Dr. Peter Marks Director, CBER Food & Drug Administration 10903 New Hampshire Avenue W071-3128 Silver Spring, MD 20993-0002 Email: <u>Peter.Marks@fda.hhs.gov</u> Dr. Tom Shimabukuro COVID-19 Vaccine Task Force Centers for Disease Control and Prevention 1600 Clifton Road, NE Corporate Square, Bldg 12 Atlanta, GA 30329 Email: <u>avv6@cdc.gov</u>

September 28, 2021

Dear Dr. Marks and Dr. Shimabukuro,

As a physician, I am compelled by conscience to write this letter. I am fully vaccinated for Covid-19, but my experience this year treating patients in a busy ICU does not comport with claims made by federal health authorities regarding the safety of Covid-19 vaccines.

I am a licensed physician practicing in the state of California. I obtained my medical degree from University of Southern California and received my post-graduate training at Georgetown University and Harvard-affiliated hospitals. I have been a doctor for more than twenty years and I have never witnessed so many vaccine-related injuries until this year. As a fully vaccinated physician, I feel pained in admitting this. But I am compelled by conscience to state the facts as I observe them on the frontlines.

The following are a few illustrative examples of Covid-19 vaccine related injuries I have observed firsthand. While causation is difficult to prove definitively, it is my clinical judgment that each of these injuries were caused by a Covid-19 vaccine, because there was no other plausible explanation for these injuries other than the fact that the patients had recently been vaccinated. I had a direct doctor-patient relationship for each of the patient accounts below and have removed all personal identifiable information. To further assure patient anonymity, certain medical but inconsequential details have been withheld or changed to ensure the absence of any PII.

- 1. An otherwise healthy patient under age 40 developed low back pain and had an episode of urinary incontinence after receiving a Covid-19 vaccine. The day after the second dose, the patient felt numbness and tingling down one leg. The symptoms rapidly progressed such that a few days later, patient was admitted to the hospital for bilateral leg paralysis. MRI showed transverse myelitis. Weekly follow-up imaging showed that the process continued to worsen and ascend, despite maximal medical therapy. Eventually patient became quadriplegic, blind and had a tracheostomy placed. Patient developed autonomic dysfunction (irregular heart rate and hypotension) and became cognitively impaired.
- 2. A generally healthy patient in the early seventies, with no smoking history or prior lung disease, received a Covid-19 vaccine and developed generalized malaise with a poor appetite and a new cough. According to the spouse, patient lost >15 lbs during this time period. The cough worsened over the course of the next month and the patient was hospitalized. CT scan of the chest showed bilateral diffuse ground-glass opacities, typical of COVID pneumonia. However, patient was

COVID negative on repeated testing. Patient clinically deteriorated and required intubation. Bronchoscopy with alveolar lavage was positive for Pneumocystis Pneumonia, a rare opportunistic infection which typically only afflicts the severely immunosuppressed such as AIDS or transplant patients. Patient developed multi organ system failure.

- 3. A generally healthy patient in the early seventies received a Covid-19 vaccine. Subsequently patient developed vague GI complaints and was diagnosed with Cytomegalovirus colitis, which was refractory to outpatient therapy. Over the next several weeks, patient was repeatedly admitted to hospital for inpatient treatment. Despite maximal medical therapy, patient developed disseminated CMV and CMV viremia, usually seen only in immunocompromised patients.
- 4. Two women in their early fifties presented to the hospital after developing acute abdominal catastrophes. Both families reported that the women had developed vague GI complaints shortly following their Covid-19 vaccine, which then progressed to acute surgical abdomen on the day of admission. Both women were taken to the OR for exploration, where multiple segments of infarcted bowel were resected. As the ischemic and thrombotic process appeared to be on-going, both patients had to have their abdomens left open in the next several days for frequent re-exploration and repeat resections, totaling more than five exploratory laparotomies each. Neither woman had a smoking history. Neither woman had any condition predisposing them to hypercoagulable state. All their work-ups were negative.
- 5. A man in his early sixties received the Covid-19 vaccine and developed dizziness which worsened over time. He had no smoking history and was otherwise healthy. On the day of hospital admission, patient experienced sudden neurologic deterioration and required intubation for airway protection. Imaging studies of the head showed cerebral venous sinus thrombosis. CVST is a very rare type of stroke, estimated by Johns Hopkins to occur 5 per million per year, with a female to male ratio of 3:1. Over 85% of the patients had at least one identifiable risk factor, such as prothrombotic state, use of oral contraceptives, malignancy or infection. My patient had zero risk factors, other than the fact that he had been vaccinated against Covid-19.
- 6. In my ICU, I have observed a recent increase in obstetric complications. In general, obstetric patients needing ICU care are rare. In a typical year, I would take care of 1-2 such patients. In the last two months alone, I have cared for at least four such patients, two with post-partum hemorrhagic shock and two with septic shock secondary to chorioamnionitis following pre-term labor. All were vaccinated.

Approximately half of the patients detailed above died. Those who survived are struggling with long-term sequelae and a diminished quality of life.

I understand that the foregoing report reflects the experience of a single physician. However, it appears statistically improbable that any one physician should witness this many Covid-19 vaccine injuries if the federal health authority claims regarding Covid-19 vaccine safety were accurate. I have spoken with colleagues who have also had similar experiences in treating patients. While some seem willing to accept these vaccine injuries as unavoidable collateral damage in a mass vaccination program, many do express dismay. None of them would speak publicly about their experience, with the former not wanting to fuel vaccine hesitancy and the latter fearing potential backlash.

Hence, I am writing this letter to share my experience. I can no longer silently accept the serious harm being caused by the Covid-19 vaccines. It is my sincere hope that the reaction to this letter will not be to focus on me, but rather to focus on addressing the serious safety issues with these products that, without doubt, you have either missed or are choosing to ignore.

On a related note, I work with a number of frontline workers that have seen these harms firsthand. They courageously worked through the pandemic and some have already had Covid-19. Many of them have not received the Covid-19 vaccines and these excellent healthcare workers are desperately needed at my hospital but yet plan to quit or be fired rather than be mandated to receive this Covid-19 vaccine. I cannot afford to lose these members of my team. Furthermore, in light of the foregoing, it is unethical to have a blanket Covid-19 vaccine mandate without regards to each individual's medical risk-benefit profile. Therefore, I implore you to lift the federal Covid-19 vaccine mandate and encourage the state of California to do the same. We must return to the practice of obtaining informed consent, born out of a private discussion between a doctor and a patient, without third-party intrusion.

Lasty, on behalf of the patients and their families who have suffered so much at the hands of this vaccine, and on behalf of my frontline healthcare colleagues who have born witness to these indescribable sufferings, I respectfully request that you at least recognize their pain and injury. Denying them the truth of their experience only adds deep insult to their injury.

Thank you for taking the time to read this letter and it is my sincere hope that it results in positive change. I can be reached at the other serious Covid-19 vaccine injuries in patients I have directly treated but have not detailed in this letter.

Sincerely,

Patricia Lee, MD