

FREEDOM OF INFORMATION ACT REQUEST

VIA FEDEX AND EMAIL

October 13, 2020

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

Re: *Harvard Pilgrim Study (IR#0338)*

Dear Mr. Marquis:

This firm represents Informed Consent Action Network (“ICAN”). On behalf of ICAN, we hereby request records pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) from the files of the Department of Health and Human Services.

Please provide the following records in the Department of Health and Human Services’ possession to foia@sirillp.com in electronic form:

- 1. Any and all documents and communications concerning Grant Number R18 HS017045, given to Principal Investigator Ross Lazarus from Harvard Pilgrim Health Care, Inc., by the AHRQ (the “Grant”). This should include, but is not limited to, any and all documents and communications concerning proposals for the Grant, awarding of the Grant, and evaluation of the Grant.**
- 2. Any and all documents and communications with Ross Lazarus, Michael Klompas, or Steve Bernstein, (the “Grant Personnel”) concerning the Vaccine Adverse Event Reporting System (“VAERS”). This request should include, but is not limited to, any documents or communications concerning giving the Grant Personnel access to, permission to use, permission to interact with, or permission to submit data to VAERS.**
- 3. Any and all documents and communications concerning both (a) the Grant or the Grant Personnel, and (b) the VAERS. This**

request should include, but is not limited to, any internal documents or communications concerning giving the Grant Personnel access to, permission to use, permission to interact with, or permission to submit data to VAERS.

4. Any and all documents and communications concerning the report entitled “ELECTRONIC SUPPORT FOR PUBLIC HEALTH: VALIDATED CASE FINDING AND REPORTING FOR NOTIFIABLE DISEASES USING ELECTRONIC MEDICAL DATA,” by Lazarus R., Klompas M., Campion FX, et al. published in the Journal of the American Medical Informatics Association’s Jan-Feb 2009 edition; 16(1):18-24, available at <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf> (the “Report”).

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 vaccine safety and provide the public with information to give informed consent. As part of its mission, ICAN investigates and disseminates information regarding vaccine safety, 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 the public understanding of the government’s vaccine safety programs, including the government’s efforts to promote vaccine safety. 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,

/s/ Elizabeth A. Brehm
Elizabeth A. Brehm, Esq.