

VIA FEDERAL EXPRESS and EMAIL

November 9, 2022

Vice Admiral Vivek H. Murthy, MD, MBA
Office of the Surgeon General
U.S. Department of Health and Human Services
200 Independence Ave SW
Humphrey Bldg. Suite 701H
Washington, D.C. 20201

Re: COVID-19 Vaccination Exemption for Breastfeeding Mothers

Dear Vice Admiral Murthy:

It has come to the attention of the undersigned attorneys, service members and veterans that the Department of Defense (DOD) is placing newborn infants at risk by requiring COVID-19 vaccination of breastfeeding military mothers. While DOD recognizes that vaccination is contraindicated for pregnancy, it does not recognize the risk posed to nursing infants from maternal vaccination. Yet the official website for the Military Health System clearly states:

"When health professionals recommend vaccinations during pregnancy, they must weigh the risks versus benefits to both the mother and baby, **before and after delivery.** These decisions may vary based on vaccine type, vaccine safety profile, and risk of the disease." (Emphasis added.)

Recognizing that COVID-19 vaccines currently used were not tested, authorized or approved for lactating or breastfeeding mothers,² we urge DOD to immediately reconsider its policy and respectfully request that all branches allow breastfeeding military mothers to receive a

¹ "Vaccines During Pregnancy and Breastfeeding," Health mil, accessed September 27, 2022.

² "5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received through 28-Feb-2021," Pfizer, April 30, 2021, p 9.

temporary medical exemption from COVID-19 vaccination for at least one year after an infant's birth.

In Dec. 2020, given the unknown mortality and morbidity rates of COVID-19 and the promise that COVID-19 vaccines were 95-100% effective, perhaps a compulsory policy seemed justified. However, based on the science that has accumulated over the past 28 months, we now know that COVID-19 vaccines neither stop infection nor transmission of SARS-CoV-2.^{3,4,5,6}

The Centers for Disease Control and Prevention (CDC) has acknowledged that people who have been vaccinated may contract and spread COVID-19 to others and has stated: "[v]accine breakthrough infections are expected" (emphasis added). In other words, any impression that vaccinated individuals, including pregnant and breastfeeding mothers, cannot get and spread the virus is false. Moreover, over time, COVID-19 vaccination appears to increase the risk of contracting other variants.^{8,9}

In fact, one of the largest (more than 123,000 subjects) and longest (6 months) studies published by a collaboration of researchers from Kaiser Permanente — one of the largest integrated managed health care consortiums in the U.S. and pharmaceutical giant Moderna, shows vaccine efficacy (VE) against the currently circulating Omicron sub-variants (BA.4 and BA.5) **dropped significantly** 14 to 30 days after receiving the vaccine. Looking at the left side of the chart on page 30 of the reference, the VE continues to fall in the following months, and then reaches **negative territory** after five months, suggesting that **the recipient is more likely to get COVID-19 than if he or she had not been vaccinated**. The right side of the same chart shows that if you get three COVID-19 vaccinations versus two, **you are more likely to contract COVID-19**. Not only did scientists from Moderna participate in the study, this study was **funded** by Moderna, and "... employees of Moderna participated in the design and conduct of the study ..." employees of Moderna participated in the design and conduct of the study ..."

In medicine, it is important to weigh the risks of an intervention versus the benefits. This study suggests that while the benefit of this intervention (vaccination) is minimal or **completely absent** against the currently circulating variants of the COVID-19 virus, other studies have clearly

³ "Dr. Deborah Birx says she 'knew' COVID vaccines would not 'protect against infection'," Fox News, accessed September 27, 2022.

⁴ "Fauci admits that COVID-19 vaccines do not protect 'overly well' against infection," Fox News, accessed September 27, 2022.

⁵"COVID-19 after Vaccination: Possible Breakthrough Infection," CDC, updated June 23, 2022.

⁶ Hung Fu Tseng et al., "Effectiveness of mRNA-1273 against infection and COVID-19 hospitalization with SARS-CoV-2 Omicron subvariants: BA.1, BA.2, BA.2.12.1, BA.4, and BA.5," *medRxiv*, October 1, 2022, doi: 10.1101/2022.09.30.22280573.

⁷ "The Possibility of COVID-19 after Vaccination: Breakthrough Infections," CDC, updated December 17, 2021.

