it's been found to be safe, [with] over 20,000 patients administered it."[7]

The scientific community also sees significant merit in exploring this possibility. On July 14, 2020, Chairman Raja Krishnamoorthi, in a House Oversight and Reform Subcommittee on Economic and Consumer Policy remote briefing on vaccines, asked about whether the federal government should be researching the effectiveness of COVID-IG shots to help inoculate individuals. Dr. Ruth Karron, Director of the Center for Immunization Research at Johns Hopkins University and Founding Director of the Johns Hopkins Vaccine Initiative, responded, "these approaches are promising, and yes, we should pursue all of these avenues."[8]

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[4] Office of Congressman Krishnamoorthi correspondence with Dr. Michael Oxman, University of California San Diego. [July 13, 2020.]

[5] *Emergent Biosolutions.* "Mount Sinai Health System, Emergent BioSolutions, and ImmunoTek Bio Centers Form Collaboration to Develop Emergent's COVID-19 Hyperimmune Globulin (COVID-HIG) Product Candidate with U.S. Department of Defense Funding." https://investors.emergentbiosolutions.com/news-releases/news-release-details/mount-sinai-health-system-emergent-biosolutions-and-immunotek (July 8, 2020)

[6] *U.S. Department of Health & Human Services.* "Trump Administration Announces Framework and Leadership for 'Operation Warp Speed.'" https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html (May 15, 2020)

[7] Snell, Kelsey, Wise, Alana, and Sprunt, Barbara. *National Public Radio.* "'Going To Be Very Disturbing': Fauci Warns Coronavirus Cases Could Reach 100K A Day." (June 30, 2020) https://www.npr.org/2020/06/30/884658409/watch-live-senate-hearing-on-reopening-schools-workplaces-amid-coronavirus

[8] *House Committee on Oversight and Reform.* "Subcommittee on Economic and Consumer Policy Briefing on "Guardrails to Ensure a Safe and Effective COVID-19 Vaccine." https://oversight.house.gov/legislation/briefings/subcommittee-on-economic-and-consumer-policy-briefing-on-guardrails-to-ensure (July 14, 2020)

Dr. Michael Oxman, Professor of Medicine and Pathology at the University of California San Diego, explained in correspondence with our offices the urgent need for the availability of this preventative COVID-IG injections procedure:

> "From my conversations with immune globulin (IG) manufacturers that can produce COVID-IG from COVID-19 convalescent plasma containing antibodies to SARS-CoV-2 for intramuscular injections, it seems that the private sector is waiting for the federal government to take the lead on research and clinical trials. If the pharmaceutical industry is not willing to shoulder the financial risk of this endeavor, then agencies such as BARDA need to step up to save lives with this promising procedure that has worked in the past for viral disease prevention. Right now, there are millions of Americans who have recovered from COVID-19, and we could potentially utilize their antibodies to save tens of thousands of American lives before a vaccine becomes widely available. We need to produce COVID-IG for intramuscular injection right now."

Further, Dr. Arturo Casadevall, Chair of the National Convalescent Plasma Center as well as Chair of Molecular Microbiology & Immunology at Johns Hopkins University, explained in correspondence with the undersigned the specific requirement of intramuscular (IM) injections, rather than intravenous (IV):

> "We need an intramuscular (IM) formulation of gamma globulin because it is much easier to administer, and this could help stem the COVID-19 epidemic. Intravenous (IV) formulations are much harder to administer because you need to have trained personnel to insert IVs and manage the infusion. In contrast, IM shots are easy to administer and do not need any specialized equipment."

The scientific community sees a clear possibility for COVID-IG injections to confer some level of immunity or to help improve immune response in individuals not yet infected with COVID-. As such, the Trump Administration must fund more clinical trials across the country for this procedure. Convalescent plasma has been used nationally to treat 28,000 patients with active COVID-19 infections, proving to be both safe and effective.[9,10] If expanded further and coupled with additional research on the use of COVID-IG to inoculate uninfected patients, this could prove to be an effective stopgap solution as we await a successful COVID-19 vaccine.

We request that BARDA and HHS provide a written summary of forthcoming plans to allocate funding for these clinical trials or provide the necessary requests to the United States Congress for appropriating the federal budgetary needs of clinical trials, prior to July 30th, 2020.

Sincerely,

Congressman Raja Krishnamoorthi

Congresswoman Katie Porter

[9] Marcus, Amy Dockser. The Wall Street Journal, "U.S. Seeks Large-Scale Expansion of Blood-Plasma Collection for Covid-19." (Date). https://www.wsj.com/articles/u-s-seeks-large-scale-expansion-of-blood-plasma-collection-for-covid-19-11593691200?mod=hp_lead_pos4

[10] Joyner, M, et al. "Safety Update: COVID-19 Convalescent Plasma in 20,000 Hospitalized Patients." *Mayo Clinic Proceedings*. https://mayoclinicproceedings.org/pb/assets/raw/Health%20Advance/journals/jmcp/jmcp_ft95_6_8.pdf (2020)