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Director, Division of Scientific Advisors & Consultants  
Center for Biologics Evaluation & Research  
Food and Drug Administration  
Silver Spring, MD 20993

Hana El Sahly, M.D.  
Chair, Vaccines and Related Biological Products  
Advisory Committee  
Food and Drug Administration  
Silver Spring, MD 20993

Dear Dr. Atreya, Dr. Sahly, and members of the Vaccines and Related Biological Products Advisory Committee:

The undersigned organizations advocate in support of patient-centered care and patient access to appropriate treatments and therapeutics. We are writing to encourage the Food & Drug Administrations (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) to recognize the value and importance of having access to multiple vaccine designs as it considers requests for Emergency Use Authorization (EUA), including the request currently before it.

We commend the FDA/VRBPAC on its important work to navigate the vital process of ensuring safety and efficacy of COVID-19 vaccines throughout this pandemic, as these vaccines have been a critical tool against the pandemic. We urge you to continue that work to ensure additional options can continue to be made available. Despite a number of approved vaccines, hesitancy remains, and availability of approved vaccines can vary based on specific transportation and storage requirements. In December 2021, the US Census Bureau found that about 42% of adults 18 and over who had not received a COVID-19 vaccine “don’t trust COVID-19 vaccines” and almost 30% reported they “plan to wait and see if it is safe.”<sup>1</sup> Additional vaccine options can play a role in addressing that concern.

Although great care has been taken to ensure all vaccines authorized through the EAU process, and ultimately through FDA approval, are safe, vaccine hesitancy continues among many Americans, which may in part be due to uneasiness surrounding mRNA and vector vaccine designs. Thus, it is imperative that Americans have access to a variety of vaccine designs and options to ensure greater vaccine uptake to protect patients and end this pandemic. Given that more than 27 million American adults 18 and over have not yet received one vaccine dose, and more than 115 million American adults 18 and over have not yet received a booster, it is critical to continue the EUA of safe and effective COVID-19 vaccinations.<sup>2</sup> Everyone deserves timely access to clinically appropriate vaccines, and we appreciate the FDA taking the health of all Americans seriously throughout the pandemic.

It is our understanding that a new COVID-19 vaccine application for a recombinant protein-based vaccine has been submitted for EUA, providing yet another potential type of COVID-19 vaccine. Recombinant protein-based vaccines are developed through an established, well-understood design process, and has been used for over a century, providing an opportunity for this type of vaccine to

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<sup>1</sup> US Census Bureau. “Household Pulse Survey Covid-19 Vaccination Tracker.” Census.gov, December 22, 2021. <https://www.census.gov/library/visualizations/interactive/household-pulse-survey-covid-19-vaccination-tracker.html>.

<sup>2</sup> “CDC Covid Data Tracker.” Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, <https://covid.cdc.gov/covid-data-tracker/>.

address vaccine hesitancy. Therefore, it is to the benefit of every American that additional vaccine options, including protein-based vaccines, are available.

These types of vaccines can in many cases also be stored for longer periods of time in a refrigerator, rather than frozen. This can lead to increased access across the United States. Importantly, the shelf life and simple storage method may also support greater vaccine access around the world, particularly in remote areas that would typically not have equitable access to a vaccine. Increasing access to vaccines globally is critical as the World Health Organization (WHO) has reported that ending the pandemic would require full vaccination of at least 70% of the world's population.<sup>3</sup> Currently only 53.7% of the world's population is fully vaccinated.<sup>4</sup> Therefore, additional EUAs for different vaccine designs can play a role in moving out of the pandemic phase of COVID-19.

On behalf of the undersigned organizations, we appreciate the FDA/VRBPAC's work in the fight against COVID-19 and ask you consider the value of utilizing a variety of vaccine designs when considering utilizing the EUA to increase available vaccines. Thank you for the opportunity to provide comment and we appreciate your attention to this matter. If we can provide further details or be of assistance, please contact us at (202) 499-4114.

Sincerely,

Alliance for Balanced Pain Management

Alliance for Patient Access

Association of Migraine Disorders

Axis Advocacy

Clinical Neurological Society of America

Derma Care Access Network

Endocrine Nurses Society

Global Healthy Living Foundation

Gout Support Group of America

Hawai'i Parkinson Association

Headache and Migraine Policy Forum

HealthyWomen

International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)

Lupus and Allied Diseases Association, Inc.

Macular Degeneration Association

Movement Disorders Policy Coalition

National Association For Continence

National Organization for Tardive Dyskinesia, Inc.

RetireSafe

The Bonnell Foundation: Living with cystic fibrosis

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<sup>3</sup> Strategy to Achieve Global Covid-19 Vaccination by Mid-2022. "World Health Organization," [https://cdn.who.int/media/docs/default-source/immunization/covid-19/strategy-to-achieve-global-covid-19-vaccination-by-mid-2022.pdf?sfvrsn=5a68433c\\_5](https://cdn.who.int/media/docs/default-source/immunization/covid-19/strategy-to-achieve-global-covid-19-vaccination-by-mid-2022.pdf?sfvrsn=5a68433c_5)

<sup>4</sup> Ritchie, Hannah, et al. "Coronavirus (COVID-19) Vaccinations." Our World in Data, 5 Mar. 2020, <https://ourworldindata.org/covid-vaccinations#what-share-of-the-population-has-received-at-least-one-dose-of-the-covid-19-vaccine>.