

# Availability of Pfizer/BioNTech COVID19 Vaccine for US Congress Continuity of Government Purpose



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TO: All Members of Congress and Staff

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DATE: December 17, 2020

SUBJECT: **Availability of Pfizer/BioNTech COVID19 Vaccine for US Congress Continuity of Government Purpose**

## **Availability of Pfizer/BioNTech COVID19 Vaccine for US Congress Continuity of Government Purpose**

The Food and Drug Administration granted an Emergency Use Authorization to the Pfizer-BioNTech COVID19 vaccine on December 12, 2020. I have been notified by the National Security Council that consistent with Presidential Policy Directive 40 (2016), Congress and the Supreme Court, along with Executive Branch agencies, will be provided with a specific number of COVID19 vaccine doses to meet long-standing requirements for continuity of government operations. These requirements are focused on essential operations and personnel. PPD-40 establishes continuity requirements for the Federal Government and states that continuity actions for the Executive Branch should be undertaken in parallel with the Legislative and Judicial branches of government. The small number of COVID19 vaccine doses we will be provided reflects a fraction of the first tranche of vaccines as it is distributed throughout the country.

The following are some questions and answer format that may be helpful to inform your individual judgment about participating in this voluntary vaccination. **My recommendation to you is absolutely unequivocal: there is no reason why you should defer receiving this vaccine. The benefit far exceeds any small risk.**

### **Questions and Answers About Pfizer/BioNTech COVID19 Vaccination:**

Where will I go to receive my vaccination?

Vaccination will take place by appointment in the **Rayburn Health Unit, 2050**

How Can I get an appointment?

**Members of Congress are asked to call 202-225-5421 to schedule their vaccination.** The first of two injections is being scheduled at this time. A second appointment will be required for the day 21 injection. My website contains the vaccine information form that you should print out, complete and bring with you to the appointment. You will also need to complete the Daily symptom inventory checklist on the back of the form to be sure that you do not have any coronavirus symptoms on the day of the vaccine [Vaccine Screening Questionnaire and Symptom Inventory](#). The OAP website ([Attending Physician](#)) contains other references to Pfizer documents and links to the CDC vaccine information pages.

Once we have completed the vaccination of the Members, we will follow a process to identify the continuity-essential staff members in the various divisions of the Capitol community in the coming weeks. The appointing process will then continue until the small vaccine supply is exhausted. A second dose scheduling process will then begin later.

### How effective is the Pfizer BioNTech COVID19 vaccine?

This Vaccine is approximately 95 per cent effective in preventing disease. It may not protect against infection (acquiring the coronavirus but not becoming sick) The phase 3 trials of the Pfizer/BioNTech vaccine involved 42,000 people, about half of whom got the experimental vaccine, and the rest a placebo. In total, 170 people fell ill with COVID19. Only 8 of them were in the vaccine group; 162 had received the placebo. Approximately 5 percent of cases were in the vaccine group, which is where the 95 per cent figure comes from. You can read about the Food and Drug Administration's vaccine full vaccine summary at [FDA Pfizer COVID19 Vaccine Summary](#).

### What is in the vaccine?

The active ingredient is messenger RNA (mRNA) that carries instructions for making the virus's spike protein, that the virus uses to gain entry to your cells. The mRNA is synthetic, not extracted from actual viruses. It is delivered in a tiny sphere of inert fatty material called a lipid nanoparticle. The RNA-bearing nanoparticles are mixed in saline solution and injected into muscle tissue in your upper arm. The mRNA is then taken up by special immune cells, which then follow instructions, coded in the mRNA, to make the coronavirus spike protein, just as they would do if they had become infected with the actual virus. The mRNA instruction only produces a small piece of the virus and cannot make a person sick nor can it cause the virus to be manufactured in the person's body. This mRNA instruction only lasts a short time inside the cell and is subsequently disintegrated by the cell. (Think of it like an Instagram picture of the face the virus that promotes recognition by others and then disappears) It does not become part of your genetic code. You cannot pass this on to other people from products of your blood nor can you pass this on to unborn children.

The COVID19 Spike protein is recognized as foreign by your immune system, which mounts an attack against it. Antibodies, B cells and T cells (long-lasting regulatory parts of your immune system) from your body are activated. Your immune system learns from this how to defeat the virus and is primed to mount a swift response if it encounters the coronavirus again.

### How long does the immune memory last?

This information is not yet known. The clinical trial participants are being followed over time to help answer that question. Some experts believe protection could last months or even years. You may need to have another booster vaccine in the future.

### How long does it take for immunity to develop fully after vaccination?

We know that partial protective immunity builds up within weeks of the first dose and is more complete 4 weeks after the second dose.

### It's a two-shot vaccine, so what happens if people miss their second shot? Is a single shot still protective?

Two shots are needed, and the second shot is required to attain immunity. The gap between doses in the trial ranged between 19 and 42 days. Only 2 percent of people in the trial missed their second dose so it isn't entirely clear what happens under those circumstances.

