PHYSICIANS FOR INFORMED CONSENT

June 16, 2021

California Department of Industrial Relations
Occupational Safety and Health Standards Board
2520 Venture Oaks Way, Suite 350
Sacramento, CA 95833
OSHSB@dir.ca.gov

RE: Reject the proposed revisions of Cal/OSHA COVID-19 prevention requirements

Dear Board Members,

On behalf of Physicians for Informed Consent, I am writing regarding the proposed revisions of the Cal/OSHA COVID-19 prevention requirements,[1] which will be considered at your June 17, 2021, board meeting. The updated guidelines aim to treat California workers differently depending on their COVID-19 vaccination status. However, key scientific data demonstrate that discrimination is unwarranted. Before you implement a new policy for the workplace, I urge you to consider the following:

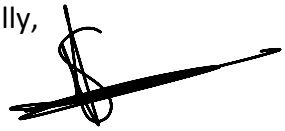
1. **There is no evidence that COVID-19 vaccines prevent the spread of SARS-CoV-2 or COVID-19. Therefore, there is no scientific justification to treat vaccinated people differently from unvaccinated people.**
   Clinical trials for the Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines were not designed to observe asymptomatic infection with SARS-CoV-2 or the effect of the vaccine on the spread (transmission) of COVID-19. Consequently, in its briefing document for each vaccine, the U.S. Food and Drug Administration (FDA) states that "it is possible that asymptomatic infections may not be prevented as effectively as symptomatic infections" and "data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination." Furthermore, "additional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection."[2-7]

2. **There is evidence that previous SARS-CoV-2 or COVID-19 infection is more effective at preventing SARS-CoV-2 or COVID-19 infection than at least one of the COVID-19 vaccines. Therefore, those previously infected with COVID-19 should have at least the same rights as those vaccinated for COVID-19.**
   The Janssen (Johnson & Johnson) COVID-19 vaccine clinical trial included over 2,000 subjects that had contracted SARS-CoV-2 before the study. The trial recorded the incidence of COVID-19 in that unvaccinated group at least 28 days after the vaccination of the other subjects in the study. The COVID-19 incidence of the unvaccinated group with prior SARS-

CoV-2 infection was 0.1% (2/2,021), whereas the COVID-19 incidence of vaccinated subjects was 0.59% (113/19,306). These data suggest that there are six times more cases of COVID-19 in vaccinated subjects than in unvaccinated subjects previously infected with SARS-CoV-2. This also means that an unvaccinated person previously infected with SARS-CoV-2 has 99.9% chance of being protected from a repeat infection.[7,8] Of note, as of April 17, 2021, there have been 165.7 million SARS-CoV-2 infections in the U.S., which is 50.2% of the U.S. population.[9]

Treating people differently depending on their COVID-19 vaccination status is not based on science. As Cal/OSHA is responsible for ensuring the safe and healthful working conditions for all workers, we urge you to reject the proposed guideline revisions and instead implement a policy that ensures all employees are treated the same, regardless of their vaccination status. We are here to assist you in these highly technical matters and welcome further discussion.

Respectfully,



Shira Miller, M.D.
Founder and President
Physicians for Informed Consent

Enclosed: Pfizer Bio-NTech COVID-19 Vaccine Risk Statement, Moderna COVID-19 Vaccine Risk Statement, Janssen (J&J) COVID-19 Vaccine Risk Statement

About Physicians for Informed Consent

Physicians for Informed Consent is a 501(c)(3) educational nonprofit organization focused on science and statistics. PIC delivers data on infectious diseases and vaccines, and unites doctors, scientists, healthcare professionals, attorneys, and families who support voluntary vaccination. In addition, the PIC Coalition for Informed Consent consists of more than 250 U.S. and international organizations. To learn more or to become a member, please visit physiciansforinformedconsent.org.

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8. U.S. Food and Drug Administration, Vaccines and Related Biological Products Advisory Committee. FDA briefing document: Janssen Ad26.COV2.S vaccine for the prevention of COVID-19. Vaccines and Related Biological Products Advisory Committee Meeting: February 26, 2021. Table 14: vaccine efficacy of first occurrence of moderate to severe/critical COVID-19, including non-centrally confirmed cases, with onset at least 14 or at least 28 days after vaccination, by baseline SARS-CoV-2 status, per protocol set; 30. https://www.fda.gov/media/146217/download.

