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## FREEDOM OF INFORMATION ACT REQUEST

VIA EMAIL March 19, 2023

Medicines and Healthcare Products Registry Agency 10 South Colonnade Canary Wharf London E14 4PU info@mhra.gov.uk

Re: AstraZeneca COVID-19 Vaccine Post-Authorization Reports (IR#1012D)

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("ICAN"). On behalf of ICAN, please provide the following records to <a href="mailto:foia@sirillp.com">foia@sirillp.com</a> in native format and/or searchable electronic form:

The following post-authorization records in the possession of MHRA concerning the Vaxzevria [formerly AstraZeneca] COVID-19 vaccine<sup>1</sup> and/ or COVID-19 vaccine ChAdOx1 S [recombinant]:

- 1) Cumulative Analysis of Post-Authorization Adverse Event Reports
- 2) Periodic Safety Update Reports (PSURs)

We ask that you waive any and all fees or charges pertaining to the processing of this request because ICAN is a United States registered not-for-profit 501(c)(3) organization whose mission is to raise public awareness about vaccine safety and other medical treatments, and to provide the public with information to give informed consent. As part of its mission, ICAN actively investigates and disseminates scientifically based health information regarding the safety of vaccines and other medical treatments, for free through its website,<sup>2</sup> a weekly health news and talk show,<sup>3</sup> and through press events and releases.

<sup>&</sup>lt;sup>1</sup> https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/patient-information-leaflet-for-covid-19-vaccine-astrazeneca.

<sup>&</sup>lt;sup>2</sup> https://www.icandecide.org/.

<sup>&</sup>lt;sup>3</sup> https://thehighwire.com/.

ICAN's weekly health news and talk show, The HighWire, provides hours of new video content to the public each week for free. The HighWire website has approximately 3.4 million weekly visitors. On Twitter, The HighWire has approximately 145,000 followers and 1 to 2.5 million impressions in a 28-day period. Between Rumble and Bitchute, The HighWire has approximately 60,000 followers and growing. Additionally, ICAN has 29,000 text subscribers and 194,245 email subscribers.

Critical to ICAN's mission is its proven ability to find and review important scientific and governmental records and meaningfully report about their social impacts. ICAN seeks the information in this FOIA request to allow it to contribute to the public understanding of governments' COVID-19 vaccine programs, including governments' regulatory processes, and criteria for vaccine safety and vaccine efficacy. The information we are requesting will not contribute to any commercial activities.

Furthermore, we ask you provide expedited processing for this request. The information requested concerns matters of urgent public concern. The only time MHRA has ever approved or authorized an mRNA vaccine for public use was for the COVID-19 vaccines.<sup>4</sup> Moreover, there has never been a faster development, testing, and regulatory approval of any vaccine on the market. The speed in which the COVID-19 vaccines have been developed, tested, and regulatorily approved for widespread public use has sparked a public debate regarding the vaccines' safety and effectiveness. The ongoing public debate regarding the safety and effectiveness of a group of novel vaccines requires complete transparency over the MHRA's approval process.

If MHRA withholds information responsive to this request, we 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.<sup>5</sup> Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter.<sup>6</sup> Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately file an administrative appeal.

<sup>&</sup>lt;sup>4</sup> https://ec.europa.eu/research-and-innovation/en/horizon-magazine/five-things-you-need-know-about-mrna-yaccine-safety.

<sup>&</sup>lt;sup>5</sup> UK 2000 c. 36 § 17(1).

<sup>&</sup>lt;sup>6</sup> UK 2000 c. 36 § 10(1).

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

Very truly yours,

/s/ Aaron Siri

Aaron Siri, Esq. Elizabeth A. Brehm, Esq. Colin Farnsworth, Esq.