IN THE UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF OHIO – Cincinnati Division

| HUNTER DOSTER, et. al. | : | Case No.: 1:22-cv-00084 |
|-----------------------------|---|-------------------------|
| Plaintiff | : | |
| v. | : | |
| Hon. FRANK KENDALL, et. al. | : | |
| Defendants | : | |

RESPONSE TO GOVERNMENT'S BRIEF REGARDING CLASS-WIDE PRELIMINARY INJUNCTIVE RELIEF

1. Introduction

This Court entered a simple, straightforward Order: "Defendants are ORDERED to file a supplemental brief, no later than July 21, 2022, and no more than ten (10) pages in length identifying why this Court should not grant a class-wide preliminary injunction." (Doc # 72, PAGEID # 4469). Presumably, this Court's Order regarding supplemental briefing was prompted by its question "as to whether any significant change precludes extending the current preliminary injunction to include all Class Members." (*Id.*, PAGEID 4467). Sifting through the 30 pages Defendants filed in opposition, it is apparent that nothing has significantly changed. Rather, Defendants' opposition serves to validate the initial preliminary injunction.

What is new, though, is that Defendants no longer hide the fact that they believe this Court should stay in what they perceive to be its lane. (Doc # 47). That is because Defendants have already judged their vaccine mandate order to be lawful, and they have made it unequivocally clear that any further decision ". . . should be left to the military chain of command, and the Legislative and Executive branches." (Doc # 73-1, PAGEID # 4499-4500). As the Court can see, nothing regarding the necessity of a preliminary injunction has changed.

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Unless enjoined, Defendants will continue to flagrantly violate the Religious Freedom Restoration Act and the First Amendment.

Plaintiffs, through Counsel, now provide this further response to Defendants' Brief [DE#73] regarding class-wide preliminary injunction relief. Almost all the issues raised by Defendants have been extensively briefed. [DE#13, 21, 30, 39, 46, 53, 56, 60]. We begin by incorporating that briefing and evidence previously submitted by reference.

2. The Class-wide Injunction Does Not Interfere with Ongoing Legal Proceedings

Defendants argue that the class certification here conflicts with other cases and rulings that found that those Defendants could substantially burden the religious freedom of service members, and they make the claim that having conflicting rulings is a good thing. Nothing could be further from the truth. First, avoiding conflicting rulings on identical facts and law is generally the point of class actions and certifications. *City of North Royalton v. McKesson Corp.* (*In re Nat'l Prescription Opiate Litig.*), 976 F.3d 664, 674 (6th Cir. 2020) ("Rule 23 permits litigation classes primarily for the purposes of aggregating and adjudicating common claims for trial, which can avoid conflicting judgments in individualized proceedings and can more efficiently resolve the claims of the class through a single lawsuit.")

Second, to avoid the risk of inconsistent rulings in other class actions, some courts have excluded from the class persons who bring individual claims. Here, if the Court desired, it could exclude from the Class those who are pursuing individual actions.¹ *Vidal v. Wolf*, 501 F. Supp. 3d 117, 136-137 (NYED 2020). Courts have wide discretion to modify the definition of a class.

¹ The Court could exclude such individuals from the Class with the following additional language, which would have the effect of giving persons a reasonable opportunity to cease or stay in progress actions: "Excluded from the class is ... or (ii) is deemed to have opted out, by asserting and maintaining a claim as a named or identified plaintiff (and not as a member of a class or a putative class) under RFRA or the First Amendment against the Government in relation to the vaccination mandate, in an action that is still pending on or after September 30, 2022, not inclusive of this action, or actions that are stayed pending final adjudication of this action."

Powers v. Hamilton County Pub. Defender Comm'n, 501 F.3d 592, 619 (6th Cir. 2007) ("district courts have broad discretion to modify class definitions").