⁸ David Rosenberg, "Natural infection vs vaccination: Which gives more protection? Nearly 40% of new COVID patients were vaccinated - compared to just 1% who had been infected previously," *Israel National News*, July 13, 2021.

vaccinated - compared to just 1% who had been infected previously," *Israel National News*, July 13, 2021.

9 Hung Fu Tseng et al., "Effectiveness of mRNA-1273 against infection and COVID-19 hospitalization with SARS-CoV-2 Omicron subvariants: BA.1, BA.2, BA.2.12.1, BA.4, and BA.5," *medRxiv*, October 1, 2022, p 30, doi: 10.1101/2022.09.30.22280573

documented the risk — not only to pregnant and breastfeeding mothers — but also young healthy athletes and people of all ages.¹¹

We do know that COVID-19 vaccines can and do cause serious injury and even death. ^{12,13,14,15,16} The CDC's Vaccine Adverse Events Reporting System (VAERS) has compiled an unprecedented number of serious adverse events that include anaphylaxis, paralysis, neurological damage, myocarditis, pericarditis, blood clots, Guillain-Barré syndrome, Bell's Palsy, miscarriages and death. ¹⁷

While U.S. public health officials have touted the "safety and efficacy" of COVID-19 vaccines for pregnant and breastfeeding mothers, they were excluded from pre-authorization clinical trials, and the limited data collected during pregnancy showed alarming abnormalities to the developing fetus as well as severe adverse pregnancy outcomes, including nearly 14% of pregnancy losses.¹⁸

Existing scientific research strongly suggests that vaccination during pregnancy and while breastfeeding is contraindicated.

Although no study has been conducted to date that detects the presence of SARS-CoV-2 spike protein in breast milk, there is significant evidence to conclude that a breastfeeding mother passes nutrients as well as toxins to her baby.¹⁹ New research indicates that the spike protein can and does travel from the COVID-19 injection site to circulate throughout the body, accumulating in various tissues and organs.^{20,21} Pfizer's own documents show that the lipid nanoparticles (LNPs) distribute throughout the body at different rates, with the ovaries experiencing a 118-fold increase in the concentration of LNPs from the time of vaccine injection to 48 hours.²² Evidence strongly suggests this process of dispersion is not harmless. The spike protein is a pathogenic protein toxic to humans and can cause significant damage as it saturates body tissues and

¹¹ Ibid.

¹² "From the 10/21/2022 release of VAERS data: Found 1,447,520 cases where Vaccine is COVID19 or COVID19-2," *MedAlerts/VAERS*.

¹³ Eun Ju Lee et al., "Thrombocytopenia following Pfizer and Moderna SARS-CoV-2 vaccination," *American Journal of Hematology*, 96, no. 5 (2021): 534–537, doi: 10.1002/aih.26132.

¹⁴ CDC, "Myocarditis and Pericarditis After mRNA COVID-19 Vaccination," Updated September 27, 2022.

¹⁵ Julianne Gee et al., "First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020–January 13, 2021," CDC, February 26, 2021.

¹⁶ Ke'ala Akau, "Sex and Gender and COVID-19 Vaccine Side Effects," Yale School of Medicine, April 5, 2021.

^{17 &}quot;VAERS COVID Vaccine Adverse Event Reports," OpenVAERS, updated September 16, 2022.

¹⁸ Tom T. Shimabukuro, MD et al, "Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons," *New England Journal of Medicine* 384, no. 24 (2021), doi: 10.1056/NEJMoa2104983.

¹⁹ L.A. Hanson et al., "The Transfer of Immunity from Mother to Child," *Annals of the New York Academy of Sciences* 987, no. 1 (2003): 199-206, April 2003, doi: 10.1111/j.1749-6632.2003.tb06049 x.

²⁰ Alana F. Ogata et al., "Circulating Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccine Antigen Detected in the Plasma of mRNA-1273 Vaccine Recipients," *Clinical Infectious Diseases* 74, no. 4 (2022): 715–718, doi: 10.1093/cid/cjab465.

²¹ Pfizer, "SARS-COV-2 mRNA Vaccine (BNT162, PF-07302048) 2.6.4 Overview of Pharmacokinetic Test," FOIA-Byram Bridle, PhD, (2021), p 5.

²² Ibid., p 7, PDF p 17.

organs.²³ Further, the spike protein crosses the blood-brain barrier and can cause damage to the brain, including impaired consciousness, nerve pain, blurred vision, cerebral hemorrhage, seizures, blood clots and stroke.²⁴ Until further studies are done, forcing vaccination on breastfeeding mothers puts the health of infants at risk.

