U.S. Sen. Johnson: Asks Moderna and Pfizer what steps they've taken to assist individuals who have experienced adverse events following COVID-19 vaccination

Posted on Friday, Jul 2, 2021

WASHINGTON — U.S. Sen. Ron Johnson (R-Wis.) on Thursday sent letters to Moderna and Pfizer to request information and data on adverse events and the steps their companies have taken to assist individuals who have reported experiencing serious adverse events following receipt of the COVID-19 vaccines. The sentor asked for this information no later than July 15.

"We all want the pandemic to be over," **the senator wrote**. "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."

The senator detailed specific examples from stories he's heard, including those from a press conference in Milwaukee on Monday. Since the press conference Twitter has labeled videos of personal testimony as misleading, and Facebook has censored private groups and individual posts.

"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," **continues Johnson**. "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."

The full text of the letters can be found here, here, and below.

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 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;
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

United States Senator

July 1, 2021

Albert Bourla

Chief Executive Officer

Pfizer

235 East 42nd Street

New York, NY 10017

Dear Mr. Bourla:

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.[9] 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 I met with was enrolled in the 12-15 year old Pfizer trial. In my discussions with this child and her mother, it appears that neither Pfizer nor its representatives administering the trial took their reports seriously, and except for one visit, did not provide any further medical help or direction. It appears that they were ignored and forgotten.

Pfizer-BioNTech's EUA memorandum contained the results of the early clinical trials, including the prevalence of certain adverse events following vaccination.[10] Among the adverse event categories included are nervous system disorders and

musculoskeletal and connective tissue disorders.[11] 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.[12]

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 Pfizer identifies and addresses adverse events associated with the Pfizer-BioNTech 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.[13] Please provide a list of all adverse events that Pfizer-BioNTech has reported since approval of the EUA;
2. Please provide an explanation of what actions Pfizer-BioNTech has taken to assist individuals who have reported serious adverse events following vaccination either during Pfizer-BioNTech's clinical trials or following approval of the EUA;
3. The memorandum on Pfizer-BioNTech's EUA submission indicates that at least 6.2 percent of individuals who received the vaccine during Pfizer-BioNTech's clinical trials reported "nervous system disorders."[14] Please provide a list of all adverse events Pfizer-BioNTech 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 Pfizer-BioNTech since approval of the EUA, including the specific adverse event reported and the frequency of each adverse event;
5. The memorandum on Pfizer-BioNTech's EUA submission indicates that at least 7.4 percent of individuals who received the vaccine during Pfizer-BioNTech's clinical trials reported "musculoskeletal and connective tissue disorders."[15] Please provide a list of all adverse events BioNTech included in the "musculoskeletal and connective tissue disorders" category;
6. Please provide a list of all adverse events categorized as "musculoskeletal and connective tissue disorders" reported to or by Pfizer-BioNTech since approval of the EUA, including the specific adverse event reported and the frequency of

each adverse event; and

7. Please provide a list of all adverse events and the frequency of each event reported to Pfizer-BioNTech 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

United States Senator