3. Plaintiffs Have Met the Evidentiary Burden on Threshold RFRA Elements

This Court already found that Plaintiffs met their evidentiary burden under RFRA. However, we address Defendants' most recent attempt to argue that they have not substantially burdened Plaintiffs' sincerely held religious beliefs in light of the newest COVID-19 vaccine to receive emergency use authorization, Novavax. Specifically, Defendants falsely claim that Novavax is not morally problematic for those who object to vaccines which have a connection to aborted fetal tissue and they cite to Novavax's self-serving and false public statements that its' product has no connection to aborted fetal tissue. The evidence is clear and admitted by Novavax itself: aborted fetal tissue was used to test its vaccine.²

Defendants next argue that Novavax will not be religiously objectionable to everyone who has an aborted fetal cell objection. We acknowledge that service members who do not have an objection to vaccines tested on the cell line from an aborted child, and have no other religious objection to Novavax, can receive this vaccine without violating their religious beliefs when it is soon available, and FDA approved.³ Defendants also fail to recognize that Plaintiffs and class members who have since gotten a vaccine (like Lts. Ramsperger and McCormick), or will do so as this case progresses, still require ongoing relief to prevent Defendants from punishing them

² <u>https://wng.org/roundups/pro-lifers-question-novavaxs-fetal-tissue-claim-1655411473</u> (last visited 7/22/2022); <u>https://personhood.org/2022/02/22/yes-novavax-used-hek293-an-aborted-fetal-cell-line/</u> (last visited 7/22/2022); <u>https://www.lifesitenews.com/opinion/novavax-covid-jab-linked-to-aborted-fetal-cells-through-laboratory-testing/</u> (last visited 7/22/2022); see, also, Declarations of Plaintiffs, DE#30-4 through DE#30-20.

³ As an aside, for those Plaintiffs and class members whose only objection is the connection to aborted fetal cells (which is, admittedly, the vast majority), it is appearing more likely every day that a vaccine may come to market in the next 6 months that will alleviate those concerns. <u>https://ir.ocugen.com/news-releases/news-release-details/ocugen-announces-fda-removes-clinical-hold-phase-23-clinical</u> (last visited 7/22/2022). Thus, and contrary to the misrepresentation contained throughout Defendants' pleadings, Plaintiffs with those specific religious objections truly seek only a temporary exemption.

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for their past non-compliance due to their religious beliefs. *Ramsek v. Beshear*, 989 F.3d 494, 500 (6th Cir. 2021) (declining to find claims moot because of possibility of prosecution for past non-compliance).

Finally, Defendants claim that Plaintiffs must provide further evidence that every member of the class had his or her religious beliefs substantially burdened. But this ignores the dispositive evidence that a Chaplain has already confirmed the sincerity *and* substantial burdening of beliefs of each service member the Court defined as a class member.

4. Less Restrictive Means are Available for All Class Members

Defendants argue that "least restrictive means" is not the same for everyone, and this requires a close, case-by-case adjudication of the facts in each individual case. We disagree. Defendants' own evidence establishes they systemically denied <u>every</u> religious accommodation, other than a handful granted to servicemembers at the end of their term of service, without even considering the various less restrictive means that are available. [DE#30-2, Transcript with Government admission about religious accommodations].

It bears noting that this burden, proving less restrictive means are not available, falls on Defendants. "[N]arrow tailoring **requires the government to show** that measures less restrictive of the First Amendment activity could not address its interest in reducing the spread of COVID." *Tandon v. Newsom*, 141 S. Ct. 1294, 1296-1297 (2021) (emphasis added). "Where the government permits other activities to proceed with precautions [as the Air Force does here], **it must show** that the religious exercise at issue is more dangerous than those activities even when the same precautions are applied." *Id.* (Emphasis added). "Otherwise, precautions that suffice for other activities suffice for religious exercise too." *Id.* In enacting RFRA, Congress "expressed its clear understanding that the heightened standard of review" (closely scrutinizing Government

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action) applies to the military. *Singh v. McHugh*, 185 F. Supp. 3d 201, 218 (D.D.C. 2016) (citing House and Senate reports).

