

In Reply Refer To: **FOIA Request 21-07865-F**

August 26, 2021

William Marshall  
Judicial Watch  
425 Third Street, Suite 800  
Washington, DC, 20024  
[bmarshall@judicialwatch.org](mailto:bmarshall@judicialwatch.org)

Dear Mr. Marshall:

This letter serves as the first partial initial agency decision to your July 27, 2021, request under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, submitted to the Department of Veterans Affairs (VA), FOIA Service requesting the following records:

1. All records reflecting the number, dates and types of adverse events resulting from COVID-19 vaccinations administered by VA officials, employees, contractors, hospitals and other VA care facilities to US veterans and/or their dependents.
2. All emails sent to and from the following VA officials regarding adverse events, or potential adverse events, resulting from the administration, or planned administration, of COVID-19 vaccinations: Secretary of Veterans Affairs, Deputy Secretary of Veterans Affairs, Chief of Staff of Veterans Affairs, Under Secretary for Health, Deputy Under Secretary for Health, and the Deputy to the Deputy Under Secretary of Health.

The time frame for the records sought is December 1, 2020 to the present.

**Referral:**

As indicated in their July 28, 2021 letter, the VA FOIA Service referred your request to the Veterans Health Administration (VHA) Central Office FOIA Office for further processing and direct response to you. Your FOIA request was received in my office on July 28, 2021, under FOIA tracking number 21-07865-F.

**Fee Waiver:**

On your July 27, 2021 request you had requested a fee waiver for search and duplication fees. 38 C.F.R. 1.561 (b)(y) indicates that News Media request is not subject to search fees or review fees. News Media requests are subject duplication fees after the first 100 pages. There are no duplication fees as this request is being sent electronically. Therefore, there are no fees assessed for this request. Please be advised, we reserve the right to assess fees as appropriate under the FOIA on any and all future FOIA requests.

**Clarification:**

Per my email to you on July 29, 2021; you were advised that clarification/further information was needed for line item 2 of your request for specific search terms you would like VA and VHA to search for within the emails of the individuals within your request. On July 29, 2021, you provided the search terms of "adverse event", "adverse events", "adverse reaction" "adverse reactions," "AER", and "side effects", each used in combination with "vaccine", "vax" and "shot".

Per phone conversation and via email on August 18, 2021, we discussed line item one of your request, and I informed you it would take manipulation of data to create new reports to respond to line item one of your request and VA does not create new records for FOIA requests. (See Frank v. DOJ, 941 F. Supp. 4, 5 (D.D.C. 1996) (stating that agency is not required to "dig out all the information that might exist, in whatever form or place it might be found, and to create a document that answers plaintiff's questions"); Krohn v. DOJ, 628 F.2d 195, 197-98 (D.C. Cir. 1980) (finding that agency "cannot be compelled to create the [intermediary records] necessary to produce" information sought); Schoenman v. FBI, No. 04-2202, 2009 WL 763065, at \*17-18 (D.D.C. Mar. 19, 2009) (rejecting plaintiff's request for search slips, created by agency after date-of-search cut-off date, holding that "FOIA 'does not obligate agencies to create or retain documents; it only obligates them to provide access to those which it in fact has created or retained'" (quoting Schoenman v. FBI, 573 F. Supp. 2d 119, 140 (D.D.C. 2008))); Moore v. Bush, 601 F. Supp. 2d 6, 15 (D.D.C. 2009) (finding that agency properly refused to issue various statements regarding brain wave technology because FOIA does not require creation of records); West v. Spellings, 539 F. Supp. 2d 55, 61 (D.D.C. 2008) (recognizing that Department of Education had no duty to create list of uninvestigated complaints to satisfy request). However, VHA does have an updated PowerPoint presentation from August 2021 on Vaccine Adverse Events Reporting within the VA that breaks down specific symptoms and provides data on reports of adverse events along with the top 10 symptoms from COVID 19 Vaccines. You agreed this information would be beneficial as you are looking for updated information.

**Search:**

Pharmacy Benefit Management (PBM) conducted a search for documents responsive to line item 1 of your FOIA request. At the conclusion of the search, one (1) PowerPoint document, totaling ten (10) slides, was determined to be responsive to your request. All information is provided in its entirety. No portions of the requested records have been withheld either in whole or in part. PBM indicated this slide set contains summary data of all adverse events reported for both employees and Veterans. These reports are spontaneously reported and unvalidated so true causality of the adverse event cannot be stated.

- Vaccine AE Updates 08.06.2021 PM Summary.pptx

Please note, Pharmacy Benefit Management (PBM) advised that VA adverse drug reporting to include all COVID-19 vaccine reactions are reported to the Food and Drug Administration (FDA) and the Center for Disease Control (CDC) via their FDA/CDC Vaccine Adverse Events Reporting System (VAERS) database. PBM advised that VAERS Data is available publicly on the Health and Human Services website at: <https://vaers.hhs.gov/data.html>.

VHA will continue to review and provide responses on a rolling basis.

