United States Senate
WASHINGTON, DC 20510

July 1, 2021

Stéphane Bancel
Chief Executive Officer
Moderna, Inc.
200 Technology Square
Cambridge, MA 02139

Dear Mr. Bancel:

On June 28, 2021, I held a press conference in Milwaukee with individuals from across the country who shared their experiences regarding significant neurological adverse events occurring shortly after receiving their COVID-19 vaccines.[1] A common part of all their stories involved the refusal or reluctance of doctors to acknowledge that their symptoms may be related to their vaccination. Because they all struggled for months with serious health issues and unanswered questions, they began seeking answers via the internet. They found out they were not alone. To date, over 4,000 people with similar health issues following vaccination have banded together on Facebook to share their experiences. Their goal is to be seen, heard, and believed so that they can obtain effective treatment and that others might avoid similar injury.

I write to request information and data on these adverse events and the steps your company has taken to assist individuals who have reported experiencing serious adverse events following receipt of the COVID-19 vaccine. I have personally met or spoken to three individuals that volunteered for clinical trials and experienced adverse events after vaccination. These people are national heroes who subjected themselves to risk for the benefit of us all. Now, they all feel abandoned by the drug companies, federal health agencies, the medical establishment, and the public who refuse to acknowledge their suffering or even consider their vaccinations might be the cause.

One of the trial participants received mRNA-1273 Moderna, Inc. vaccinations on August 26 and September 28, 2020 at the Coastal Carolina Research Center. The vaccines were from lots # 700632001 and 7006632004, respectively. She was told to report any adverse events to Coastal Carolina Research Center or Advarra Independent Review Board. In my discussions with her, it appears that neither organization took her reports seriously or provided any medical help or assistance. It appears that she was ignored and forgotten. She has searched Moderna's

[1] *See generally* Press Conference: Senator Ron Johnson, People Who Want to Be Seen, Heard and Believed by the Medical Community, June 28, 2021, available at https://rumble.com/vj5xbf-senator-ron-johnson-milwaukee-news-conference html.

Emergency Use Authorization (EUA) submission, and does not believe her adverse event was included.

Moderna's EUA memorandum contained the results of the early clinical trials, including the prevalence of certain adverse events following vaccination.[2] Among the adverse events categories included are nervous system disorders, vascular disorders, and musculoskeletal and connective tissue disorders.[3] These adverse event categories appear to be consistent with some of the experiences of the individuals and families who spoke at the June 28th press conference.[4]

We all want the pandemic to be over. Operation Warp Speed and your company's success in producing a generally safe and effective vaccine have played a key role in ending it. But just because a vaccine is generally safe, does not mean it is 100 percent safe. The small percentage of people experiencing serious adverse events deserve to be taken seriously and their health issues thoroughly researched and addressed. In order to better understand how Moderna identifies and addresses adverse events associated with Moderna's mRNA COVID-19 vaccine, I ask that you provide the following information, by no later than July 15, 2021 at 5:00pm.

1. The EUA also requires manufacturers of COVID-19 vaccines to report serious adverse events, such as death or substantial disruption to the ability to conduct normal life functions.[5] Please provide a list of all adverse events that Moderna has reported since approval of the EUA;

2. Please provide an explanation of what actions Moderna has taken to assist individuals who have reported serious adverse events following vaccination either during Moderna's clinical trials or following approval of the EUA;

3. The FDA memorandum on Moderna's EUA submission indicates that at least 4.1 percent of individuals who received the vaccine during Moderna's clinical trials reported "nervous system disorders."[6] Please provide a list of all adverse events Moderna included in the "nervous system disorder" category;

4. Please provide a list of all adverse events categorized as "nervous system disorders" reported to or by Moderna since approval of the EUA, including the specific adverse event reported and the frequency of each adverse event;

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[2] Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum: Moderna COVID-19 Vaccine EUA FDA Review Memorandum, Dec. 18, 2020, available at https://www.fda.gov/media/144673/download.

[3] *Id.* at p. 42.

[4] *See generally* Press Conference: Senator Ron Johnson, People Who Want to Be Seen, Heard and Believed by the Medical Community, June 28, 2021, available at https://rumble.com/vj5xbf-senator-ron-johnson-milwaukee-news-conference html.

[5] *See e.g.* Letter from Denise M. Hinton, Chief Scientist, Food and Drug Administration, to Carlota Vinals, ModernaTX, Inc. re Moderna COVID-19 Vaccine EUA Letter of Authorization, page 6, Feb. 25, 2021.

[6] Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum: Moderna COVID-19 Vaccine EUA FDA Review Memorandum, at p. 42 Dec. 18, 2020, available at https://www fda.gov/media/144673/download.

5. The FDA memorandum on Moderna's EUA submission indicates that at least 1 percent of individuals who received the vaccine during Moderna's clinical trials reported "vascular disorders."[7] Please provide a list of all adverse events Moderna included in the "vascular disorders" category;

6. Please provide a list of all adverse events categorized as "vascular disorders" reported to or by Moderna since approval of the EUA, including the specific adverse event reported and the frequency of each adverse event;

7. The FDA memorandum on Moderna's EUA submission indicates that at least 3.9 percent of individuals who received the vaccine during Moderna's clinical trials reported "musculoskeletal and connective tissue disorders."[8] Please provide a list of all adverse events Moderna included in the "musculoskeletal and connective tissue disorders" category;

8. Please provide a list of all adverse events categorized as "musculoskeletal and connective tissue disorders" reported to or by Moderna since approval of the EUA, including the specific adverse event reported and the frequency of each adverse event; and

9. Please provide a list of all adverse events and the frequency of each event reported to Moderna relating to its COVID-19 vaccine that were not otherwise identified during clinical trials.

Thank you for your attention to this matter.

Sincerely,

Ron Johnson
U.S. Senator

[7] *Id.*
[8] *Id.*