Sifting through all its proof compels the conclusion that Defendants wholly fail to meet their burden under *Tandon*. At no point in its submissions do Defendants prove that a military member who does not receive a vaccine due to a religious objection is a greater risk to the military mission than someone who does not receive a vaccine due to a medical or administrative reason. Logically, Defendants could never meet their burden as the risks would always be the same. Once, again, nothing has changed.

"Risks of contagion turn on [the failure to receive the vaccine]; the virus does not care why they [did not do so]. So long as that is the case, why do the orders permit people who [have medical or administrative exemptions to avoid the requirement, but not permit religious exemptions]"? *Maryville Baptist Church v. Beshear*, 957 F.3d 610, 615 (6th Cir. 2020). When applying a parallel statute that "mirrors RFRA" in the prison context, the Supreme Court unanimously rejected a similar request for "a degree of deference that [wa]s tantamount to unquestioning acceptance." *Holt v. Hobbs*, 574 U.S. 352, 357, 364 (2015). Instead, the Court applied strict scrutiny to hold that the prison's failure to provide a religious accommodation violated the statute. *Id.* at 369–70. *Holt* provides the proper framework for resolving RFRA claims against the military. *Singh*, 185 F. Supp. 3d at 221-22.

In *Dahl v. Bd. of Trustees of W. Mich. Univ.*, 15 F.4th 728 (6th Cir. 2021), as here, the defendant "requires [persons] to be vaccinated against COVID-19, but it considers individual requests for medical and religious exemptions on a discretionary basis. [Plaintiff] applied for religious exemptions. The [defendants] ignored or denied their requests..." *Id.* And, to be clear, in *Dahl*, it was not even the denial of an educational benefit, a scholarship, or even membership

on a particular sport team but, instead, merely the denial of participation in team sport activities. *Id.* In contrast, the consequences to Plaintiffs and the Class here are far more severe.

In other words, Defendants' own evidence establishes they have not engaged in this very analysis in handling these adjudications of religious exemptions. Their own evidence also establishes that their medical and administrative exemptions are not confined to **any** position, career field, or duty location. Those favored exemptions were granted for service members throughout the Air and Space Force. For example, any pregnant Air Force member receives an exemption, no matter her assignment or duty station. Plaintiffs also adduced evidence that the unvaccinated Air Force members and their unites were able to accomplish its mission for the past year (and prior to that). [DE#30-4 through DE#30-20]. Defendants do not refute this evidence.

"But wait," say Defendants – their favored medical and administrative exemptions are allegedly temporary, while they claim Plaintiffs seek permanent exemptions. This is false. Plaintiffs' position, which they have been clear about from the start, is that they all seek temporary exemptions. And, Air Force Instruction 48-110 *only* allows temporary accommodations for religious and administrative exemptions.⁴ FDA approval of Covaxin, for instance, is likely to result in a number of the original 18 Plaintiffs and the Class receiving the vaccine once it becomes available to them. Unfortunately, that is not something that Plaintiffs control. Rather, ironically, it is solely within the control of the Government and FDA regulators.

Lastly, Defendants' own internal guidance for their medical personnel does provide for permanent medical exemptions from the COVID-19 vaccine.⁵ Their guidance demonstrates that

⁴ <u>https://static.e-publishing.af.mil/production/1/af_sg/publication/afi48-110/afi48-110.pdf</u> (at ¶2-6) ("For the Air Force, permanent exemptions for religious reasons are not granted; the MAJCOM commander is the designated approval and revocation authority for temporary immunization exemptions.").

⁵ See attached COVID-19 Vaccine Exemptions Guidance for AFMS Medical Personnel and COVID-19 mRNA Vaccine Provider Medical Exemption Guidance 11 SEPT 2021 allowing permanent medical exemptions.

Defendants have also chosen to disregard the same CDC guidance which they purport to base their compelling interest on when it comes to certain medical exemptions they are granting.⁶ The disparate treatment is blatant.