9. **Statistical Analysis of the Frequency SARS-CoV-2 Infections in the United States**

A Stanford University systematic review that included 69 antibody studies estimated that the COVID-19 infection-fatality rate (IFR) in the United States ranges from 0.3% to 0.4%.[a] Data analysis herein uses the midpoint of that range, 0.35%. An IFR of 0.35% is also supported by an analysis published in *Clinical Infectious Diseases* that estimated that there were 44.8 million symptomatic COVID-19 illnesses in February–September 2020.[b] Additionally, since 33% of all SARS-CoV-2 infections are asymptomatic,[c] there were an estimated 66.9 million (44.8 million/[100%-33%]) total number of SARS-CoV-2 infections in that time period. There were also 213,000 COVID-19 deaths in February–September 2020,[d] resulting in a COVID-19 IFR of 0.32% (213,000/66.9 million). As of April 17, 2021, there have been about 580,000 COVID-19 deaths in the U.S.[d] As the COVID-19 IFR is about 0.35%, as of April 17, 2021 there have been about 165.7 million SARS-CoV-2 infections (580,000/0.35%), which is 50.2% of the population of the U.S. (330 million).

[a]Ioannidis, JPA. The infection fatality rate of COVID-19 inferred from seroprevalence data. Bulletin of the World Health Organization. 2020 Oct 14 [cited 2021 Apr 16]. https://www.who.int/bulletin/online_first/BLT.20.265892.pdf?ua=1.
[b]Reese H, Iuliano AD, Patel NN, Garg S, Kim L, Silk BJ, Hall AJ, Fry A, Reed C. Estimated incidence of coronavirus disease 2019 (COVID-19) illness and hospitalization—United States, February–September 2020. *Clin Infect Dis*. 2020; Nov 25;ciaa1780. https://doi.org/10.1093/cid/ciaa1780.
[c]Oran DP, Topol EJ. The proportion of SARS-CoV-2 infections that are asymptomatic: a systematic review. Ann Intern Med. 2021 May;174(5):655-62. https://doi.org/10.7326/M20-6976.
[d]Worldometer. Coronavirus: United States. https://www.worldometers.info/coronavirus/country/us/.

This vaccine has not been approved or licensed, and is still under investigation.[1]
COVID-19 – PFIZER-BIONTECH VACCINE RISK STATEMENT (VRS)

PFIZER-BIONTECH COVID-19 VACCINE:

Short-Term Efficacy & Safety Data

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1. WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 vaccine (BNT162b2) is made from synthetic genetic material that is immersed in fatty substances, including cholesterol and polyethylene glycol (PEG). More specifically, modified RNA molecules that encode for a mutated spike (S) protein antigen of the SARS-CoV-2 virus, the virus that can cause COVID-19, are immersed in lipid nanoparticles. The drug is administered in two intramuscular 30 mcg doses, 21 days apart.[1]

2. HOW WAS THE VACCINE STUDIED PRIOR TO OBTAINING EUA?

The Pfizer-BioNTech COVID-19 vaccine obtained emergency use authorization (EUA) on Dec. 11, 2020, from the U.S. Food and Drug Administration (FDA) and is currently investigational.[1] The vaccine was studied through nonclinical data from rats and nonhuman primates, and clinical data from humans. The EUA was based on a human clinical trial comparing approximately 22,000 subjects who received the vaccine with 22,000 subjects who did not receive the vaccine (Table 1).[2] The trial included a median observation period of two months; 50.6% of subjects were followed up for about two months after the second dose.[2] The FDA states that due to the length of the clinical trial's observation period, "it is not possible to assess sustained efficacy over a period longer than 2 months."[3]

3. DOES THE VACCINE PREVENT HOSPITALIZATIONS AND DEATHS?

Since only two hospitalized cases of COVID-19 were observed, the clinical trial did not have enough statistical power to measure the vaccine's ability to prevent hospitalizations from COVID-19.[3] See Table 1. The FDA states, "A larger number of individuals at high risk of COVID-19 and higher attack rates would be needed to confirm efficacy of the vaccine against mortality."[3]

4. HOW EFFECTIVE IS THE VACCINE IN ADULTS AND THE ELDERLY?

Vaccine effectiveness was calculated by observing the vaccination status of 178 COVID-19 cases, where a COVID-19 case was defined as the presence of at least one COVID-19 symptom and a positive SARS-CoV-2 test at least seven days after the second dose. In subjects 18 to 64 years old, the vaccine was 89%–98% effective over a two-month observation period.[3,4] However, since there were only 15 COVID-19 cases observed in subjects 65 to 74 years old and only five cases in subjects 75 years or older, the clinical trial did not have enough statistical power to accurately measure the vaccine's effectiveness in those age groups.[4] The vaccine may be only 53% effective in subjects 65 to 74 years old and 0% effective in subjects 75 years or older.[4]

See Table 1. Subjects 65 years or older comprise about 80% of all COVID-19 deaths, and subjects 75 years or older comprise about 60% of all COVID-19 deaths.[5]