### Are there any side effects?

Sometimes, but they are mild and last 1-2 days. It is best to think of these as evidence of your immune system responding as expected to the vaccine rather than something bad. In the trial, the vaccine was well-tolerated, and an independent data monitoring committee reported no serious safety concerns. The worst side effects were fatigue and headaches, more common after the second dose. Approximately 26% reported mild fatigue with the first injection and 21% with the second injection.

Approximately 56% of people reported mild injection site pain, 47 percent of people reported mild fatigue and 27 percent a mild headache. These are common reactions you would have with vaccination. Older adults reported fewer and milder side effects.

Warmth, slight swelling and a little bit of firmness are typically seen at the injection site. In the clinical trials, 55% had mild injection site soreness, 3% had mild redness and 4% had mild swelling. These numbers increased slightly with the second dose

Three percent of individuals in the clinical trial developed a fever (temperature greater than 100.4) with the first injection while 16% did on the second injection. Approximately 11% developed mild muscle pains on the first injection while 15% it on the second injection

#### Did some people have life-threatening allergic reactions?

Yes, but this appears infrequently. An estimate of this specific risk cannot be derived from the clinical trial as individuals who answered “yes” on prior severe allergic reactions were excluded from the study. So far, There are 2 cases in United Kingdom and 1 case in the United States where individuals who are known to have severe allergic reactions to other drugs (so severe they required hospitalization or requirements to always carry epinephrine autoinjector pens) had difficulty breathing requiring emergency measures administered at the vaccine clinic. Our vaccination clinic is prepared should something like that arise to provide immediate therapy. You will be required to wait for 15 minutes of observation at our vaccination clinic before you leave as an additional safety measure. You will be asked to inform the vaccine center staff if you fall into the category of having had a severe allergic reaction to a previous medicine or vaccination. CDC has not determined this to be a reason against receiving the vaccine. You will still be able to receive the vaccine, but additional observation periods and other measures for your safety will be implemented.

Is there a risk of Bell's Palsy? Bell's palsy is a temporary injury to one of the facial nerves. People who develop this notice that one side of their face stops moving (their eye won't close, and they have trouble smiling, chewing food, whistling and often drooling from the effected corner of their mouth). It is not an unusual occurrence in healthy people. A few cases of Bell's palsy occurred in vaccine recipients, but not more than would have been expected to occur in a group of people who did not receive vaccine. It is possible that with many more people receiving vaccine, Bell's palsy may be seen more often and then included as a risk of the COVID19 vaccine.

#### Does it work in older people?

Yes. Trial participants were aged up to 85, and the efficacy in people over 65 was 94 percent – slightly lower than the overall number but still very protective, and much higher than some vaccine experts thought.

#### What about other vulnerable groups?

The vaccine appears to be equally effective regardless of recipients' age, sex and ethnicity. It has been tested extensively in people who have already had the virus and it did not cause any ill effects. It has also been tested in people with “stable” pre-existing conditions – also known as comorbidities – including diabetes, cancer, hepatitis B, hepatitis C and well-managed HIV.

#### What if I am pregnant or breast-feeding?

Additional tests are now underway to further determine the safety and effectiveness of the vaccine in individuals who are pregnant. It is best for individuals who are pregnant to consult with their obstetrician about receiving this vaccine. The risk of coronavirus to pregnant women exceeds any slight risk of this vaccine and you should consider taking it. The vaccine is not excreted in breast milk.

#### Does it protect everyone?

No. In the trials, out of about 20,000 people who were given the vaccine, eight caught COVID19 and one became seriously ill. In contrast, 164 people who received the placebo fell ill, nine severely. It isn't known why some people didn't respond to the vaccine.

#### Does it stop people from catching and transmitting the virus?

The answer is not known. The trial was designed to test for symptomatic COVID19 and confirmed infection with the virus. Assessing whether the vaccine prevents transmission is a matter for a future study.

#### Has the full data from the trial been published yet?

No, it has not, but there is nothing unusual about that. The manufacturers have promised that full details will appear in scientific publications. Additional information will be incorporated into the FDA's ongoing assessment of the vaccine as they prepare for issuing a licensed product approval later in 2021.

#### Does this vaccine contain any preservatives or was it made using fetal tissue?

The vaccine does not contain any preservatives, (thimerosal (mercury) for example). No fetal stem cells or human blood products are involved in its production.

Does the vaccine have unusual cold storage requirements?

The vaccine must be kept at -70° C, (94 degrees below zero Fahrenheit) which requires special cooling equipment. Once thawed, the vaccine can be stored in a regular fridge at 2°C to 8°C for up to five days. The vaccine lasts only a short time at room temperature. These special handling characteristics require us to take specific measures for this vaccination such as requiring appointments and only using one location at this time.

What is the interval between the vaccine doses?

The preferred interval is 21 days. However, it is possible to receive the vaccination anytime between 17 and 21 days after the first injection.

Can I arrange for my spouse or family members to receive this vaccination?

