United States Senate

WASHINGTON, DC 20510

June 28, 2021

Rochelle Walensky, MD, MPH
Director
Center for Disease Control and Prevention
395 E St., SW
Washington, DC 20024

Janet Woodcock, MD
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Director Walensky and Acting Commissioner Woodcock,

It has come to our attention that several hundred individuals in the United States have experienced life-altering injuries after receiving COVID-19 vaccines.[1] These injuries include severely painful paresthesia focused on the face, tongue and scalp, heart issues, brain fog, mental status changes, and even paralysis of the lower extremities. For many of these individuals, these illnesses have been present for more than five months. We are enclosing a letter these individuals sent to the Centers for Disease Control (CDC) on May 24, 2021, describing the suffering they have experienced. We ask that you keep the contents of the enclosed letter confidential.

The very existence of these infirmities is financially, physically, and emotionally debilitating for the afflicted individuals and their families. These individuals have previously expressed to both CDC Director Walensky and Food and Drug Administration Acting Commissioner Woodcock that they desire answers and assistance. Thus far, their requests have been ignored or gone without a substantive response.

The widespread lack of acknowledgement of adverse events following receipt of a COVID-19 vaccination has made it nearly impossible for some of these individuals to obtain the medical treatment they need. If any of the COVID-19 vaccines truly cause adverse events of the severity noted above, even in a small percentage of cases, these risks must be disclosed, particularly to the medical community so that healthcare professionals are properly informed and may provide necessary treatment, care, and information to the general public as they weigh the risks and benefits of being vaccinated.

[1] Pfizer, Modern, Janssen, and Astra Zeneca.

In support of those who are experiencing severe and life-altering injuries after receipt of a Covid-19 vaccine, we ask that you respond to their personal inquiries with the CDC and expediently provide an answer, no later than July 12, 2021 to the following questions. The health and safety of the injured may depend upon the contents of your response.

1. On page 38 of the FDA's Emergency Use Authorization (EUA) Memorandum for the Pfizer vaccine, it is noted that 1,158 individuals experienced an unsolicited adverse event after receipt of the Pfizer vaccine that resulted in a nervous system disorder. Of those, 185 individuals experienced a disorder not classified as a "headache."[2] ***What specific nervous system disorders were experienced by those 185 individuals?***
2. On page 42 of the FDA's EUA Memorandum for the Moderna vaccine, it is noted that 651 individuals experienced an unsolicited adverse event after receipt of the Moderna vaccine that resulted in a nervous system disorder. Of those, 197 individuals experienced a disorder not classified as a "headache."[3] ***What specific nervous system disorders were experienced by those 197 individuals?***
3. On page 45 of the FDA's EUA Memorandum for the Janssen vaccine, it is noted that 101 individuals experienced an unsolicited adverse event after receipt of the Janssen vaccine that resulted in a nervous system disorder. Of those, 28 individuals experienced a disorder not classified as a "headache."[4] ***What specific nervous system disorders were experienced by those 28 individuals?***
4. The European Medical Association has publicized potential risks associated with the Astra Zeneca COVID-19 vaccine that include "nervous system disorders, including immune-mediated neurological conditions."[5] ***During the FDA Clinical Trials of the Astra Zeneca Covid-19 vaccine, did any trial participants who were provided the vaccine experience nervous system disorders, including immune-mediated neurological conditions? If so, how many individuals experienced these disorders and what were the specific details surrounding these disorders and conditions?***
5. ***Is the CDC working with physicians and researchers at the FDA, NIH, or other medical research bodies to provide the various individuals, who experienced adverse effects from the receipt of a COVID-19 vaccine, treatment and care? If not, why? If yes, how can patients find and access assistance from these medical physicians and researchers?***
6. ***Is the CDC working with the broader medical community involved in the vaccination of Americans to ensure they are aware of symptoms associated with the unsolicited adverse events (UAES) of COVID-19 vaccines and know how to properly treat these patients and report these events to the CDC?***

We look forward to your response.

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[2] https://www.fda.gov/media/144416/download
[3] https://www.fda.gov/media/144673/download
[4] https://www.fda.gov/media/146338/download
[5] https://www.ema.europa.eu/en/documents/assessment-report/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-public-assessment-report_en.pdf

Sincerely,

Michael S. Lee
United States Senator

Ron Johnson
United States Senator