In subjects 65 to 74 years old, the vaccine may be only 53% effective, and in subjects 75 years or older, the vaccine may be 0% effective.[4] People 65 years or older comprise about 80% of all COVID-19 deaths.[5]

5. IS THE VACCINE EFFECTIVE IN CHILDREN?

The vaccine's EUA was expanded for use in children 12 to 15 years of age on May 10, 2021, "although limited scientific information is available," per Pfizer.[6] In subjects 12 to 15 years of age, the vaccine was 75%–100% effective over a two-month observation period.[7] However, the FDA states, "There were no reports of severe COVID-19 cases."[8] As such, similar to other age groups, the ability of the vaccine to prevent hospitalizations or deaths from COVID-19 is not known. And, since there was only one case of COVID-19 in subjects 16 to 17 years old, the study did not have enough statistical power to measure effectiveness in that age group.[4] See Table 1.

SHORT-TERM EFFICACY DATA		
Enrolled subjects	**Efficacy, approx. 2-month observation period (95% confidence interval)**	
Confirmed COVID-19 hospitalizations[3]	NA*	?
Confirmed COVID-19 (age 18–64)[4]	89%–98%	✓
Confirmed COVID-19 (age 65–74)[4]	53%–100%	?
Confirmed COVID-19 (age 75 or older)[4]	-12%–100%	?
Confirmed COVID-19 (age 16-17)[4]	-3,970%–100%	?
Confirmed COVID-19 (age 12–15)[7]	75%–100%	✓
Asymptomatic SARS-CoV-2 infection[3]	NA*	✗
SARS-CoV-2 spread (transmission)[3]	NA*	✗
SHORT-TERM SAFETY DATA		
Severe adverse events (age 16 or older)[2]	2x risk in vaccine group	⚠
Severe adverse events (age 12–15)[11,12]	6x risk in vaccine group	⚠
Pregnant/breastfeeding[8]	NA*	?
Immunocompromised[8]	NA*	?
Children younger than 12[3]	NA*	✗

Not tested ✗ | Insufficient data to prove efficacy or safety ? | Evidence of short-term benefit ✓ | Evidence of risk ⚠

*No data provided by the FDA.

Table 1: Short-term efficacy and safety data from the Pfizer-BioNTech COVID-19 vaccine clinical trial. The data show that among subjects 18 to 64 and 12 to 15 years of age, the vaccine was effective at preventing COVID-19 cases that did not result in hospitalization. However, the data were not sufficient in showing vaccine effectiveness for hospitalized COVID-19 cases, cases in the elderly, and asymptomatic cases. In addition, subjects 16 years or older who received the COVID-19 vaccine had double the risk of a severe adverse event compared to those who did not receive the vaccine, and the risk in vaccinated children 12 to 15 years of age was six times greater.

6. DOES THE VACCINE PREVENT INFECTION OR TRANSMISSION?

The Pfizer clinical trial was not designed to observe asymptomatic infection with SARS-CoV-2 or the effect of the vaccine on the spread (transmission) of COVID-19. Consequently, the FDA states that "it is possible that asymptomatic infections may not be prevented as effectively as symptomatic infections" and "data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination." Furthermore, "additional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection."[3] Approximately 33% of SARS-CoV-2 infections are asymptomatic.[9]

7. WHAT IS THE RISK OF A SEVERE SIDE EFFECT FROM THE VACCINE?

For subjects 16 years or older, the Pfizer COVID-19 vaccine clinical trial found the overall incidence of severe adverse events during the two-month observation period to be 1.1%, or 1 in 91, in the vaccinated group and 0.6% in the unvaccinated group, resulting in a vaccine risk of 0.5% or 1 in 200 vaccinated subjects.[2] Consequently, subjects who received the vaccine had nearly double the risk of a severe adverse event occurring in the two-month observation period compared to subjects who did not receive the vaccine. See Table 1. Severe adverse events include fever greater than 102.1° F; vomiting that requires IV hydration; diarrhea of six or more loose stools in 24 hours; and severe fatigue, severe headache, severe muscle pain, or severe joint pain that prevents daily activity.[10]

For children 12 to 15 years of age, the Pfizer COVID-19 vaccine clinical trial found the overall incidence of severe adverse events during the two-month observation period to be 10.7%, or 1 in 9, in the vaccinated group and 1.9% in the unvaccinated group, resulting in a vaccine risk of 8.8% or 1 in 11 vaccinated children.[11,12] Consequently, children who received the vaccine had nearly six times the risk of a severe adverse event occurring in the two-month observation period compared to children who did not receive the vaccine. See Table 1. In addition, the incidence of COVID-19 in the unvaccinated group was 1.6%,[7] therefore, there were almost seven times more severe adverse events observed in the vaccinated group than there were COVID-19 cases in the unvaccinated group.