As a Continuity of Government program, I am not authorized to offer COVID19 vaccination to spouses or family members. I suggest that they consult their local health care provider or county health department to determine access to coronavirus vaccine as it is distributed throughout the United States.

Can you arrange to ship the dose intended for me to my State of residence

The vaccine has very specific cold storage and reconstitution requirements, it cannot be sent to another location.

Can I stop wearing a mask and quit social distancing guidelines?

Absolutely not, it is critical for the success of this vaccine that you continue strict adherence to social distancing guidelines, maximum teleworking of your staff, and use of your mask or face cover.

My doctor has asked me to get other vaccines at this time such as tetanus or shingles is that okay?

No other vaccine should be administered within 14 days of the coronavirus vaccination. This is to ensure a prompt and accurate assessment of adverse effects attributable to the coronavirus vaccine.

I feel well and am presently in quarantine for coronavirus, can I receive the COVID19 vaccination ?

No, you must complete your quarantine prior to coming to receive the vaccination.

When I was sick with COVID19 infection my doctors gave me an injection of a special antibody to fight the virus. Can I receive the COVID19 vaccine at this time?

No, you must wait at least 90 days after receiving any therapeutic antibody injections for the treatment of COVID 19.

I have recovered from COVID19 infection earlier this year, should I receive the vaccine now?

Yes, you should receive the vaccine. Individuals with previous infection received the vaccine in the clinical trials without appreciable adverse effect. The duration of protection from natural infection is not known and vaccination may extend your degree and duration of protection.

If I start with the Pfizer/BioNTech COVID19 vaccine, can I switch to another vaccine such as the Moderna vaccine?

No, both of your vaccinations must be with the same manufacturer's vaccine product.

## **CORONAVIRUS PREVENTION SUMMARY GUIDELINES**

During these unprecedented times, we would like to emphasize actions you can take to help minimize your chances of being exposed to or transmitting COVID-19. These guidelines reflect the existing CDC recommendations with some modifications to reflect a sustained, increase in disease transmission in our region and further measures to reduce coronavirus transmission.

- Complete the Daily Health Screening Inventory each morning. ([Daily Health Screening Inventory](#)) If you answered yes, do NOT attend any activities. Contact the OAP (see below) to discuss any need for further

evaluation. If you had not yet had your 2021 influenza vaccination, please let us know and we can arrange this for you here at the OAP

- Face coverings are a critical necessity for all events where you are in the presence of someone outside your family unit. Please wear the face cover at any time you are outside your home. For recognition by a Chair or to speak in the Hall of the House or committee hearing , you must wear a face cover.
- Consider switching from cloth face covers to more effective personal protection “masks for filtration” such as a surgical mask with ear loops or string ties. See my website on mask selection recommendations. ([Face Shield and Mask Wear Update](#))
- Always maintain at least 6-feet of separation between yourself and other individuals outside your family unit. Look for signage with additional guidance at choke point areas such as elevators, escalators, line queues, and waiting areas among others.
- Make frequent use of hand sanitizer gels/wipes and surface cleaning wipes.
- During events, pay increased attention to your surroundings with a focus on avoiding prolonged (more than 5 minutes) and/or close contacts. Remember that the standard of close contact is more than 15 minutes at closer than 6 feet when added up over an entire 24-hour period. It is relatively easy to become classified as a close contact of an identified infected colleague if you are not careful and become subject to quarantine.
- During vehicle transportation, you must wear your face cover and open windows in the vehicle if possible. Shared rides and vehicle occupancy must be kept to an absolute minimum.
- Travel in commercial travel systems places you at increased risk for acquiring coronavirus due to crowding at gates, terminals, jetways, train and bus stations, aircraft seating configurations and vehicle boarding and disembarkation. Individuals’ compliance with social distancing in these situations has been highly variable, and you need to take personal interest in your protective stance. Wherever possible, wear a face shield in addition to a face cover if you anticipate close crowding at these occasions. Do not remove your mask or face shield to consume a beverage or eat a meal while in transit. During this time of dramatic and sustained increase in coronavirus transmission nationally, if you can remain in the Washington, DC region and avoid travel, that would be preferable.
- Due to experience in the Congress of increased disease frequency occurring in certain circumstances, CDC and I recommend that you DO NOT ATTEND dinners, celebrations, receptions, or restaurant gatherings outside of your family unit. Select outside seating or carry-out if available when dining alone or with your family unit. Do not schedule or attend office-based receptions or celebrations.
- While face cover removal is briefly allowed for eating in designated areas, you **MAY NOT** sit at a table with a beverage, or a partially consumed food item without a face cover for a prolonged period. Replace your face cover immediately after your meal/beverage is consumed.

For medical concerns (COVID or non-COVID related) contact the OAP at the numbers below. A physician is available to discuss your concern and provide guidance for further evaluation as needed.

- 8:30 AM – 5:00 PM weekdays: Call the OAP Main Office at 202-225-5421.
- All other times: Contact the Capitol Operator at 202-224-2145 and ask for the On-Call Physician.

Further information is available at: <https://attendingphysician.house.gov/>

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