April 29, 2021

Department of Health and Human Services (HHS)
Freedom of Information Officer
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201
Email: FOIARequest@hhs.gov

Subject : FOIA Appeal – CDC FOIA request - #21-00899-FOIA – Expedite processing requested

Dear Chief FOIA Officer,

I hereby appeal your refusal to release the VAERS and Vaccine Safety Datalink (VSD) data and analyses under the FOIA, 5 U.S.C. § 552. Your April 12, 2021 letter states that reports / preliminary reports / correspondences (including emails) and statistical tables related to

1 the disproportionality analyses done on the VAERS
2 the safety analyses done on the Vaccine Safety Datalink (VSD Rapid Cycle Analysis)

for the Covid-19 vaccines currently used are withheld in full under Section 308(d) of the Public Health Service Act [42 U.S.C. Section 242m, as amended] and Exemption (b)(3) because releasing those documents would permit identification of any individual. Also your letter states that the documents which have been located contain "trade secrets and commercial or financial information obtained from a person that is privileged or confidential." and are withheld under Exemption (b)(4).

However, because of the overriding public importance of this issue, especially in light of the ongoing immunization campaign against Covid-19, various safety concerns among the general public, its reliance on the CDC's VAERS and VSD analyses, and the harm done to the process of scientific inquiry by your unreasonable withholding, we do seek an expedited appeal at this time with respect to the wrongfully withheld VAERS and VSD data.

Your April 12, 2021 letter completely fails to demonstrate any entitlement to claim a withholding under Exemption(b)(3) : if the raw data contains patient-level records which you say may be traceable to individual patients, your agency would redact any patient names or identifying information. Anyway, as I've requested reports and preliminary reports related to statistical analyses (the protocol of VSD's RCA has even been released publicly : https://www.cdc.gov/vaccinesafety/pdf/VSD-1342-COVID19-RCA-Protocol_FinalV1.1_508.pdf and some results have been presented through some VRBPAC meeting materials available online : https://www.fda.gov/media/146269/download), no patient-level information is expected, only numerical results and interim analyses related to Covid-19 vaccines and MedDRA / ICD-10 codes associated to adverse reactions, so identification of any individual is impossible.

Your April 12, 2021 letter also completely fails to demonstrate any entitlement to claim a discretionary exemption. You have not demonstrated that the VAERS and VSD datas qualify under discretionary exemption four ("trade secrets and commercial or financial information obtained from a person and privileged or confidential"). Specifically, you have not asserted "trade secret" status. All reports, preliminary reports and correspondences related to data mining and statistical analyses per-

formed on MedDRA and ICD-10 codes are obviously not “commercial or financial information.” You have not and cannot demonstrate that public release would confer a competitive disadvantage on the HMOs from which the data were obtained. Nor can you demonstrate that release would impose any burden on the ability of the CDC to obtain similar data in the future.

Your refusal to release the VSD data is also contrary to the traditional practice in the scientific community of making raw data publicly available so that other researchers can confirm – or refute – the conclusions reached in your studies or presentations done for the FDA’s VRBPAC meeting mentioned above. Also the release of those data cannot possibly interfere with the publication of any studies based upon the data.

In sum, you have no lawful basis to withhold those VAERS and VSD data and related analyses; it’s release is required as a matter of policy and good science; and your withholding is not justified.

Sincerely,

Surya ARBY