Of note, approximately 3,400 or 8% of subjects 16 years or older experienced "suspected COVID-19" because they had symptoms but were not confirmed by testing for SARS-CoV-2; two of these cases required hospitalization, both of which were in the vaccinated group. These cases could represent other influenza-like illness and adverse events; 409 such cases occurred in the vaccinated group within seven days of injection whereas 287 such cases occurred in the unvaccinated group in the same time period. Only the cases that were reported as serious were recorded as adverse events.[3] In the clinical trial, only 5% of all illnesses suspected of being COVID-19 were actually found to be COVID-19.

After emergency use authorization for the Pfizer COVID-19 vaccine was obtained and mass vaccination began, the Centers for Disease Control and Prevention (CDC) recorded about 5,000 "health impact events" among 215,000 vaccinated subjects (1 in 43) that, similar to the definition of severe adverse events in the clinical trial, prevented the ability to perform normal daily activities, including work, and required medical attention.[13]

Additionally, as there were only 11,600 subjects 16 to 55 years of age who received the vaccine,[3] and since as of April 12, 2021, about 1 in 12,500 people 18 to 39 years of age contracted a fatal case of COVID-19 in the U.S.,[5] the clinical trial did not have enough subjects to be able to prove the vaccine is safer than the disease in subjects who are 18 to 39 years of age. Furthermore, since only about 1,100 vaccinated children 12 to 15 years of age were observed,[6] there were not enough children included in the trial to be able to prove the vaccine is safer than the disease in children 12 to 15 years of age. As of April 12, 2021, the chance of a subject 0 to 17 years of age contracting SARS-CoV-2 and dying from COVID-19 is 1 in 290,000.[5]

Moreover, per the FDA, there are currently insufficient data to make conclusions about the safety of the vaccine in subpopulations such as pregnant and lactating individuals, and immunocompromised individuals.[8] And, because all subjects were observed for only two months, the long-term safety of the vaccine for any age group is not known.

- For subjects 16 years or older, Pfizer recorded almost 2x more severe adverse events (1 in 91) in the vaccinated group than the unvaccinated group.[2]
- For children 12 to 15 years of age, Pfizer recorded 6x more severe adverse events (1 in 9) in the vaccinated group than the unvaccinated group.[11,12]

8. IS THE COVID-19 VACCINE EFFECTIVE AND SAFER THAN COVID-19?

The extent to which the Pfizer-BioNTech COVID-19 vaccine is effective and safer than COVID-19 is not known. The clinical trial indicates that in subjects 65 to 74 years old, the vaccine may be only 53% effective, and in subjects 75 years or older, the age group that comprises about 60% of all COVID-19 deaths, the vaccine may be 0% effective. Also, in children 16 to 17 years of age, there were insufficient data to accurately measure vaccine efficacy. Critically, the clinical trial did not have enough statistical power to measure the vaccine's ability to prevent hospitalizations and deaths, and it did not assess if the vaccine prevents asymptomatic infection or spread (transmission) of the virus.

In terms of safety, the Pfizer clinical trial recorded severe adverse events in 1 in 91 vaccinated subjects age 16 years or older and in 1 in 9 subjects age 12 to 15 years. The CDC recorded that 1 in 43 vaccinated subjects 16 years or older was unable to perform normal daily activities and required medical attention. Importantly, for people 12 to 39 years of age, the clinical trial did not include enough subjects to be able to prove that the vaccine is safer than the disease. Furthermore, because the clinical trial observation period lasted only two months, the incidence of long-term side effects from the vaccine for any age group is not known.

All references are available at physiciansforinformedconsent.org/covid-19-vaccines.

These statements are intended for informational purposes only and should not be construed as personal medical advice.

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This vaccine has not been approved or licensed, and is still under investigation.[1]

COVID-19 – MODERNA VACCINE RISK STATEMENT (VRS)

MODERNA COVID-19 VACCINE:

Short-Term Efficacy & Safety Data

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1. WHAT IS THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 vaccine (mRNA-1273) is made from synthetic genetic material that is immersed in fatty substances, including cholesterol and polyethylene glycol (PEG). More specifically, modified RNA molecules that encode for a mutated spike (S) protein antigen of the SARS-CoV-2 virus, the virus that can cause COVID-19, are immersed in lipid nanoparticles. The drug is administered in two intramuscular 100 mcg doses, 28 days apart.[1]

