United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510–6250

July 19, 2023

The Honorable Lloyd J. Austin III
Secretary
Department of Defense

Dear Secretary Austin:

I am continuing to examine the data integrity issues on the Defense Medical Epidemiology Database (DMED) and the Department of Defense's (DoD) misleading and incomplete responses to my office on this matter. In a response dated July 5, 2023, DoD admitted that it provided incomplete data to my office in February 2022 regarding increases in registered diagnoses in DMED.[1] This acknowledgement came *after* I sent DoD information I received from a whistleblower that called into question the accuracy of the data that DoD previously produced to me.[2] DoD's pattern of deception regarding DMED data is unacceptable.

For over a year, I have been examining the significant increases in certain registered diagnoses in DMED. In late January 2022, three DoD whistleblowers provided my office with data showing significant increases in certain registered diagnoses on DMED in 2021 compared to a five-year average from 2016-2020.[3] Based on this information, I sent you a letter on February 1, 2022, identifying 15 registered diagnoses that, according to the three DoD whistleblowers, showed significant increases in 2021 compared to the average from 2016-2020.[4] On February 15, 2022, DoD informed my office that in late January 2022, it found that "the data in DMED was corrupt for the years 2016-2020 when accessed after September 2021."[5] DoD claimed that this data corruption resulted in increases in registered medical diagnoses on DMED in 2021 compared to the five-year average from 2016-2020.[6] DoD assured my office that as of January 29, 2022, it corrected the programming error that corrupted the data and that "DMED data via the online application was restored on January 30, 2022."[7]

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[1] Letter from Gilbert Cisneros, Jr., Dep't of Defense, to Sen. Ron Johnson, Ranking Member, Permanent Subcomm. on Investigations, July 5, 2023 (enclosed).
[2] Letter from Sen. Ron Johnson, Ranking Member, Permanent Subcomm. on Investigations, to Lloyd Austin, Sec., Dep't of Defense, Mar. 21, 2023, https://www ronjohnson.senate.gov/services/files/C7B70308-BB0B-451F-83B5-8B354BF83862/.
[3] Letter from Ron Johnson, Ranking Member, Permanent Subcommittee on Investigations, to Lloyd Austin, Secretary, U.S. Dep't of Defense, Feb. 1, 2022, https://www.ronjohnson.senate.gov/services/files/FB6DDD42-4755-4FDC-BEE9-50E402911E02.
[4] *Id.*
[5] Temporary Data Inaccuracies in the Defense Medical Epidemiology Database, Dep't of Defense, Feb. 15, 2022, available at https://www ronjohnson.senate.gov/services/files/C7B70308-BB0B-451F-83B5-8B354BF83862/ at 7.
[6] *Id.*
[7] *Id.* at 8.

In its February 15, 2022 response, DoD included a chart that listed the 15 registered diagnoses I had previously identified and showed the percent change in health encounters in 2021 compared to a five-year average from 2016-2020 before and after DoD fixed the data issue on DMED.[8] Then, in early 2023, I received DMED data from another DoD whistleblower that showed different percent changes compared to what DoD provided. In my March 21, 2023 letter to you, I included the chart below that showed the data DoD provided my office compared to the data from the recent DoD whistleblower (highlighted):[9]

Medical Encounter Conditions	**Before DoD Corrected DMED** Reported change to number of health care encounters (2021 compared to 2016-2020 average) using erroneous data[10]	**After DoD Corrected DMED** DMED query results for change to number of health care encounters (2021 compared to 2016-2020 average) following data correction[11]	**Recent DoD Whistleblower DMED Data** From 2023 showing change to number of health care encounters (2021 compared to 2016-2020 average)[12]
Diseases of the nervous system	1,048% increase	5.7% decrease	9.5% increase
Hypertension	2,181% increase	1.9% increase	12.6% increase

[8] *Id.* at 7-8.

[9] Letter from Sen. Ron Johnson, Ranking Member, Permanent Subcomm. on Investigations, to Lloyd Austin, Sec., Dep't of Defense, Mar. 21, 2023, https://www ronjohnson.senate.gov/services/files/C7B70308-BB0B-451F-83B5-8B354BF83862/.

[10] The information contained in this column is based on information from DoD whistleblowers provided in January 2022. DoD claims that this data was based on faulty information. Temporary Data Inaccuracies in the Defense Medical Epidemiology Database, Dep't of Defense, Feb. 15, 2022, available at https://www ronjohnson.senate.gov/services/files/C7B70308-BB0B-451F-83B5-8B354BF83862/ at 6-9.

