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United States Senate

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS WASHINGTON, DC 20510-6250

April 20, 2023

The Honorable Xavier Becerra Secretary Department of Health and Human Services 200 Independence Ave S.W. Washington, D.C. 20201

Ms. Carole Johnson Administrator Health Resources and Services Administration 5600 Fishers Lane Rockville, MD 20857

Dear Secretary Becerra and Administrator Johnson:

I am writing regarding the Health Resources and Services Administration's (HRSA) review process for determining who is eligible to receive compensation for COVID-19 vaccine injuries.

HRSA administers the Countermeasures Injury Compensation Program (CICP) which "provides compensation for covered serious injuries or deaths that, based on compelling, reliable, valid, medical and scientific evidence, are found to be directly caused by the administration or use of a covered countermeasure or are determined to meet the requirements of a countermeasure injury table."¹ One such countermeasure that is covered by the CICP are the COVID-19 vaccines.²

If an individual believes they suffered an injury by a covered countermeasure, such as the COVID-19 vaccines, they can file a claim through the CICP within one year of receiving the vaccine.³ According to HRSA, after an individual submits a "Request for Benefits Package, which should include proof of administration or use of a covered countermeasure" as well as complete medical records, then "CICP medical staff will review the package and decide if [the individual] is eligible for program benefits. If found eligible, [the individual] will be asked to submit additional documentation to determine how much compensation [that person] should receive."4

¹ Countermeasures Injury Compensation Program (CICP) Data, Health Resources and Services Administration, Apr. 2023, https://www.hrsa.gov/cicp/cicp-data.

² Covered Countermeasures, Health Resources and Services Administration, Dec. 2022, https://www.hrsa.gov/cicp/covered-countermeasures.

³ Countermeasures Injury Compensation Program (CICP), Health Resources and Services Administration, Jan.

^{2023,} https://www.hrsa.gov/cicp.

According to CICP data, as of April 1, 2023, 8,133 claims have been filed relating to COVID-19 vaccine injuries or deaths.⁵ CICP staff have apparently identified 22 claims connected to COVID-19 vaccines injuries that are "eligible for compensation and pending benefits determination."⁶ HRSA reported that one those claims had "no eligible reported expenses."⁷ The following three claims have been compensated as indicated below:⁸

Alleged Countermeasure	Alleged Injury	Compensation Amount
COVID-19 Vaccine	Anaphylaxis	\$2,019.55
COVID-19 Vaccine	Myocarditis	\$1,582.65
COVID-19 Vaccine	Myocarditis	\$1,032.69
Total Compensation:		\$4,634.89

According to HRSA, the following table displays 19 COVID-19 vaccine claims that are "eligible for compensation and the program is either waiting for documentation from the requester to determine benefits or benefits determination is in progress."⁹

Number	Alleged Countermeasure	Alleged Injury
1	COVID-19 Vaccine	Myocarditis
2	COVID-19 Vaccine	Myocarditis
3	COVID-19 Vaccine	Myocarditis
4	COVID-19 Vaccine	Myocarditis
5	COVID-19 Vaccine	Myocarditis
6	COVID-19 Vaccine	Myocarditis
7	COVID-19 Vaccine	Myocarditis
8	COVID-19 Vaccine	Myocarditis
9	COVID-19 Vaccine	Myocarditis

⁵ Table 1. Alleged COVID-19 Countermeasure Claims Filed, Health Resources and Services Administration, Apr. 2023, https://www.hrsa.gov/cicp/cicp-data/table-1. In addition to the 8,133 claims filed relating to COVID-19 vaccine injuries, there are 3,292 claims relating to other COVID-19 countermeasures. Of the 11,425 total claims filed relating to COVID-19 countermeasures, 10,719 are pending review or in review. CICP staff have made decisions on 706 claims, including 22 claims that are "eligible for compensation and pending benefits determination," and 684 claims that have been denied. Of the 22 claims that are eligible for compensation, 3 claims have been compensated, 1 claim has "no eligible reported expenses;" and 18 claims are "pending compensation." Of the 684 denied claims HRSA reports that 47 claims were denied based on "requested medical records not submitted;" 117 claims were denied based on "standard of proof not met and/or covered injury not sustained;" 269 claims were denied based on "missed filing deadline;" and 251 claims were denied based on being "not CICP covered product/not specified." Countermeasures Injury Compensation Program (CICP) Data, Health Resources and Services Administration, Apr. 2023, https://www hrsa.gov/cicp/cicp-data.

⁷ *Id.* According to HRSA, the alleged injury associated with this claim was myocarditis. *See* Table 5. CICP Claims Eligible for Compensation, but No Eligible Reported Losses or Expenses (Fiscal Years 2010 – 2023), Health Resources and Services Administration, Apr. 2023, https://www.hrsa.gov/cicp/cicp-data/table-5.

⁸ Table 4. CICP Claims Compensated (Fiscal Years 2010 – 2023), Health Resources and Services Administration, Apr. 2023, https://www.hrsa.gov/cicp/cicp-data/table-4.

