Covid-19 Vaccination Under EUA Requirement for Employers

Employer Notice: In reference to your requirement that employees receive a covid-19 emergency use authorization (EUA) investigational vaccine, as your employee, I am requesting you read the following statements in its entirety, provide the required information and sign the form, return and retain a copy for your records. This letter is not intended as a refusal of the required covid-19 injection but is simply a requisite inquiry.

1) If I agree to receive an EUA Covid-19 injection, does my employee **health insurance plan** provide complete coverage should I experience an adverse event, or even death?

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2) As an employee, does my **life insurance policy** provide any coverage in the event that I die from receiving an EUA Covid-19 injection?

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3) As an employee, will you be providing **Workers' Compensation, disability insurance, or other resources** if I have an adverse event to an EUA Covid-19 injection and am unable to come to work for days, weeks, or months, or if I am disabled for life?

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4) The Food and Drug Administration (FDA) requires that EUA vaccine recipients be provided with certain **vaccine-specific information** to help them make an informed decision about vaccination.[1] The EUA fact sheets that must be provided are specific to each authorized Covid-19 injection and are developed by the manufacturers (Pfizer/BioNTech, Moderna, and Janssen/Johnson & Johnson). The fact sheets must provide up-to-date information on the injections and their ingredients; vaccine recipients must also receive information about adverse events. Have you read, understood, and provided me (and all other employees) with these fact sheets and current information on adverse events—and can you furnish a list of vaccine ingredients guaranteed to be complete—so that I/we can make an educated decision?

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5) Have you reviewed the **material adverse events** experienced to date by people who have received EUA Covid-19 injections, reported to the Vaccine Adverse Event Reporting System (VAERS)?[2] Reported adverse events include death, anaphylaxis, blood clots and related complications, leaky blood vessels and related complications, heart problems (myocarditis and pericarditis), neurological disorders, autoimmune disorders, other chronic and inflammatory conditions, blindness and deafness, infertility, fetal damage, miscarriage, and stillbirth.

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6) The FDA's guidance[3] on emergency use authorization of medical products requires the FDA to "ensure that recipients are informed to the extent practicable given the applicable circumstances…[t]hat they have the option to accept or refuse the EUA product…" Are you aware of this statement? Have you informed all employees that they have the option to refuse?

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7) With respect to the emergency use of an unapproved product, the Federal Food, Drug and Cosmetic Act, Title 21 U.S.C. 360bbb-3(e)(1)(A)(ii)(I-III) reiterates that individuals be informed of "**the option to accept or refuse administration of the product**, [and] of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."[4] In the event that the FDA decided to grant full approval to Covid-19 vaccines, state legislation would be required to allow companies to mandate the Covid-19 injections. Are you aware of these facts?

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8) EUA products are unapproved, unlicensed, and experimental. Under the Nuremberg Code— the foundation of ethical medicine—no one may be coerced to participate in a medical experiment. The individual's consent is absolutely essential. No court has ever upheld a mandate for an EUA vaccine. In Doe #1 v. Rumsfeld, 297 F. Supp. 2d 119 (2003),[5] a federal court held that the U.S. military **could not mandate EUA vaccines for soldiers**: "[T]he United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs" (Id. at 135). Are you aware of this?

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9) The United States Code of Federal Regulations[6] and the FDA require the informed consent of human subjects for medical research. The EUA Covid-19 injections are unapproved, unlicensed, investigational vaccines that are still in their experimental stage. It is unlawful to conduct medical research on a human being, even in the event of an emergency, unless steps are taken to secure the **full informed consent** of all participants. Are you aware of this?

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10) According to Federal Trade Commission (FTC) Guidelines[7] and the FTC's "Truth In Advertising,"[8] promotional materials—and especially materials involving health-related products—cannot mislead consumers, omit important information, or express claims. All of this falls under the rubric of "**deceptive advertising**" (whereby a company is providing or endorsing a product), whether presented in the form of an ad, on a website, through email, on a poster, or in the mail. For example, statements such as "all employees are required to get the Covid-19 vaccine to make the workspace safe" or "it's safe and effective" leave out critical information. Critical information includes the facts that Covid-19 injections are unapproved EUA vaccines that "may" or "may not" prevent Covid, won't necessarily make the workplace safer, and could in fact cause harm. Not providing links or attachments of the manufacturers' fact sheets and current information on adverse events is omitting safety information. Are you aware of this?