[11] The information contained in this column shows the percent changes *after* DoD claimed it corrected the data problem in DMED. *Id.*

[12] The information contained in this column is based on whistleblower DMED data from January 2023 and February 2023. The whistleblower data is sourced from the "Ambulatory Data" contained in DMED for each medical encounter noted above. For all medical encounters listed, the whistleblower used the following criteria – Service: All; Grade: All; Data Sources: Hospitalizations Ambulatory Data Reportable Events; Gender: All; Marital Status: All; Query Type: ICD-10 Based Query Oct 2015 to present; Age: All; Time: 2016 2017 2018 2019 2020 2021; Condition: Primary Diagnosis; Race: All; Occurrence: All Occurrences. The whistleblower used the following ICD codes for each medical encounter – Diseases of the nervous system: G00-G99; Hypertension: I10-I15; Tachycardia: I47; Testicular cancer: C62; Ovarian dysfunction: E28; Migraines: G43; Pulmonary embolism: I26; Female infertility: N97; Malignant neoplasms of thyroid and other endocrine glands: C73-C75; Breast cancer: C50; Demyelinating: G35-G37; Guillain-Barre syndrome: G61.0; Malignant neoplasms of digestive organs: C15-C26; Multiple sclerosis: G35; Malignant neoplasms of esophagus: C15.

Tachycardia	302% increase	8.3% decrease	4.9% increase
Testicular cancer	369% increase	3% increase	16.3% increase
Ovarian dysfunction	437% increase	23.9% increase	38.2% increase
Migraines	452% increase	1.6% increase	12.1% increase
Pulmonary embolism	468% increase	25.4% increase	41.2% increase
Female infertility	472% increase	13.2% decrease	4.3% decrease
Malignant neoplasms of thyroid and other endocrine glands	474% increase	16.1% decrease	4.3% decrease
Breast cancer	487% increase	1.1% increase	14.7% increase
Demyelinating	487% increase	17.7% decrease	8.3% decrease
Guillain-Barre syndrome	551% increase	17.2% decrease	3.2% increase
Malignant neoplasms of digestive organs	624% increase	0.2% increase	14.4% increase
Multiple sclerosis	680% increase	16.7% decrease	7.1% decrease
Malignant neoplasms of esophagus	894% increase	27.8% increase	56.6% increase

I asked you whether DoD agrees with the percent changes provided by the DoD whistleblower. DoD responded, "Yes. DoD officials replicated these analyses and they are similar to those described in your letter."[13] DoD explained that the reason for the differences in their data versus the whistleblower data was because DoD's February 2022 response was based on incomplete information that did not capture all the data from 2021:

> "When DoD provided the percent changes in February 2022, the encounter data for December 2021 was not yet available in DMED. **This is because the data lag by about 3 months, so the December 2021 data would not have been available until March 2022.** The December 2021 data was available in February 2023 when the data query described in your letter was performed."[14]

[13] Letter from Gilbert Cisneros, Jr., Dep't of Defense, to Sen. Ron Johnson, Ranking Member, Permanent Subcomm. on Investigations, July 5, 2023.
[14] *Id.* (emphasis added).

DoD's excuse for the apparent data discrepancies would have been understandable if it had flagged this specific data limitation in its February 15, 2022 response.[15] Further, on July 5, 2022 (over one year ago), DoD provided my office additional background information on DMED data integrity issues.[16] As part of this response, DoD attached an "information paper" that was identical to the February 15, 2022 response.[17] As noted above, DoD told my office that the "December 2021 data would have not been available until March 2022."[18] Based on this assertion, DoD should have been able to produce an updated chart based on complete information to my office when it responded in July 2022. Instead, DoD failed to do this and once again provided my office with incomplete and misleading DMED data.[19]

DoD's July 5, 2023 response contained even more potentially misleading calculations. DoD asserted that in certain registered diagnoses "new case rate[s] [were] higher among Service members with a prior SARS-CoV-2 infection compared to those with a prior COVID-19 vaccination. This suggests that it was more likely to be SARS-CoV-2 infection and not COVID-19 vaccination that was the cause of these increased cases in 2021."[20] Based on DoD's explanation of how it made its calculations to support this claim, it is unclear whether or how it accounted for Service members who had a prior COVID-19 infection *and* received a COVID-19 vaccination.