⁹ Table 3. CICP Claims Pending Compensation, Health Resources and Services Administration, Apr. 2023, https://www.hrsa.gov/cicp/cicp-data/table-3.

Number	Alleged Countermeasure	Alleged Injury
10	COVID-19 Vaccine	Myocarditis and Pericarditis
11	COVID-19 Vaccine	Pericarditis
12	COVID-19 Vaccine	Myopericarditis
13	COVID-19 Vaccine	Angioedema
14	COVID-19 Vaccine	Myocarditis
15	COVID-19 Vaccine	Myopericarditis
16	COVID-19 Vaccine	Myocarditis
17	COVID-19 Vaccine	Myopericarditis
18	COVID-19 Vaccine	Myopericarditis
19	COVID-19 Vaccine	Myocarditis

While HRSA publicly lists alleged COVID-19 vaccine injuries, it apparently does not aggregate its data by specific manufacturer.¹⁰ In order to better understand HRSA's review process for CICP claims, please provide the following information:

- 1. How would an individual know to file a CICP claim if they believe they were injured from a COVID-19 vaccine? Has HRSA conducted an advertising campaign about the CICP? If not, why not?
- 2. It is surprising to see such a low number of COVID-19 vaccine CICP claims because according to the Vaccine Adverse Event Reporting System, as of March 31, 2023, there have been 1,541,275 adverse events and 35,048 deaths associated with the COVID-19 vaccines.¹¹ Does HRSA expect an increase in COVID-19 vaccine CICP claims?
- 3. What criteria is necessary for an individual to receive CICP compensation for a COVID-19 vaccine injury?
- 4. Is there a cap on the amount of money an individual can receive as compensation?
- 5. How many HRSA or contracted employees review CICP claims?

¹¹ See VAERS database query: United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 3/31/2023, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers html on Apr 12, 2023 3:23:49 PM. Query criteria – Vaccine Products: COVID-19 Vaccine (COVID19); COVID-19-2 (COVID-192). Group By: Month Received. State/Territory: All locations. Event Category: All Events. Show Totals: True. Show Zero Values: False; VAERS database query: United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 3/31/2023, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Apr 12, 2023 3:28:50 PM. Query criteria – Vaccine Products: COVID-19 Vaccine (COVID19); COVID-19-2 (COVID-19. Group By: Month Received. State/Territory: All locations. Event Category: By: Month Received. State/Territory: All locations. Event Category: Death. Show Totals: True. Show Zero Values: False.

¹⁰ Countermeasures Injury Compensation Program (CICP) Data, Health Resources and Services Administration, Apr. 2023, https://www.hrsa.gov/cicp/cicp-data.

- 6. Provide all records¹² referring or relating to COVID-19 vaccine CICP claims, between and among HHS employees or representatives and employees or representatives of COVID-19 vaccine manufacturers, including but not limited to Pfizer, BioNTech, Moderna, and Johnson & Johnson.
- 7. Why does the CICP "not maintain its aggregated data concerning alleged countermeasures, including vaccines, by a specific manufacturer"?¹³
- 8. Does the CICP collect data on vaccine lot numbers associated with filed claims? If so, please provide the vaccine lot numbers for the 19 COVID-19 vaccine CICP claims listed above.
- 9. As of April 1, 2023, HRSA reported that there are 18 CICP claims related to COVID-19 vaccines that are "pending compensation."¹⁴ However, HRSA displayed 19 COVID-19 vaccine claims that are "eligible for compensation and the program is either waiting for documentation from the requester to determine benefits or benefits determination is in progress."¹⁵ Please clarify the difference in the reported number of CICP claims.
- 10. When did HRSA receive its first CICP claim regarding an alleged COVID-19 vaccine injury? When did HRSA receive its first CICP claim regarding an alleged COVID-19 vaccine death?
- 11. Of the three COVID-19 vaccine CICP claims that have received compensation as of April 2023, please provide the dates for when each claim was filed and the requested amount of compensation for each claim.¹⁶

Please provide this information as soon as possible but no later than May 4, 2023. Thank you for your attention to this matter.

Sincerely,

Ron Johnson Ranking Member Permanent Subcommittee on Investigations

¹² "Records" include any written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (emails, email attachments, and any other electronically-created or stored information), calendar entries, inter-office communications, meeting minutes, phone/voice mail or recordings/records of verbal communications, and drafts (whether or not they resulted in final documents).

¹³ Countermeasures Injury Compensation Program (CICP) Data, Health Resources and Services Administration, Apr. 2023, https://www.hrsa.gov/cicp/cicp-data.

¹⁴ Id.

¹⁵ Table 3. CICP Claims Pending Compensation, Health Resources and Services Administration, Apr. 2023, https://www.hrsa.gov/cicp/cicp-data/table-3.

¹⁶ Table 4. CICP Claims Compensated (Fiscal Years 2010 – 2023), Health Resources and Services Administration, Apr. 2023, https://www.hrsa.gov/cicp/cicp-data/table-4.

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cc: The Honorable Richard Blumenthal Chairman Permanent Subcommittee on Investigations

> The Honorable Christi A. Grimm Inspector General Department of Health and Human Services