WHAT YOU NEED TO KNOW

about covid-19 vaccines

For informational purposes only.

The purpose of this document is to engage in fact-based discussion. Everything is sourced from .gov websites.

HOW WERE THE VACCINES BROUGHT TO MARKET?

myth: "Because of the public health emergency declared by the Secretary of Health and Human Services, the vaccines were brought to market."

fact: According to the FDA, the public health emergency declared January 2020 does not enable the FDA to authorize Emergency Use Authorizations. The vaccines were brought to market due to a separate determination.

> Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

Source: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

In other words, the public health emergency alone would not have made the vaccines available to the public. It was the separate determination below that enabled the FDA to authorize emergency use.

> February 4, 2020, the Secretary determined pursuant to his authority under section 564 of the FD&C Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019

Source: https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration

ARE THE VACCINES APPROVED?

YES AND NO.

myth: "The vaccines are approved by the FDA and have met all safety standards of other vaccines on the market."

fact: The FDA approved Pfizer's Covid-19 vaccine for individuals aged 16 years or older on 23 Aug 2021, however is still under Emergency Use Authorization for adolescents 12 through 15 years of age and the administration of a third dose to certain immunocompromised individuals 12 years of age and older.

Unfortunately, even with FDA approval, there are a few unknowns about Pfizer's Covid-19 vaccine for ages 16 years or older.

Pediatric Use

The safety and effectiveness of COMIRNATY in individuals younger than 16 years of age have not been established.

If the safety + effectiveness of this product has not been established for ages younger than 16 years old, then why has the FDA authorized emergency use of this product for ages 12-15 years old?

Male fertility

COMIRNATY has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility.

No clinical trial data for immunocompromised patients or patients that already had Covid-19.

The study excluded participants who were

immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19.

Why is this product recommended for those already diagnosed with Covid-19 when the Phase 3 clinical trial excluded this population?

Source: https://www.fda.gov/media/151707/download

Pregnancy + Breastfeeding

Available data on COMIRNATY administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to COMIRNATY during pregnancy. Women who are vaccinated with COMIRNATY during pregnancy are encouraged to enroll in the registry by visiting https://mothertobaby.org/ongoing-study/covid19-vaccines/.

MotherToBaby is enrolling pregnant people who have received a COVID-19 vaccine into an observational study. All of our research is conducted by phone — you will not be asked to visit an office. Vaccines are an important tool to prevent illness, yet there is limited data about the use of COVID-19 vaccines for people who are pregnant. Our study will provide critical information for future moms-to-be and the medical community.

It is not known whether COMIRNATY is excreted in human milk. Data are not available to assess the effects of COMIRNATY on the breastfed infant or on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for COMIRNATY and any potential adverse effects on the breastfed child from COMIRNATY or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

Vaccine-associated risks in pregnancy and the effects on the breastfed infant or on milk production/excretion are unknown. All patients currently accepting this product will be the observational data to inform future mothers of potential adverse effects.

Limited long-term data

The safety of COMIRNATY was evaluated in participants 16 years of age and older in 2 clinical studies conducted in Germany (Study 1), United States, Argentina, Brazil, Turkey, South Africa, and Germany (Study 2). Study BNT162-01 (Study 1) was a Phase 2-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age and 36 participants, 56 through 85 years of age. Study C4591001 (Study 2) is a Phase 1/2/3 multicenter, multinational, randomized, saline placebo-controlled, double-blinded (Phase 2/3), dose-finding, vaccine candidate-selection and efficacy study that has enrolled approximately 44,047 participants (22,026 COMIRNATY; 22,021 placebo) 16 years of age or older (including 378 and 376 participants 16 through 17 years of age in the vaccine and placebo groups, respectively). Upon issuance of the Emergency Use Authorization (December 11, 2020) for COMIRNATY, participants were unblinded to offer placebo participants COMIRNATY. Participants were unblinded in a phased manner over a period of months to offer placebo participants COMIRNATY.

Phase 3 Clinical Trial placebo participants were given Comirnaty during the clinical trial meaning all long-term data is compromised.

At the time of the analysis of the ongoing Study 2 with a data cut-off of March 13, 2021, there were 25,651 (58.2%) participants (13,031 COMIRNATY and 12,620 placebo) 16 years of age and older followed for ≥4 months after the second dose.

This same study is ongoing as of FDA approval. Data provided is only interim versus final clinical trial results. Estimated completion date is May 2023.

Estimated Primary Completion Date ⓘ :	May 2, 2023
Estimated Study Completion Date ⓘ :	May 2, 2023

https://clinicaltrials.gov/ct2/show/NCT04368728?term=C4591001&draw=2&rank=4

Intellectual property protected ingredients

Each dose of COMIRNATY
contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each 0.3 mL dose of the COMIRNATY also includes the following ingredients: lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.