DoD's failure to provide my office with complete DMED data or immediately disclose relevant limitations to information it produced to Congress shows a complete disregard for transparency. I am grateful to the whistleblowers who continue to come forward to provide my office with information you and other DoD officials are unwilling to produce. In this instance, without the whistleblower's disclosure, I doubt DoD would have ever acknowledged that it provided incomplete information to my office in February 2022 and again in July 2022. To better understand DoD's assertions in its July 5, 2023 response, please provide the following information:

1. Please explain whether DoD accounted for individuals who had a prior COVID-19 infection *and* received a COVID-19 vaccination when determining that for certain conditions, "new case rate[s] [were] higher among Service members with a prior SARS-CoV-2 infection compared to those with a prior COVID-19 vaccination. This suggests that it was more likely to be SARS-CoV-2 infection and not COVID-19 vaccination that was the cause of these increased cases in 2021."[21]

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[15] In its February 15, 2022 response, DoD wrote that it created its chart of the percent changes in health encounters by "comparing available 2021 data to 2016-2020." In that response, DoD never explained what it meant by "available 2021 data." Temporary Data Inaccuracies in the Defense Medical Epidemiology Database, Dep't of Defense, Feb. 15, 2022, available at https://www ronjohnson.senate.gov/services/files/C7B70308-BB0B-451F-83B5-8B354BF83862/ at 7.
[16] Letter from Gilbert Cisneros, Jr., Dep't of Defense, to Sen. Ron Johnson, July 5, 2022.
[17] *Id.*
[18] Letter from Gilbert Cisneros, Jr., Dep't of Defense, to Sen. Ron Johnson, Ranking Member, Permanent Subcomm. on Investigations, July 5, 2023.
[19] Letter from Gilbert Cisneros, Jr., Dep't of Defense, to Sen. Ron Johnson, July 5, 2022.
[20] Letter from Gilbert Cisneros, Jr., Dep't of Defense, to Sen. Ron Johnson, Ranking Member, Permanent Subcomm. on Investigations, July 5, 2023.
[21] *Id.*

2. Have any Service members experienced adverse medical conditions associated with the COVID-19 vaccines? If so, how many and what are those conditions? How did DoD make this determination? Has DoD conducted any independent investigation into whether adverse medical conditions are associated with the COVID-19 vaccines? If so, what has DoD found? If not, why not?

Please provide this information as soon as possible but no later than August 2, 2023. Thank you for your attention to this matter.

Sincerely,

Ron Johnson
Ranking Member
Permanent Subcommittee on Investigations

Enclosure

cc: The Honorable Richard Blumenthal
Chairman
Permanent Subcommittee on Investigations

The Honorable Robert Storch
Inspector General
Department of Defense

Mr. Manish Malhotra
Chairman and Chief Executive Officer
Unissant, Inc.

Enclosure

UNDER SECRETARY OF DEFENSE
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WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

JUL - 5 2023

The Honorable Ron Johnson
United States Senate
Washington, DC 20510

Dear Senator Johnson:

Thank you for your March 21, 2023 letter to the Secretary of Defense regarding the Defense Medical Epidemiology Database (DMED). I am responding on the Secretary's behalf as this matter falls under my purview.

As explained in the Department's February 15, 2022 letter to you, Department officials found that the data in DMED covering the years 2016 to 2020 had been corrupted during a server migration. Department officials resolved the programming error in January 2022. The difference in the rates between the Department's February 2022 response and subsequent queries is that data for December 2021 was not available at the time of the Department's February 2022 response. Data is made available with a 3-month data lag, so data for December 2021 only became available in March 2022. Further investigation by Department officials of that data determined that increases in new cases of the conditions listed in your letter in 2021 were more likely to be related to a SARS-CoV-2 infection (the virus that causes coronavirus disease 2019 (COVID-19)) than receipt of a COVID-19 vaccine.

Enclosed are responses to each of the questions posed in your letter. Thank you for your continued strong support for our Service members, veterans, and their families.

Sincerely,

Gilbert R. Cisneros, Jr.

Enclosure:
As stated

Enclosure

1. *For the February 15, 2022 document DoD provided my office, how did DoD calculate the percent change for the 15 registered diagnoses listed above?*

   Response: The Department of Defense (DoD) calculated the percent change for the 15 registered diagnoses in the same manner as described in your letter. The data were sourced from the "Ambulatory Data" contained in Defense Medical Epidemiology Database (DMED) for each diagnosis. For all diagnoses listed, the following criteria was used – Service: All; Grade: All; Data Sources: Hospitalizations Ambulatory Data Reportable Events; Gender: All; Marital Status: All; Query Type: International Classification of Diseases, 10th Edition (ICD-10) Based Query Oct 2015 to present; Age: All; Time: 2016 2017 2018 2019 2020 2021; Condition: Primary Diagnosis; Race: All; Occurrence: All Occurrences. The same ICD codes were used as for the data set forth in your letter for each of the medical conditions.

2. *Do the percent changes DoD provided my office in February 2022 for the 15 registered diagnoses listed above remain unchanged? If not, why not and what are the updated percent changes?*

   Response: The percent changes are different now compared to those provided in February 2022. When DoD provided the percent changes in February 2022, the encounter data for December 2021 was not yet available in DMED. This is because the data lag by about 3 months, so the December 2021 data would not have been available until March 2022. The December 2021 data was available in February 2023 when the data query described in your letter was performed. DoD was able to replicate the data query with the inclusion of the December 2021 data.