2. HOW WAS THE VACCINE STUDIED PRIOR TO OBTAINING EUA?

The Moderna COVID-19 vaccine obtained emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) on Dec. 18, 2020, and is currently investigational.[2] The vaccine was studied through nonclinical data from rats, mice, hamsters, and nonhuman primates, and clinical data from humans.[3] The EUA was based on a human clinical trial comparing approximately 15,000 subjects who received the vaccine with 15,000 subjects who did not receive the vaccine (Table 1).[1] The trial included a median observation period of nine weeks; 53.6% of subjects were followed up for about two months after the second dose.[1] The FDA states that due to the length of the clinical trial's observation period, "it is not possible to assess sustained efficacy over a period longer than 2 months."[1]

3. DOES THE VACCINE PREVENT HOSPITALIZATIONS AND DEATHS?

Since only 10 hospitalized cases and one death of COVID-19 were observed, the clinical trial did not have enough statistical power to accurately measure the vaccine's ability to prevent hospitalizations or deaths from COVID-19.[1,4] The vaccine may be only 13% effective against hospitalized COVID-19 cases. See Table 1. The FDA states, "A larger number of individuals at high risk of COVID-19 and higher attack rates would be needed to confirm efficacy of the vaccine against mortality."[1]

4. HOW EFFECTIVE IS THE VACCINE IN ADULTS AND THE ELDERLY?

Vaccine effectiveness was calculated by observing the vaccine status of 196 COVID-19 cases, where a COVID-19 case was defined as a positive SARS-CoV-2 test together with the presence of at least either one COVID-19 respiratory symptom or two non-respiratory symptoms, at least 14 days after the second dose. In subjects 18 to 64 years old, the vaccine was 91%–98% effective over a two-month observation period.[8] However, since there were only 33 COVID-19 cases observed in subjects 65 years or older, the clinical trial did not have enough statistical power to accurately measure the vaccine's effectiveness in that age group. The vaccine may be only 61% effective in subjects 65 years or older and 0% effective in subjects 75 years or older.[5] See Table 1. Subjects 65 years or older comprise about 80% of all COVID-19 deaths, and subjects 75 years or older comprise about 60% of all COVID-19 deaths.[6]

In subjects 65 years or older, the vaccine may be only 61% effective, and in subjects 75 years or older, the vaccine may be 0% effective.[5] People 65 years or older comprise about 80% of all COVID-19 deaths.[6]

5. IS THE VACCINE EFFECTIVE IN CHILDREN?

Safety and efficacy data was not collected for children younger than 18 years old.[1] See Table 1.

SHORT-TERM EFFICACY DATA		
Enrolled subjects	Efficacy, approx. 2-month observation period (95% confidence interval)	
Confirmed COVID-19 hospitalizations[4]	13%–99%	?
Confirmed COVID-19 deaths[1]	NA*	?
Confirmed COVID-19 (age 18–64)[5]	91%–98%	✓
Confirmed COVID-19 (age 65 or older)[5]	61%–96%	?
Confirmed COVID-19 (age 75 or older)[5]	NA*	?
Asymptomatic SARS-CoV-2 infection[4]	20%–68%	?
SARS-CoV-2 spread (transmission)[1]	NA*	☒
SHORT-TERM SAFETY DATA		
Severe adverse events (age 18–64)[1]	2x risk in vaccine group	⚠
Severe adverse events (age 65 or older)[1]	2x risk in vaccine group	⚠
Pregnant/breastfeeding[1]	NA*	?
Immunocompromised[1]	NA*	?
Children younger than 18[1]	NA*	☒

Not tested ☒ Insufficient data to prove efficacy or safety ? Evidence of short-term benefit ✓ Evidence of risk ⚠

**No data provided by the FDA.*

Table 1: Short-term efficacy and safety data from the Moderna COVID-19 vaccine clinical trial. The data shows that among subjects younger than 65, the vaccine was effective at preventing COVID-19 cases that did not result in hospitalization. However, the data was not sufficient in showing vaccine effectiveness for hospitalized COVID-19 cases, cases in the elderly, and asymptomatic cases. In addition, subjects who received the COVID-19 vaccine had double the risk of a severe adverse event compared to people who did not receive the vaccine.

6. IS THE VACCINE EFFECTIVE IN PREVENTING INFECTION WITH SARS-COV-2 OR THE SPREAD OF COVID-19?

The Moderna clinical trial was not designed to observe asymptomatic infection with SARS-CoV-2 or the effect of the vaccine on the spread (transmission) of COVID-19. Consequently, the FDA states that "it is possible that asymptomatic infections may not be prevented as effectively as symptomatic infections" and "data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination." Furthermore, "additional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection."[1] Approximately 40% of SARS-CoV-2 infections are asymptomatic.[7]

To try to address the limitations above, Moderna performed an analysis of a few cases that tested positive but reported no symptoms. However, the analysis still lacked statistical power to produce an accurate measurement, and the vaccine may be only 20% effective in preventing asymptomatic cases.[4]

As all subjects were observed for only two months, the long-term efficacy and safety of the vaccine for any age group is not known.