The New England Journal of Medicine (NEJM) in June 2021 published an article titled, "Preliminary Findings of mRNA COVID-19 Vaccine Safety in Pregnant Persons," which illustrated insufficient evidence concerning the "safety and efficacy" of COVID-19 vaccines in pregnant and breastfeeding mothers.²⁵

Table 6 of Pfizer's "Cumulative Analysis of Post-Authorization Adverse Event Reports" outlines a series of adverse events occurring in the infant exposed to the COVID-19 vaccine via breastfeeding: "Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each)."²⁶

Similarly, in November 2020, the Australian Government Department of Health Therapeutic Goods Administration (TGA) decided to recommend against COVID-19 vaccines for use during pregnancy or breastfeeding due to insufficient data and lack of long-term safety studies. The research leading to their conclusion also noted data limitations, missing information, as well as safety concerns.²⁷

Furthermore, in December 2020, the UK Medicines and Healthcare Products Regulatory Agency (MHRA), similar to the U.S. Food and Drug Administration (FDA), issued the following warning to all healthcare professionals regarding the Pfizer vaccine:

"COVID-19 mRNA Vaccine BNT162b2 is not recommended during pregnancy."

²³ Patrick Whelan, MD, PhD, "<u>RE: Notice of Meeting: Establishment of a Public Docket: Request for Comments related to consideration of vaccines against SARS-CoV-2</u>," Letter to U.S. Food and Drug Administration Vaccines and Related Biological Products Advisory Committee: December 8, 2020.

²⁴ E.M. Rhea et al., "The S1 protein of SARS-CoV-2 crosses the blood–brain barrier in mice," *Nat Neurosci*, 24, (2021): 368–378, doi: 10.1038/s41593-020-00771-8.

²⁵ Tom T. Shimabukuro, MD et al., "Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons," *New England Journal of Medicine* 384, no. 24 (2021), doi: 10.1056/NEFMoa2104983.

²⁶ "5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2)," Pfizer, February 28, 2021, p 12.

²⁷ TGA Health Safety Regulation, "<u>Delegate's Overview and Request for ACV's Advice</u>," Australian Department of Health, January 15, 2021, pp 11, 20, 21, & 23.

"... It is unknown whether COVID-19 mRNA Vaccine BNT162b2 is excreted in human milk. A risk to the newborns/infants cannot be excluded. COVID-19 mRNA Vaccine BNT162b2 should not be used during breast-feeding."²⁸

The UK's MHRA Summary of the Public Assessment Report for the COVID-19 Vaccine Pfizer/BioNTech states:

- "... sufficient reassurance of safe use of the vaccine in pregnant women cannot be provided at the present time: however, use in women of childbearing potential could be supported provided healthcare professionals are advised to rule out known or suspected pregnancy prior to vaccination. Women who are breastfeeding should also not be vaccinated.²⁹
- "... The Public Assessment Report summarises the initial assessment at the time of approval in December 2020. The text in the original report remains unchanged."³⁰

No adequate studies have since been done to demonstrate that vaccination with mRNA vaccines during breastfeeding is safe for babies. Despite this lack of scientific evidence of safety and even though toxicity conclusions as of August 2022 did not change, the TGA and MHRA both updated their guidance to recommend COVID-19 vaccines for breastfeeding mothers.

Lastly, a new study just published on Sept. 26, 2022, detected messenger RNA (mRNA) from COVID-19 vaccines in human breast milk and these researchers expressed that "caution is warranted about breastfeeding children younger than 6 months in the first 48 hours after maternal vaccination until more safety studies are conducted." While the study surprisingly concluded that COVID-19 vaccination is safe for breastfeeding mothers, its authors cited several limitations including the small sample size of just 11 mothers and "... the potential interference of COVID-19 vaccine mRNA with the immune response to multiple routine vaccines given to infants during the first 6 months of age needs to be considered. It is critical that lactating individuals be included in future vaccination trials to better evaluate the effect of mRNA vaccines on lactation outcomes." ³²

This data (or lack thereof) has driven many pregnant and breastfeeding military women to have legitimate safety concerns regarding COVID-19 vaccines. Mounting VAERS reports confirming adverse reactions in breastfeeding infants after maternal vaccination reinforce these well-founded

²⁸ Medicines and Healthcare Products Regulatory Agency, "<u>Decision Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 Vaccine–REG 174 Information for UK Healthcare Professionals</u>," GOV.UK, updated December 16, 2020, Section 4.6 Fertility, pregnancy and lactation.