Unfortunately, according to Pfizer's Chairman and CEO, the full ingredient list is protected by intellectual property rights for the mRNA vaccines.

https://www.pfizer.com/news/hottopics/why_pfizer_opposes_the_trips_intellectual_property_waiver_for_covid_19_vaccines

The biggest question is what are the ingredients used in the manufacturing process to create the 30 mcg of mRNA with the viral spike coding?

Currently, we don't know due to intellectual property right protection.

Limitation of effectiveness

5.5 Limitation of Effectiveness

COMIRNATY may not protect all vaccine recipients.

This product is intended to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), not SARS-Cov-2 itself. This limitation of effectiveness addresses the intention to prevent Covid-19 which means the following may still occur even if fully vaccinated:

+ SARS-Cov-2 transmission/infection
+ Covid-19 diagnosis
+ Complications of Covid-19
+ Hospitalizations from Covid-19 complications
+ Death from Covid-19 complications

THIS PRODUCT IS NOT GUARANTEED BY THE MANUFACTURER OR FDA TO WORK FOR EVERYONE.

This is a crucial element to understand while discussing any future vaccine mandates. The narrative for mandates suggests these products are required to prevent the spread of Covid-19. According to the FDA + the manufacturer, that is an incorrect assumption.

what about the other vaccines?

MODERNA IS NOT FDA-APPROVED

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.

Source: https://www.fda.gov/media/144637/download

JOHNSON & JOHNSON IS NOT FDA-APPROVED

FDA has authorized the emergency use of the Janssen COVID-19 Vaccine, which is not an FDA approved vaccine.

Source: https://www.fda.gov/media/146304/download

CAN THE VACCINES BE REMOVED FROM THE MARKET?

YES, THE FDA CAN REVOKE ANY EUA.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

Source: https://www.fda.gov/media/144413/download

The FDA has already done it for another product. The EUA that was granted in March 2020 for a drug that was determined to no longer be effective in treating COVID was revoked in June 2020. It was revoked also due to ongoing serious cardiac adverse events and other serious side effects.

Q. Why was the Emergency Use Authorization (EUA) for hydroxychloroquine sulfate (HCQ) and chloroquine phosphate (CQ) revoked?

A. FDA has a responsibility to regularly review the appropriateness of an Emergency Use Authorization (EUA), including review of emerging scientific data associated with the emergency use of an authorized product. Based on FDA's continued review of the scientific evidence available for hydroxychloroquine sulfate (HCQ) and chloroquine phosphate (CQ) to treat COVID-19, FDA has determined that the statutory criteria for EUA as outlined in Section 564(c)(2) of the Food, Drug, and Cosmetic Act are no longer met. Specifically, FDA has determined that CQ and HCQ are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA. Additionally, in light of ongoing serious cardiac adverse events and other serious side effects, the known and potential benefits of CQ and HCQ no longer outweigh the known and potential risks for the authorized use. This conclusion warrants revocation of the EUA for HCQ and CQ for the treatment of COVID-19.

Source: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and

ARE THERE LONG-TERM ADVERSE REACTIONS?

So far, the FDA has disclosed the following warnings for each vaccine:

PFIZER BIONTECH "COMIRNATY"

Cardiac Disorders: myocarditis, pericarditis
Gastrointestinal Disorders: diarrhea, vomiting
Immune System Disorders: severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema)
Musculoskeletal and Connective Tissue Disorders: pain in extremity (arm)

Source: https://www.fda.gov/media/151707/download

MODERNA *STILL UNDER EUA*

Myocarditis and Pericarditis
Reports of adverse events following use of the Moderna COVID-19 Vaccine under EUA suggest increased risks of myocarditis and pericarditis, particularly following the second dose. Typically, onset of symptoms has been within a few days following receipt of the Moderna COVID-19 Vaccine. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms, but information is not yet available about potential long-term sequelae. The decision to administer the Moderna COVID-19 Vaccine to an individual with a history of myocarditis or pericarditis should take into account the individual's clinical circumstances. The CDC has published clinical considerations relevant to myocarditis and pericarditis associated with administration of the Moderna COVID-19 Vaccine (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

Source: https://www.fda.gov/media/144637/download

JOHNSON & JOHNSON *STILL UNDER EUA*

Thrombosis with Thrombocytopenia

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites (including but not limited to the large blood vessels of the abdomen and the veins of the lower extremities) combined with thrombocytopenia and with onset of symptoms approximately one to two weeks after vaccination. The reporting rate of thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine has been highest in females ages 18 through 49 years; some cases have been fatal. The clinical course of these events shares features with autoimmune heparin-induced thrombocytopenia. In individuals with suspected thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine, the use of heparin may be harmful and alternative treatments may be needed. Consultation with hematology specialists is strongly recommended. The American Society of Hematology has published considerations relevant to the diagnosis and treatment of thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine (*https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia*). *(see Full EUA Prescribing Information)*.