7. WHAT IS THE RISK OF A SEVERE SIDE EFFECT FROM THE VACCINE?

The Moderna COVID-19 vaccine clinical trial found the overall incidence of severe adverse events during the two-month observation period to be 2% or 1 in 50 in vaccinated subjects between 18 and 64 years old and 1.2% in the unvaccinated group, resulting in a vaccine risk of 0.8% or 1 in 125 vaccinated subjects. The incidence of severe adverse events was 1.7% or 1 in 59 in vaccinated subjects 65 years or older and 0.8% in the unvaccinated group, resulting in a vaccine risk of 0.9% or 1 in 111 vaccinated subjects.[1] Consequently, subjects who received the vaccine had nearly double the risk of a severe adverse event occurring in the two-month observation period compared to subjects who did not receive the vaccine. See Table 1. A severe adverse event was one that persisted for longer than a week and either prevented the ability to perform daily activities and required medical intervention, or required hospitalization.[1,8]

Additionally, as there were only 7,500 subjects 18 to 53 years of age who received the vaccine,[1] and since as of March 23, 2021, about 1 in 13,000 people 18 to 39 years of age contracted a fatal case of COVID-19 in the U.S.,[6] the clinical trial does not have sufficient data to determine safety in subjects who are 18 to 39 years of age. Per the FDA, "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."[1] And, because all subjects were observed for only two months, the long-term safety of the vaccine for any age group is not known. The FDA states, "Long-term safety and long-term effectiveness are areas the Sponsor [Moderna] identified as missing information."[1]

- Moderna recorded almost 2x more severe adverse events (1 in 50) in vaccinated subjects between 18 and 64 years old than the unvaccinated group.[1]
- Moderna recorded almost 2x more severe adverse events (1 in 59) in vaccinated subjects 65 years or older than the unvaccinated group.[1]

8. IS THE COVID-19 VACCINE EFFECTIVE AND SAFER THAN COVID-19?

The extent to which the Moderna COVID-19 vaccine is effective and safer than COVID-19 is not known. The clinical trial indicates that in subjects 65 years or older, the vaccine may be only 61% effective, and in subjects 75 years or older, the age group that comprises about 60% of all COVID-19 deaths, the vaccine may be 0% effective. The clinical trial did not have enough statistical power to measure the vaccine's ability to prevent hospitalizations and deaths, and the trial had limited data to assess whether the vaccine prevents asymptomatic infection or spread (transmission) of the virus.

Severe adverse events in the vaccine group occurred in 1 in 50 subjects between 18 and 64 years old and in 1 in 59 subjects 65 years or older in the Moderna clinical trial. Those subjects were unable to perform normal daily activities for more than seven days and required medical attention. Furthermore, for people 18 to 39 years of age, the clinical trial did not include enough subjects to be able to show that the vaccine is safer than the disease, and because the clinical trial observation period lasted only two months, the incidence of long-term side effects from the vaccine for any age group is not known.

All references are available at physiciansforinformedconsent.org/covid-19-vaccine.

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This vaccine has not been approved or licensed, and is still under investigation.[1]

COVID-19 – JANSSEN (J&J) VACCINE RISK STATEMENT (VRS)

JANSSEN (JOHNSON & JOHNSON) COVID-19 VACCINE:

Short-Term Efficacy & Safety Data

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1. WHAT IS THE JANSSEN (JOHNSON & JOHNSON) COVID-19 VACCINE?

The Janssen (Johnson & Johnson) COVID-19 vaccine (Ad26.COV2.S) is made from inactivated adenovirus viral particles that are modified to include genetic material that codes for part of the SARS-CoV-2 virus, the virus that can cause COVID-19. More specifically, DNA that codes for a mutated spike (S) protein of the SARS-CoV-2 virus is embedded into inactivated adenovirus viral particles and grown in a fetal cell line. The drug is administered in one intramuscular dose of 50 billion viral particles.[1]

2. HOW WAS THE VACCINE STUDIED PRIOR TO OBTAINING EUA?

The Janssen COVID-19 vaccine has obtained emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) and is currently investigational.[2] The vaccine was studied through nonclinical data from mice, rabbits, hamsters and nonhuman primates, and clinical data from humans.[3] The EUA was based on a human clinical trial comparing approximately 22,000 subjects who received the vaccine with 22,000 subjects who did not receive the vaccine (Table 1).[4] The trial included a median observation period of eight weeks; 54.6% of subjects were followed up for at least eight weeks after vaccination.[4] The FDA states that due to the length of the clinical trial's observation period, "it is not possible to assess sustained efficacy over a period longer than 2 months."[4]