5. Equities and Public Interest Strongly Favor a Class-Wide Injunction

Defendants argue that granting a preliminary injunction to the class would ". . . amplify harm 'across the Force, creating significant and irreparable harm in good order and discipline, force health protection, and military readiness; seriously endangering the Department of the Air Force's ability to decisively execute its mission." (Doc # 73-1, PAGEID # 4482). Nevertheless, they fail to cite one instance of how the Air and Space Force has been harmed by these same unvaccinated Airmen (now class members) for the past *two years*. Notwithstanding this, for 10, now going on 11, months, these same class members have been unable to travel, attend required schooling, and deploy. Not because they were physically unable to travel or deploy, but because Defendants made the decision to treat their unvaccinated Airmen this way once vaccines became available. (Doc # 73-1, PAGEID # 4480). It is not surprising then that Lt. Gen. Schneider cannot cite a single example of this alleged irreparable harm in his 18-page declaration.⁷ The class he references that would cause this serious endangerment to the Air

https://www.medrxiv.org/content/10.1101/2022.03.17.22272529v1 (last visited 7/25/ 2022)

Specifically, Defendant's documents state, "The benefits of vaccination in pregnancy against COVID-19 outweigh the risks." However, Defendants have decided that pregnant women qualify for a temporary medical exemption, while granting no requests for an accommodation for those who seek a religious accommodation. ⁶ *Id*.

⁷ Plaintiffs note that although not needed here, there is a large and growing body of evidence that unvaccinated individuals who have had COVID-19 are far more protected than those who are vaccinated with 1 dose of J&J or 2 doses of an mRNA vaccine. So, it is unsurprising that Lt. Gen. Schneider cannot cite a single example of harm. *See, also, Effects of Previous Infection and Vaccination on Symptomatic Omicron Infections*, New England Journal of Medicine, Altarawneh, et. al., June 15, 2022, <u>https://www.nejm.org/doi/full/10.1056/NEJMoa2203965</u> (last visited 7/25/2022).

Protection of prior natural infection compared to mRNA vaccination against SARS-CoV-2 infection and severe COVID-19 in Qatar – "Natural infection was associated with stronger and more durable protection against infection, regardless of the variant, than mRNA primary-series vaccination."

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Force mission accounts for less than 2% of the entire Air and Space Force based on Lt. Gen. Schneider's numbers, spread out over and between hundreds of thousands of other service members.⁸ Given that the Air and Space Force has systemically been driving out or coercing religious believers to accede to its vaccination requirement in the face of sincerely held religious beliefs, the actual numbers at this point are likely far less than that.

As this Court has already concluded, ". . . the limited scope of this preliminary injunction will not cause substantial harm to the Air Force because '[Plaintiffs'] religious-based refusal to take a COVID-19 vaccine simply isn't going to halt a nearly fully vaccinated Air Force's mission to provide a ready national defense." *Doster v. Kendall*, --- F. Supp.3d ---, 2022 U.S. Dist. LEXIS 59381 at 48 (SDOH 2022). (*citing Air Force Officer v. Austin*, --- F. Supp.3d ---, 2022 WL 468799, at *12 (NDGA 2022)). The continued preservation of Constitutional rights is always in the public interest and here it is no different. (*Dahl v*, 15 F.4th 728 at 736, "it is always in the public interest to prevent the violation of a party's constitutional rights.").

SARS-CoV-2 Naturally Acquired Immunity vs Vaccine-induce Immunity, Reinfections versus Breakthrough Infections: a Retrospective Cohort Study – "Naturally acquired immunity confers stronger protection against infection and symptomatic disease caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 twodose vaccine-induced immunity." https://pubmed.ncbi.nlm.nih.gov/35380632/ (last visited 7/25/ 2022)