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11) Since the Covid lockdowns began over one year ago, there have been over 178 reported breaches of unsecured protected health information (PHI), incidents investigated by the Office for Civil Rights (OCR). These breaches exposed millions of people's personal health information. Although many of these incidents were attributed to hacking, some of the breaches to PHI fell directly under the 1996 Health Insurance Portability and Accountability Act (HIPAA), such as sharing a patient's or person's information with an unauthorized individual or incorrectly handling PHI.[9] Can you please explain your obligations to me, under HIPAA law, with respect to your requirement that I receive this injection?

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12) Whereas pharmaceutical companies that manufacture EUA vaccines have been protected from liability related to injuries or deaths caused by experimental agents since the Public Readiness and Emergency Preparedness (PREP) Act[10] was enacted in 2005, **companies and all other institutions or individuals who mandate experimental vaccines on any human being are not protected from liability**. Are you aware that you do not enjoy such liability protection?

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13) Are you aware that employees could file a **civil suit against** you should they suffer an adverse event, death, or termination from their place of employment?

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14) On September 22, 2021, according to the FDA's Letter of Authorization (Reissued),[11] "On December 11, 2020, the FDA issued an EUA for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: December 23, 2020, February 25, 2021, May10, 2021, June 25, 2021, August 12, 202, and on August 23, 2021, FDA approved COMIRNATY (COVID-19 Vaccine, mRNA) and reissued the letter in its entirety for both Pfizer-BioNTech COVID-19 Vaccine and certain uses of COMIRNATY (COVID-19 Vaccine, mRNA)."

    The Pfizer-BioNTech COVID-19 Vaccine meets "The Criteria for Issuance of Authorization...because there is no adequate, approved, and available alternative Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19." However, "Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA."

    "COMIRNATY (COVID-19 Vaccine, mRNA) is now licensed for individuals 16 years of age and older. There remains, however, a significant amount of PfizerBioNTech COVID-19 Vaccine that was manufactured and labeled in accordance with this emergency use authorization. The authorization remains in place with respect to the Pfizer-BioNTech COVID-19 Vaccine." Additionally, "the licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably...The products are legally distinct with certain differences that do not impact safety or effectiveness."

    Are you aware both FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine are **same formulation but legally distinct**; however, only one, FDA-approved COMIRNATY, is **not available for distribution to this [individuals 16 years of age and older] population in its entirety** and all of the vaccines currently available for the prevention of COVID-19, required to continue my employment, are all still under EUA?

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As the legally authorized officer of the employer/company, I have read all of the above information, have provided my employees with all of the information that the FDA requires be provided to recipients of the Covid-19 injections, and do hereby agree to assume 100% financial responsibility for covering any and all expenses from adverse events, including death, through insurance coverage or directly. In addition, I affirm that the employee will not be subjected to the loss of their job should they decline to receive a Covid-19 injection.

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Authorized officer of company requiring injection	Company	Date
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Employee	Company	Date
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Witness	Company	Date

Footnotes to the Form

[1] Centers for Disease Control and Prevention. COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers. https://www.cdc.gov/vaccines/covid-19/eua/index.html

[2] In the United States, see Vaccine Adverse Event Reporting System, https://vaers.hhs.gov; CDC WONDER, "About the Vaccine Adverse Event Reporting System (VAERS)," https://wonder.cdc. gov/vaers.html; National Vaccine Information Center, "Search the U.S. Government's VAERS Data," https://www.medalerts.org/

[3] U.S. Department of Health and Human Services. Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders. January 2017. https://www.fda.gov/media/97321/download

[4] 21 U.S. Code § 360bbb–3 — Authorization for medical products for use in emergencies. https://www.law.cornell.edu/uscode/text/21/360bbb-3

[5] Doe #1 v. Rumsfeld, 297 F. Supp. 2d 119 (2003). https://www.courtlistener.com/opinion/2326816/doe-v-rumsfeld/

[6] https://www.govregs.com/regulations/expand/title21_chapterI_part50_subpartB_section50.24#regulation_2

[7] Federal Trade Commission. Advertising FAQ's: A Guide for Small Business. https://www.ftc.gov/tips-advice/business-center/guidance/advertising-faqs-guide-small-business

[8] Federal Trade Commission. Truth in Advertising. https://www.ftc.gov/news-events/media-resources/truth-advertising

[9] U.S. Department of Health and Human Services. Office for Civil Rights. Breach Portal: Notice to the Secretary of HHS Breach of Unsecured Protected Health Information. https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf;jsessionid=618E88DD94EE65D46D5785CB2A643553

[10] Congressional Research Service. The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures. Updated Mar. 19, 2021. https://crsreports.congress.gov/product/pdf/LSB/LSB10443

[11] September 22, 2021, Pfizer-BioNTech Letter of Authorization (Reissued): https://www.fda.gov/media/150386/download