3. DOES THE VACCINE PREVENT HOSPITALIZATIONS AND DEATHS?

The FDA states, "The totality of these data indicates vaccine efficacy in the prevention of severe COVID-19 requiring hospitalization."[4] However, more than 60% (26 of 43) of the severe/critical cases were observed in South Africa, whereas less than 19% (8 of 43) were observed in the U.S.[5] The fact that severe/critical COVID-19 is more than four times more likely to occur in South Africa (26 of 113) than in the U.S. (8 of 152) suggests that conditions in the U.S. reduce the severity of COVID-19. Since only eight severe/critical cases of COVID-19 were observed in the U.S. at least 28 days after vaccination, the clinical trial did not have enough statistical power to measure the vaccine's ability to prevent hospitalizations from COVID-19 in the U.S.[5] See Table 1. There were also no COVID-19 deaths observed in the U.S., and the FDA states, "A larger number of individuals at high risk of COVID-19 and higher attack rates would be needed to confirm efficacy of the vaccine against mortality."[4]

4. HOW EFFECTIVE IS THE VACCINE IN ADULTS AND THE ELDERLY?

Vaccine effectiveness was calculated by observing the vaccination status of 437 COVID-19 cases, where a COVID-19 case was defined as a positive SARS-CoV-2 test and the presence of either two typical COVID-19 symptoms or one or more severe COVID-19 symptoms. In subjects 18 to 64 years old, the vaccine was 56%–73% effective against cases occurring at least 28 days after vaccination.[6] However, since there were only 46 COVID-19 cases observed in subjects 65 to 74 years old and only four cases in subjects 75 years or older, the clinical trial did not have enough statistical power to accurately measure the vaccine's effectiveness in those age groups. The vaccine may be only 39% effective in subjects 65 years or older and 0% effective in subjects 75 years or older.[6] See Table 1. Subjects 65 years or older comprise about 80% of all COVID-19 deaths, and subjects 75 years or older comprise about 60% of all COVID-19 deaths.[7]

In subjects 65 years or older, the vaccine may be only 39% effective, and in subjects 60 years or older with risk factors for severe COVID-19, the vaccine may be 0% effective.[6,8] People 65 years or older comprise about 80% of all COVID-19 deaths.[7]

SHORT-TERM EFFICACY DATA		
Enrolled subjects	Efficacy, approx. 2-month observation period (95% confidence interval)	
Confirmed COVID-19 hospitalizations (U.S.)[4]	NA*	?
Confirmed severe/critical COVID-19 cases (U.S.)[5]	-9%–100%	?
Confirmed COVID-19 (age 18–64)[6]	56%–73%	✓
Confirmed COVID-19 (age 65 or older)[6]	39%–85%	?
Confirmed COVID-19 (age 75 or older)[6]	NA*	?
Confirmed COVID-19 (age 18–59 with risk factors)[8]	44%–77%	?
Confirmed COVID-19 (age 60 or older with risk factors)[8]	-13%–72%	?
Asymptomatic SARS-CoV-2 infection[10]	40%–81%	?
SARS-CoV-2 spread (transmission)[4]	NA*	?
Children younger than 18[4]	NA*	?

SHORT-TERM SAFETY DATA		
Grade 3 systemic reactions[13]	3x risk in vaccine group	⚠
Children younger than 18[4]	NA*	?
Pregnant/breastfeeding and their infants[4]	NA*	?
Immunocompromised[4]	NA*	?

Not tested ☒ Insufficient data to prove efficacy or safety ? Evidence of short-term benefit ✓ Evidence of risk ⚠

*No data provided by the FDA.

Table 1: Short-term efficacy and safety data from the Janssen (J&J) COVID-19 vaccine clinical trial. This data shows that among subjects younger than 65, the vaccine was effective at preventing COVID-19 that did not result in hospitalization in the U.S. However, the data was not sufficient in showing vaccine effectiveness for hospitalized COVID-19 cases in the U.S., cases with risk factors for severe symptoms, cases in the elderly, and asymptomatic cases. In addition, subjects who received the COVID-19 vaccine had triple the risk of a severe adverse event compared to people who did not receive the vaccine.

The clinical trial also included an analysis of vaccine effectiveness for subjects with risk factors making them more vulnerable to severe COVID-19 symptoms, such as obesity, diabetes, and hypertension. In subjects 18 to 59 years old with these risk factors, the vaccine was 44%–77% effective against cases occurring at least 28 days after vaccination.[8] However, since there were only 41 COVID-19 cases observed in subjects 60 years or older, the clinical trial did not have enough statistical power to accurately measure the vaccine's effectiveness in that age group. The vaccine may be 0% effective in subjects 60 years or older with risk factors.[8] See Table 1.