3. *Does DoD agree with the percent changes provided by a DoD whistleblower (indicated above)? If not, why not?*

   Response: Yes. DoD officials replicated these analyses and they are similar to those described in your letter.

4. *What steps has DoD taken or will DoD take to investigate whether the increases in certain registered medical diagnoses, including those above, are associated with COVID-19 vaccine adverse events?*

   Response: The analyses performed using DMED data as described in your letter show the occurrences of outpatient clinic visits for these conditions, which include a mixture of previously existing and new cases of disease. For the coronavirus disease 2019 (COVID-19) vaccine to be considered a cause of increase for these medical conditions, one must examine the patterns of new cases. DMED provides remote access to a subset of data contained within the Defense Medical Surveillance System (DMSS). Because DMED does not have a function for users to query new cases for groups of diagnoses, the Armed Forces Health Surveillance Division (AFHSD) used data from the DMSS to identify patterns of new cases over time for each of these conditions. For all diagnoses listed, AFHSD identified the first occurrence of a hospital or outpatient clinic visit with the diagnosis listed in the first diagnostic position. This was defined as the new case date for the disease. The new cases of each condition were evaluated for all Active Component Service members in the Army, Navy, Air Force, and Marine Corps annually between 2016 and 2021. If the COVID-19

vaccine were a cause of these diseases, then one would also expect to see an increase in new cases in 2021 corresponding with the timing of the vaccine mandate. The results are shown in Table 1.

Table 1. New cases of disease, Active Component, 2016-2021

	Cases (2016 - 2020)	5-year average (2016 - 2020)	Cases 2021	% Change
Diseases of the nervous system	387,674	77,535	80,700	4.1
Hypertensive diseases	55,042	11,008	13,529	**22.9**
Paroxysmal tachycardia	3,885	777	847	9.0
Malignant neoplasm of testis	831	166	180	8.3
Ovarian dysfunction	5,388	1,078	1,454	**34.9**
Migraine	78,173	15,635	18,677	**19.5**
Pulmonary embolism	2,406	481	691	**43.6**
Female infertility	10,936	2,187	2,169	-0.8
Malignant neoplasms of thyroid and other endocrine glands	722	144	146	1.1
Malignant neoplasm of breast	556	111	119	7.0
Demyelinating diseases of the central nervous system	1,401	280	286	2.1
Guillain-Barre syndrome	174	35	40	**14.9**
Malignant neoplasms of digestive organs	731	146	173	**18.3**
Multiple sclerosis	977	195	181	-7.4
Malignant neoplasm of esophagus	40	8	9	**12.5**
Myocarditis, unspecified	547	109	275	**151.4**

Data from the Defense Medical Surveillance System (DMSS)
Analysis performed by the Armed Forces Health Surveillance Division (AFHSD) on April 17, 2023

For conditions that had more than a 10 percent increase in the number of new cases, AFHSD analyzed their onset rates in 2021 to determine whether the increase in cases in 2021 was more likely to be related to prior SARS-CoV-2 infection or prior COVID-19 vaccination. The conditions that had more than a 10 percent increase were hypertensive disease, ovarian dysfunction, migraine, pulmonary embolism, Guillain-Barre syndrome, malignant neoplasms of digestive organs, malignant neoplasm of esophagus, and myocarditis. The total Active Component time in service in 2021 was expressed as person-years and used as the denominator for the calculation of new case rates for each of the outcomes. These results are shown in Table 2.

Table 2. New case rate of disease (per 100,000 person-years), Active Component Service members, 2021

	Overall	Prior COVID-19 infection	Prior COVID-19 vaccination
Hypertensive disease	1,060.9	1,194.5	1,072.3
Ovarian dysfunction	645.9	745.9	618.1
Migraine	1,479.7	1,840.1	1,428.5
Pulmonary embolism	51.9	157.3	44.0
Guillain-Barre syndrome	3.0	4.7	3.3
Malignant neoplasms of digestive organs	13.0	12.1	13.9
Malignant neoplasm of esophagus	0.7	0.7	0.5
Myocarditis, unspecified	20.6	69.8	21.7

For almost all conditions, the new case rate was higher among Service members with a prior SARS-CoV-2 infection compared to those with a prior COVID-19 vaccination. This suggests that it was more likely to be SARS-CoV-2 infection and not COVID-19 vaccination that was the cause of these increased cases in 2021. The exceptions were malignant neoplasm of digestive organs and malignant neoplasm of esophagus, where the new case rate was similar between those with a prior SARS-CoV-2 infection and those with a prior COVID-19 vaccination. This suggests that the increased new case rates of these malignant neoplasms may have been due to some other factor.

AFHSD will continue to monitor the new case rate of these conditions overall and by prior SARS-CoV-2 infection and COVID-19 vaccination status.