The purpose of this memorandum is to provide you with bases for objecting to the administration of the COVID-19 Pfizer /BioNTech Manufacturing GbmH vaccine. Given the current licensing status of the vaccine, we see several bases for objection, regulatory, procedural and based on the individual conscience of the servicemember.

1. Regulatory objection.

   The regulatory objection exists for service members who have already had COVID-19. DoD regulations specifically allow an exemption from vaccination for service members who show evidence of immunity based on "documented infection". See Army Reg. 40-562/Air Force Inst.48-110_IP, Para. 2-6a(1)(b), *Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases*, 7 Nov 2013. Accordingly, service member who have previously tested positive for COVID-19 should advise their commanders that they are exempt from additional vaccination for the disease pursuant to this regulation. Moreover, service members who have already received the shot after having been diagnosed with the virus should notify me using the email below; their rights under the Regulation may have been violated by the service's failure t check their vaccination status.

2. Procedural objections.

   The procedural objections to the administration of the vaccine are based on the requirements of the license issued to BioNTech, the German manufacturing company that actually holds the license for the production and distribution of the vaccine in the United States.

   As an initial matter, you should note that the vaccine licensed by the FDA is the one produced by BioNTech, not Pfizer. See, FDA Letter to BioNTech GmbH, "BLA Approval", 23 Aug 2021, pp.1-2. This particular vaccine is marketed with the name "COMIRNATY." The Pfizer version of the vaccine has not been licensed for US use and will continue to be dispensed under the Emergency Use Authorization granted by the FDA. FDA has indicated that there is not enough COMIRNATY to provide everyone with licensed product (see, Letter from D. Hinton, FDA Chief Scientist, to E. Harkins, Pfizer Inc., 23 Aug 2021, p. 5). There may

well be shortages of the vaccine on military facilities, causing medical providers to resort to using the EUA vaccine instead of the COMIRNATY vaccine. YOU CAN ONLY BE OREDERED TO TAKE THE VACCINE IDENTIFIED ON THE LABEL OF THE VIAL AS "COMIRNATY".

You should request to see the vial from which the injection is taken before you get the shot. If the vial does not say "COMIRNATY", the vaccine is not licensed for use, and you may not be ordered to take the shot. You should advise the administering health care provider that you will not take an unlicensed vaccine in violation of federal law. You should also notify me at the email address below that your facility was attempting to inoculate service members with unlicensed vaccine.

There are date restrictions on the licensed vaccine as well. These requirements are found on Page 2 of the FDA licensing letter of the August 23, 2021, under the section entitled to "Dating Period". Specifically, the license granted to BioNTech states that the vaccine is licensed for use within nine months from the date of manufacture as long as the vaccine is stored between -130° F and -76° F. If the vaccine has been stored outside of these parameters, or is past the nine-month date of manufacture, its use is not authorized by FDA and is considered to be off-license.

The U.S. Department of Defense previously demonstrated problems managing vaccines with expiration dates and specific storage requirements. During the anthrax vaccination program DoD was inoculating service members with vaccine that was outdated and stored in conditions well outside those licensed by FDA. It is not unreasonable to expect that the relatively short time of vaccine efficacy-nine months-and the stringent requirements for its storage at extremely low temperatures will prove to be problematic for many DoD medical facilities.

We suggest that the service member being inoculated ask that, along with the lot number of the vaccine vial used, the date on the vial be annotated on his shot record. The service

member should reject any vaccination with a lot number date that is more than nine months old.

The request should be made to the technician administering the vaccine, asking, "Would you please put the vial date on my record as well? If I have a reaction, I want to make sure that there is a clear record of the lot and date of manufacture." 0bviously if there is no date on the vial (this happened with anthrax vaccine), then the vaccine should be refused. Please notify me at the email below if you encounter this situation.

The service member should also inquire about the storage condition of the vaccine being administered to her. Specifically, she should ask if the vaccine has been stored in a refrigerator prior to being administered, and what kind of temperature is typically maintained in the storage area. If it was kept in a standard refrigerator or even a standard refrigerator freezer (or kept unrefrigerated), then the storage is not compliant with the terms of the FDA license and the service member should refuse vaccination on that ground.

The request should be made to the technician administering the vaccine, asking, "How is the vaccine stored here at (base name) facility? Is it in a refrigerator, or some other cold storage? Any idea how cold it is in that storage?" Again, please notify me at the email below if you encounter this situation.

1. Conscience or religious objections.

The BioNTech vaccine used a fetal cell line in early phase research and development to confirm efficacy prior to production and manufacture (note that Johnson & Johnson uses a fetal cell line for production and manufacture). These fetal cell lines were derived from two elective abortions that occurred in the 1970s and 1980s. The cells from these fetuses have continued to be grown as a cell line for use in medical research (*see, COVID-19 Vaccines & Fetal Cells*, Michigan Dept. of Health and Human Services Release, 21 Apr 2021).

Service members may have a conscientious objection to being injected with a substance either using or in some way derived from the use of human tissue, and specifically from the tissue of aborted fetuses. Such objections may be based on religious grounds, see, e.g., Guidance from the National Catholic Bioethics Center, 11 May 2020, or on conscience-based concerns over the use of involuntarily killed fetus material used in the vaccine. *See*, Congressional Research Service*, Defense Health Primer: Military Vaccinations*, 6 Aug 2021; Army Reg. 40-562/Air Force Inst.48-110_IP, Para. 2-6(b)3, *Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases*, 7 Nov 2013. Service members seeking to use this objection should go through their individual command chain to apply for a conscientious objection exception to the vaccine.

Note that the successful use of a conscientious objection to the COVID vaccine may have significant impact on the service member's career. It is quite likely the service member will be classified as not world-wide deployable. This may result in an administrative separation from active and reserve duty.

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