

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

VIA ELECTRONIC FILING

November 6, 2020

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
Commissioner Stephen M. Hahn, M.D.
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Dear Commissioner Hahn,

Enclosed is a Citizen Petition filed by Del Bigtree and the Informed Consent Action Network (“ICAN”) regarding efficacy endpoints of the Phase III trials of mRNA-1273 (NCT04470427), BNT162 (NCT04368728), AZD1222 (NCT04516746), and Ad26.COV2.S (NCT04505722) which raises exigent concerns that demand your immediate attention.

ICAN looks forward to receiving a timely decision. We, as counsel to the petitioners, remain available to answer questions and provide any relevant additional information.

Very truly yours,

/s/ Aaron Siri

Aaron Siri
Elizabeth Brehm
Jessica Wallace
SIRI & GLIMSTAD LLP
200 Park Avenue
17th Floor
New York, NY 10166
Telephone: (212) 532-1091
Facsimile: (646) 417-5967
Email: aaron@sirillp.com