²⁹ Medicines and Healthcare Products Regulatory Agency, "<u>Summary of the Public Assessment Report of COVID-19 Vaccine Pfizer/BioNTech</u>," GOV.UK, updated August 16, 2022, Section 3.4 Toxicity conclusions.
³⁰ Third

³¹ Nazeeh Hanna, MD et al., "Detection of Messenger RNA COVID-19 Vaccines in Human Breast Milk," *JAMA Pediatrics*, September 26, 2022, doi: 10.1001/jamapediatrics.2022.3581.

concerns. As of Oct. 7, 2022, there were 657 reports with **one death** registered in the VAERS system on babies who suffered adverse events after being exposed to COVID-19 vaccines through breastfeeding. 33,34

The most common serious events among breast-fed infants whose mothers had received the COVID-19 vaccine were: life-threatening bleeding; anticholinergic syndrome; liver problems; anaphylactic shock; neuroleptic syndrome; neurological side-effects such as convulsions or encephalitis and hypoglycemia. In most of the reported cases, several life-threatening side effects were recorded in the same baby.³⁵

Therefore, breastfeeding mothers should be able to weigh the potential risks of a COVID-19 vaccine against the potential benefits for themselves and their infants.

While DOD states "no immunization products are medically contraindicated in breastfeeding women."³⁶ it also states that due to the lack of COVID-19 vaccination testing, pregnant mothers may request a temporary medical exemption from COVID-19 vaccination.³⁷ Under current DOD policy, breastfeeding military service mothers are not entitled to these same exemptions, but precisely the same lack of testing applies to them.

Both pregnant and breastfeeding women directly contribute to the health and normal development of their babies through what they ingest, breathe and inject into their bodies. Therefore, breastfeeding military mothers should have the same exemption rights as pregnant military service members.

For all the reasons set forth above, we strongly urge DOD to reconsider its policy and grant a temporary medical exemption to any breastfeeding mother who requests it.

Since CDC has recently reversed restrictive COVID-19 guidelines stating "there is significantly less risk of severe illness, hospitalization and death compared to earlier in the pandemic" and has also streamlined its "guidance to help people better understand their risk, [and] how to protect themselves and others ..." it is only fitting that DOD recognizes the change in illness risk, and allow for its breastfeeding service members to assess their personal risk and necessary level of protection.38

³³ Ranit Feinberg, "648 cases of side effects were reported to the VAERS system on breastfed infants whose mothers received the Covid-19 vaccine," Real Time News, accessed September 28, 2022.

³⁴ "From the 9/23/2002 Release of VAERS Data: The is VAERS ID 1166062," MedAlerts/VAERS.

³⁵ Ranit Feinberg, "648 cases of side effects were reported to the VAERS system on breastfed infants whose mothers received the Covid-19 vaccine," Real Time News, accessed September 28, 2022.

³⁶ AFI 48-110, "Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases," last revised February 16, 2018, section 2-5.c. p 5. PDF p 11.

³⁷ Ibid, 2-6.a.(1)(a), p 6, PDF p 12.

^{38 &}quot;CDC Streamlines COVID-19 Guidance to Help the Public Better Protect Themselves and Understand Their Risk," CDC Newsroom, August 11, 2022.

Thank you for your careful consideration.

Sincerely yours,

Robert F. Kennedy, Jr., Esq.

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Chairman and Founder,

Children's Health Defense

Mary Holland, Esq.

President and General Counsel,

Children's Health Defense

Jaclyn Frederick, Lieutenant Colonel

United States Air Force

Steven Petrosino, Ph.D., Lieutenant Colonel

United States Marine Corps Retired

Melissa Kalas, Major

United States Air Force Reserves

Candace White, Major

United States Marine Corps



Catherine LH Cochran, Major NC Army National Guard



Emilee D. Senn, Captain United States Air Force



Zachary B. Senn, Captain United States Air Force



Devon Rousseau, 1st Lieutenant United States Air Force

Fachly

Rachel Arp, Petty Officer 1st Class (PO1) United States Navy



May Anderson, Master Sergeant (MSG)
United States Army

Con S

Crystal Stueve, Staff Sergeant (SSG)

United States Army

Zachary Wisdom, Senior Airmen United States Air Force