Of note, the clinical trial also included over 2,000 unvaccinated subjects that had contracted SARS-CoV-2 before the study. The trial recorded the incidence of COVID-19 in that group at least 28 days after the vaccination of the other subjects in the study. The COVID-19 incidence of the group with prior SARS-CoV-2 infection was 0.1% (2/2,021), whereas the COVID-19 incidence of vaccinated subjects was 0.59% (113/19,306).[9] These data suggest that there are six times more cases of COVID-19 in vaccinated subjects than in subjects previously infected with SARS-CoV-2.

5. IS THE VACCINE EFFECTIVE IN CHILDREN?

Efficacy data was not available and safety data was insufficient in children younger than 18 years.[4] See Table 1.

6. IS THE VACCINE EFFECTIVE IN PREVENTING INFECTION WITH SARS-COV-2 OR THE SPREAD OF COVID-19?

The FDA states, "The evaluation of vaccine efficacy against asymptomatic disease and its interpretation are limited at this time, since the measurements were performed in a small subset of participants." The trial only analyzed about 2,600 subjects for the potential of asymptomatic infection and found 18 cases in the vaccinated group and 50 cases in the unvaccinated group, resulting in a vaccine effectiveness potentially as low as 40%.[10] See Table 1. Consequently, the FDA states that "it is possible that asymptomatic infections may not be prevented as effectively as symptomatic infections" and "data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination." Furthermore, "additional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection."[4]

Of note, the 50 asymptomatic cases described above comprised 3.8% of the 1,304 unvaccinated subjects included in that analysis.[10] The trial also recorded 432 unvaccinated symptomatic COVID-19 cases confirmed by a central laboratory.[11] Since such cases comprised 68% of all COVID-19 cases that tested positive for SARS-CoV-2,[4] the trial recorded an estimated 635 (432/68%) symptomatic COVID-19 cases among 19,544 unvaccinated subjects (3.25%).[12] These data suggest that 54% (3.8%/[3.25%+3.8%]) of all COVID-19 cases in the clinical trial were asymptomatic.

7. WHAT IS THE RISK OF A SEVERE SIDE EFFECT FROM THE VACCINE?

The Janssen COVID-19 vaccine clinical trial found the overall incidence of grade 3 systemic adverse events within seven days of vaccination to be 1.8% or 1 in 55 in the vaccinated group and 0.6% in the unvaccinated group, resulting in a vaccine risk of 1.2% or 1 in 84 vaccinated subjects.[13] Consequently, subjects who received the vaccine had about triple the risk of a grade 3 systemic adverse event within seven days of vaccination compared to subjects who did not receive the vaccine. See Table 1. Systemic adverse events included fatigue, headache, myalgia, nausea, and fever.[4] A grade 3 adverse event is a severe event that prevents the ability to perform normal daily activities, including work, and requires medical attention.[14]

Additionally, as there were only 5,031 subjects 18 to 39 years of age who received the vaccine,[3] and since as of March 23, 2021, about 1 in 13,000 people 18 to 39 years of age contracted a fatal case of COVID-19 in the U.S.,[7] the clinical trial does not have sufficient data to determine safety in subjects who are 18 to 39 years of age. Per the FDA, "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 their infants, and immunocompromised individuals."[4] And, because all subjects were observed for only two months, the long-term safety of the vaccine for any age group is not known.

Janssen recorded almost 3x more severe adverse events (1 in 55) in the vaccinated group than the unvaccinated group.[13]

8. IS THE COVID-19 VACCINE EFFECTIVE AND SAFER THAN COVID-19?

The extent to which the Janssen COVID-19 vaccine is effective and safer than COVID-19 is not known. The clinical trial indicates that in subjects 65 years or older, the vaccine may be only 39% effective, and in subjects 75 years or older, the age group that comprises about 60% of all COVID-19 deaths, the vaccine may be 0% effective; also, in subjects 60 years or older with risk factors for severe COVID-19 the vaccine may not be effective. The clinical trial did not have enough statistical power to measure the vaccine's ability to prevent hospitalizations and deaths in the U.S., and the trial had limited data to assess whether the vaccine prevents asymptomatic infection or spread (transmission) of the virus.

Grade 3 systemic adverse events in the vaccine group occurred in 1 in 55 subjects in the Janssen clinical trial. Furthermore, for people 18 to 39 years of age, the clinical trial did not include enough subjects to be able to show that the vaccine is safer than the disease, and because the clinical trial observation period lasted only two months, the incidence of long-term side effects from the vaccine for any age group is not known.

All references are available at physiciansforinformedconsent.org/covid-19-vaccine.

These statements are intended for informational purposes only and should not be construed as personal medical advice.

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