Please be advised you may appeal this full grant response to:

Office of the General Counsel (024)  
Department of Veterans Affairs  
810 Vermont Avenue, N.W.  
Washington, D.C. 20420  
Email: [ogcfoiaappeals@va.gov](mailto:ogcfoiaappeals@va.gov)

If you should choose to file an appeal, your appeal must be postmarked or electronically transmitted no later than ninety (90) calendar days from the date of this letter. Please include a copy of this letter with your written appeal and clearly state why you disagree with the determinations set forth in this response.

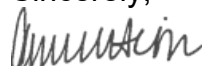
You may also seek assistance and/or dispute resolution services for any other aspect of your FOIA request from VHA's FOIA Public Liaison and/or Office of Government Information Services (OGIS) as provided below:

VHA FOIA Public Liaison:  
Email Address: [vhafioa2@va.gov](mailto:vhafioa2@va.gov)  
Phone Number: (877) 461-5038

Office of Government Information Services (OGIS)  
Email: [ogis@nara.gov](mailto:ogis@nara.gov)  
Fax: (202) 741-5769  
Mailing address:  
Office of Government Information Services  
National Archives and Records Administration  
8601 Adelphi Road  
College Park, MD 20740-6001

If you need any further assistance or would like to discuss any aspect of your request, please do not hesitate to contact me at (319) 530-7694 or via email at [Amber.Heim@va.gov](mailto:Amber.Heim@va.gov).

Sincerely,



Amber Heim  
VHA FOIA Officer

Enclosure: Vaccine AE Updates 08.06.2021 PM Summary.pptx (10 slides)



# Vaccine Adverse Event Reporting

VA Center for Medication Safety (VAMedSAFE)

August 2021

# Vaccine AE Reports (All Reports-Employee and Veteran Reports)

Product	Reports	All AE's /10,000 Doses	Anaphylaxis /10,000 Doses	Sent to VAERS
J&J (4)	853	58.9	0.276	839 (99.4%)
Moderna (65)	19301	63.2	0.213	19275 (99.9%)
Pfizer (52)	8412	32.2	0.199	8396 (99.8%)
Grand total	28566	49.2	0.208	28510 (99.8%)

## Vaccine AE Reports – Serious/Non-Serious (Employee and Veterans) (Unvalidated Information per Reporter Completed AE Template)

	Reports
Serious*	1741
Non-Serious	26825
Grand total	28566

\*Events where Death, hospitalization, and/or Life-Threatening Event is marked as part of the report but is unvalidated and does not confirm association with vaccine

# VA ADERS – CV AESI Reports

Symptom	J&J	MODERNA	PFIZER
CARDIAC ARREST	0	19	5
CEREBROVASCULAR ACCIDENT	8	30	15
DEEP VEIN THROMBOSIS	13	18	4
MYOCARDIAL INFARCTION	0	13	6
PULMONARY EMBOLISM	9	21	13



# VA ADERS – TIME TO EVENT (MEDIAN DAYS-RANGE)

Symptom	J&J	MODERNA	PFIZER
CARDIAC ARREST	0	6 (1-34)	1 (1-11)
CEREBROVASCULAR ACCIDENT	12.5 (0-40)	7 (0-68)	1 (0-24)
DEEP VEIN THROMBOSIS	20 (3-125)	18.5 (2-68)	30 (9-75)
MYOCARDIAL INFARCTION	0	10 (0-93)	1.5 (0-9)
PULMONARY EMBOLISM	21 (4-56)	14 (3-79)	12 (0-38)

# VA ADERS – CV AESI Reports Breakdown by Employee/Veteran

Symptom	J&J		MODERNA		PFIZER	
	EMP	VET	EMP	VET	EMP	VET
CARDIAC ARREST	0	0	0	19	0	5
CEREBROVASCULAR ACCIDENT	0	8	5	25	1	14
DEEP VEIN THROMBOSIS	1	12	5	13	1	3
MYOCARDIAL INFARCTION	0	0	3	10	1	5
PULMONARY EMBOLISM	0	9	3	18	0	13

# VA ADERS – Other AESI Reports

Symptom	J&J	MODERNA	PFIZER
EMBOLISM	1	0	0
EMBOLISM VENOUS	0	2	1
THROMBOCYTOPENIA	3	14	8
THROMBOSIS	7	9	5
VENOUS THROMBOSIS	0	1	0

# VA ADERS – TIME TO EVENT (MEDIAN DAYS-RANGE)

Symptom	J&J	MODERNA	PFIZER
EMBOLISM	7	0	0
EMBOLISM VENOUS	0	4 (2-6)	50
THROMBOCYTOPENIA	17 (5-27)	5 (0-79)	8 (0-42)
THROMBOSIS	12 (0-40)	14 (0-55)	12 (0-67)
VENOUS THROMBOSIS	0	1	0

# VA ADERS – Other AESI Reports Breakdown by Employee/Veteran

Symptom	J&J		MODERNA		PFIZER	
	EMP	VET	EMP	VET	EMP	VET
EMBOLISM	0	1	0	0	0	0
EMBOLISM VENOUS	0	0	0	2	0	1
THROMBOCYTOPENIA	0	3	4	10	2	6
THROMBOSIS	0	7	2	7	1	4
VENOUS THROMBOSIS	0	0	0	1	0	0

# AEs – Top 10 by MedDRA Preferred Term

COVID-19 Vaccines - Top 10 Symptoms