Guillain-Barré Syndrome

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination.

Source: https://www.fda.gov/media/146304/download

ALL THREE VACCINES

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

Altered Immunocompetence
Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Janssen COVID-19 Vaccine.

ARE THE VACCINES 100% EFFECTIVE?

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

Source: https://www.fda.gov/media/144413/download

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

Source: https://www.fda.gov/media/144637/download

The Janssen COVID-19 Vaccine may not protect all vaccinated individuals.

Source: https://www.fda.gov/media/146304/download

WILL THERE BE BOOSTER SHOTS?

According to the CDC, booster shots should be expected in Fall 2021.

Centers for Disease Control and Prevention

Updated Aug. 20, 2021

When can I get a COVID-19 vaccine booster?

Not immediately. The goal is for people to start receiving a COVID-19 booster shot beginning in the fall, with individuals being eligible starting 8 months after they received their second dose of an mRNA vaccine (either Pfizer-BioNTech or Moderna). This is subject to authorization by the U.S. Food and Drug Administration and recommendation by CDC's Advisory Committee on Immunization Practices (ACIP). FDA is conducting an independent evaluation to determine the safety and effectiveness of a booster dose of the mRNA vaccines. ACIP will decide whether to issue a booster dose recommendation based on a thorough review of the evidence.

Who will be the first people to get a booster dose?

If FDA authorizes and ACIP recommends a booster dose, the goal is for the first people eligible for a booster dose to be those who were the first to receive a COVID-19 vaccination (those who are most at risk). This includes healthcare providers, residents of long-term care facilities, and other older adults.

Source: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

Is a product effective if those that already completed the full vaccine series are at risk and in need of a potential booster within eight months of completion?

If the Covid-19 vaccines are mandated to receive an education or gain/remain employeed, will all boosters be required as well?

WHAT IF I'M TOLD I HAVE TO SIGN A REFUSAL FORM?

There is currently no known legal requirement to sign a refusal form. If your employer or institution requires a refusal form, ask the following questions:

- What is the mandating authority for the refusal form? Is it the employer, State government, or Federal government?

- Are all the statements made within the refusal form accurate and sourced from the FDA? For example, is it explicitly stated that the Covid-19 vaccines can limit asymptomatic spread? Does the CDC state getting the vaccine will eliminate the need for masks and social distancing? Are the short- and long-term risks of the vaccine known? Ask for their sources on every statement made within the refusal form.

- What will happen if you don't sign the refusal form?

IT IS HIGHLY SUGGESTED TO GET EVERYTHING IN WRITING AND WORK WITH YOUR HR DEPARTMENT AS SOON AS POSSIBLE.

Educate your employer on the limitations of compensation if serious injury or death occurs from receiving the vaccine.

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.

Source: https://www.hrsa.gov/cicp

Health Resources & Services Administration

Countermeasures Injury Compensation Program (CICP)

Type of Injury Covered	• Serious physical injuries • Deaths
Program Funding	Appropriated Funds
Payment of Legal Fees and Costs	Attorneys' fees and costs are not paid by the program.
Appeal Rights	One step administrative reconsideration possible. No judicial appeal permitted.

Source: https://www.hrsa.gov/cicp/cicp-vicp

If seriously injured or there is a fatal outcome from receiving the Covid-19 vaccines, according to the Health Resources & Services Administration, any attorneys' fees will not be reimbursed. There is no judicial appeal permitted either. Also, the manufacturers will not pay for serious injury or death caused by these products. Claims are funded through taxpayer dollars via appropriated funds.

EDUCATE YOUR EMPLOYER ON ALL CIRCUMSTANCES AROUND THE COVID-19 VACCINES. KNOW YOUR RIGHTS AND ADVOCATE FOR YOURSELF AND YOUR EMPLOYEES.

WHAT IS INFORMED CONSENT?

"PATIENTS HAVE THE RIGHT TO RECEIVE INFORMATION AND ASK QUESTIONS ABOUT RECOMMENDED TREATMENTS SO THAT THEY CAN MAKE WELL-CONSIDERED DECISIONS ABOUT CARE. SUCCESSFUL COMMUNICATION IN THE PATIENT-PHYSICIAN RELATIONSHIP FOSTERS TRUST AND SUPPORTS SHARED DECISION MAKING."

Source: https://www.ama-assn.org/delivering-care/ethics/informed-consent