

FREEDOM OF INFORMATION ACT REQUEST

REQUEST FOR EXPEDITED PROCESSING

VIA EMAIL

May 22, 2020

Gorka Garcia-Malene
Freedom of Information Act Officer
National Institutes of Health
Building 31, Room 5B35
9000 Rockville Pike
Bethesda, MD 20892
Email: [nihfoia@mail.nih.gov](mailto:.nihfoia@mail.nih.gov)

Re: *NIAID Safety & Efficacy Data for mRNA-1273 (IR#303)*

Dear Sir or Madam:

This firm represents the Informed Consent Action Network (“ICAN”). On behalf of ICAN, please provide the following records to foia@sirillp.com in electronic form:

All safety and efficacy data and information regarding mRNA-1273, including from the Phase I clinical trial of this experimental vaccine conducted by the National Institute of Allergy and Infectious Diseases.

Request For Expedited Processing

ICAN requests expedited processing for this request. ICAN is “primarily engaged in disseminating information to the general public” and there is an “urgency to inform the public concerning actual or alleged Federal Government activity.” 5 U.S.C. § 552(a)(6)(E)(v)(II).

Specifically, ICAN’s mission is to raise public awareness about public health safety and to provide the public with information to give informed consent regarding related health interventions. mRNA-1273 is a leading, if not the leading, experimental vaccine against novel coronavirus, SARS-CoV-2, also known as COVID-19. Information regarding this vaccine, and in particular the safety and efficacy information regarding this vaccine, are a matter of immediate concern to the American public, given the extensive media and public interest in the fate of the clinical trials for preventing this virus and the pressures placed on the NIH developing a vaccine for COVID-19. News articles have also widely reported about the above vaccine and its clinical trials and hence the information requested above is a matter of immediate attention and concern to

the American public. See, e.g., <https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins>; <https://science.sciencemag.org/content/early/2020/02/19/science.abb2507/tab-pdf?versioned=true>; <https://time.com/5835785/moderna-coronavirus-vaccine-phase-2/>; <https://www.businesswire.com/news/home/20200427005839/en/Moderna-Announces-IND-Submitted-U.S.-FDA-Phase>; <https://www.cnbc.com/2020/05/07/fda-approves-moderna-vaccine-candidate-for-phase-2-study.html>; <https://www.modernatx.com/modernas-work-potential-vaccine-against-covid-19>; <https://www.nytimes.com/2020/05/07/health/coronavirus-vaccine-moderna.html>

ICAN certifies that the information in the request is true and correct to the best of ICAN's knowledge and belief.

Fees and charges for this search are to be waived pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii) since ICAN is a not-for-profit 501(c)(3) organization and its mission is to raise public awareness about public health safety and provide the public with information to give informed consent regarding related health interventions. As part of its mission, ICAN investigates and disseminates information regarding public health safety issues, including through their website, and through press events and releases. ICAN is seeking the information in this FOIA request to allow it to contribute to its mission. The information requested in this FOIA request will not contribute to any commercial activities.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We, therefore, request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN of course reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately file an administrative appeal.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact me at (212) 532-1091 or via email at foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

A handwritten signature in blue ink, appearing to read 'A. Siri', written over a white background.

Aaron Siri, Esq.