EMPLOYEE CONCERNS ABOUT COVID VACCINES

For informational purposes only.

The purpose of this document is to engage in fact-based discussion with your employer should vaccine mandates be considered to gain or retain employment. Everything is sourced from .gov websites.

THE CDC DOES NOT KNOW IF IT WILL EVER RECOMMEND

stopping mask usage and avoiding close contact with others even after vaccination.



There is not enough information currently available to say if or when CDC will stop recommending that people <u>wear masks</u> and <u>avoid close contact with others</u> to help prevent the spread of the virus that causes COVID-19. Experts need to understand more about the protection that COVID-19 vaccines provide before making that decision. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.

Do I need to wear a mask when I receive a COVID-19 vaccine?

Yes. CDC recommends that during the pandemic people <u>wear a mask</u> that covers their nose and mouth when in contact with others outside your household, when in healthcare facilities, and when receiving any vaccine, including a COVID-19 vaccine. Anyone who has trouble breathing or is unable to remove a mask without assistance should not wear a mask.

Source: cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

I HAVE SEVERAL CONCERNS ABOUT PFIZER'S VACCINE

The following information is provided from Pfizer's COVID-19 Fact Sheet

Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine. The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.

According to Pfizer, the recipient has the option to accept **or refuse** its COVID-19 Vaccine.

The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.

<u>Source: fda.gov/media/144413/download</u>

I HAVE SEVERAL CONCERNS ABOUT MODERNA'S VACCINE

The following information is provided from Moderna's COVID-19 Briefing to the FDA on 17 Dec 2020

Safety in certain subpopulations

There are currently insufficient data to make conclusions about the safety of the vaccine in subpopulations such as children less than 18 years of age, pregnant and lactating individuals, and immunocompromised individuals.

FDA review of a combined developmental and perinatal/postnatal reproductive toxicity study of mRNA-1273 in female rats concluded that mRNA1273 given prior to mating and during gestation periods at dose of 100 µg did not have any effects on female reproduction, fetal/embryonal development, or postnatal developmental except for skeletal variations which are common and typically resolve postnatally without intervention

Vaccine-enhanced disease

Available data do not indicate a risk of vaccine-enhanced disease, and conversely suggest effectiveness against severe disease within the available follow-up period. However, risk of vaccine-enhanced disease over time, potentially associated with waning immunity, remains unknown and needs to be evaluated further in ongoing clinical trials and in observational studies that could be conducted following authorization and/or licensure.

Adverse reactions that are very uncommon or that require longer follow-up to be detected

Following authorization of the vaccine, use in large numbers of individuals may reveal additional, potentially less frequent and/or more serious adverse events not detected in the trial safety population of approximately 30,000 participants over the period of follow-up at this time. Active and passive safety surveillance will continue during the post-authorization period to detect new safety signals.

Moderna is expected to be granted authorization under the FDA's Emergency Use Authorization on 19–20 December 2020, however it is not an approved FDA vaccine. <u>Source: **fda**.gov/media/144434/download</u>

I HAVE SEVERAL CONCERNS ABOUT CLINICAL TRIALS

The Phase 3 Clinical Trial with the saline placebo is only 5 months into a 2 year trial.

A Study to Evaluate Efficacy, Safety, and Immunogenicity

of mRNA-1273 Vaccine in Adults Aged 18 Years and Older to Prevent COVID-19

Actual Study Start Date 1 :	July 27, 2020
Estimated Primary Completion Date 1 :	October 27, 2022
Estimated Study Completion Date 6 :	October 27, 2022

No Study Results Posted on ClinicalTrials.gov for this Study

Source: clinicaltrials.gov/ct2/show/study/NCT04470427?term=mRNA-1273-P301&draw=2&rank=1

According to the CDC, rare side effects and delayed reactions might not be evident until the vaccine is administered to millions of people.



While clinical trials provide important information on vaccine safety, the data are somewhat limited

because of the relatively small number (hundreds to thousands) of study participants. Rare side effects and delayed reactions might not be evident until the vaccine is administered to millions of people. Therefore, the federal government established the Vaccine Adverse Event Reporting System (VAERS), a surveillance system to monitor adverse events following vaccination.

<u>Source: cdc.gov/vaccinesafety/ensuringsafety/history/index.html</u>

I HAVE SEVERAL CONCERNS ABOUT INJURY COMPENSATION

The program for compensation differs than the current vaccine injury compensation program.

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the Pfizer-BioNTech COVID-19 Vaccine used to prevent COVID-19, visit www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

<u>Source: fda.gov/media/144413/download</u>

What are the differences between the Countermeasures Injury Compensation Program (CICP) and the National Vaccine Injury Compensation Program (VICP)?

You have ONE YEAR from the date you were administered or used the covered countermeasure alleged to have caused the injury to request benefits.

A countermeasure is a vaccination, medication, device, or other item recommended to diagnose, prevent or treat a declared pandemic, epidemic or security threat. On the rare chance you suffered a serious injury, or the death of a loved one, from the administration or use of a covered countermeasure, you may qualify for benefits.

Type of Injury	 Serious physical
Covered	injuries
	• Deaths

Only serious physical injuries or death are compensated under CICP.

Program Funding	Appropriated Funds
Payment of Legal Fees and Costs	Attorneys' fees and costs are not paid by the program.

If I were eligible for compensation, my attorneys' fees and costs are not covered.

Appeal Rights	One step administrative
	reconsideration possible.
	No judicial appeal
	permitted.

There is no judicial appeal permitted should my application and reconsideration be denied.

Source: hrsa.gov/cicp

AS AN EMPLOYEE, I WILL NOT CONSENT TO MANDATORY VACCINATION.

I need more clarification from the CDC, FDA, and manufacturers prior to consenting to a vaccine.