Effects of Previous Infection and Vaccination on Symptomatic Omicron Infections – "The effectiveness of previous infection alone against symptomatic BA.2 infection was 46.1% (95% confidence interval [CI], 39.5 to 51.9). The effectiveness of vaccination with two doses of BNT162b2 and no previous infection was negligible (–1.1%; 95% CI, –7.1 to 4.6), but nearly all persons had received their second dose more than 6 months earlier... Previous infection alone, BNT162b2 vaccination alone, and hybrid immunity all showed strong effectiveness (>70%) against severe, critical, or fatal Covid-19 due to BA.2 infection. Similar results were observed in analyses of effectiveness against BA.1 infection and of vaccination with mRNA-1273."

https://www.nejm.org/doi/pdf/10.1056/NEJMoa2203965?articleTools=true (last visited 7/25/ 2022)

Duration of immune protection of SARS-Cov-2 natural infection against reinfection in Qatar – "Effectiveness of primary infection against severe, critical, or fatal COVID-19 reinfection was 97.3% (95% CI: 94.9- 98.6%), irrespective of the variant of primary infection or reinfection, and with no evidence for waning." <u>https://www.medrxiv.org/content/10.1101/2022.07.06.22277306v1.full.pdf</u> (last visited 7/25/ 2022)

⁸ "Similarly, an injunction expanded to apply to 10,000 or more service members. . ." and "As of March 14, 2022, the Department of the Air Force had approximately 501,00 uniformed Service members - . . ." Doc # 73-1, PAGEID # 4490, 4493.

6. Response to Defendants' Arguments About Ambiguities in the Class Definition and the Scope of Injunctive Relief.

We agree with Defendants that questions and disputes have arisen concerning the definition of the class, and the scope of relief, and that clarification of those issues will inure to everyone's benefit.

a. Class Definition

We submit that, for clarification purposes, the Court modify the class definition as

follows:

All active-duty, active reserve, reserve, national guard, inductees, and appointees of the United States Air Force and Space Force, including but not limited to Air Force Academy Cadets, Air Force Reserve Officer Training Corps (AFROTC) Cadets, Members of the Air Force Reserve Command, and any Airman who has sworn or affirmed the United States Uniformed Services Oath of Office or Enlistment and is currently under command and could be deployed, who: (i) submitted a religious accommodation request to the Air Force from the Air Force's COVID-19 vaccination requirement, where the request was submitted or was pending, from September 1, 2021 to the present; (ii) were confirmed as having had a sincerely held religious belief substantially burdened by the Air Force's COVID-19 vaccination requirement by or through Air Force Chaplains; and (iii) either had their requested accommodation denied or have not had action on that request. Excluded from this definition shall be any person within the above class who: (i) opts out, by electronic mail addresses to be filed with Court.⁹

b. Scope of Preliminary Injunctive Relief

We do agree with Defendants that the scope and language of the injunction should be

clarified. We suggest that it be addressed as follows:

Defendants, and their officers, agents, servants, employees, and attorneys, and other people acting in concert or participation with them, who receive notice of this preliminary injunction, are PRELIMINARILY ENJOINED from: (i) taking, furthering, or continuing

⁹ This would allow individuals who wish to be separated and have "had enough" of the Government's bad faith to voluntarily separate. We recognize that the Government's bad faith and illegality have not gone unnoticed by America's youth, but if a member wants to opt out and exit the service, we understand. <u>https://www.nbcnews.com/news/military/every-branch-us-military-struggling-meet-2022-recruiting-goals-officia-rcna35078</u> (last visited 7/22/2022).

any disciplinary or separation measures against the members of the Class for their refusal to receive the COVID-19 vaccine, while keeping in place the current temporary exemption; such disciplinary or separation measures include, but are not limited to, "adverse administrative actions, non-judicial punishment, administrative demotions, administrative discharges, and courts-martial;" for the benefit of Defendants, this includes continuing any administrative separation or punitive processes or initiating the same. However, if there are any court-martials that are in process with members in which the members have been sworn or a witness having been sworn such that jeopardy has attached, those actions shall be stayed, and the Government shall provide notice to this Court of a listing of any such actions within 7 days for further consideration or resolution of this issue;¹⁰ (ii) Defendants shall not place or continue active reservists on no points, no pay status for their refusal to get vaccinated for COVID-19 due to their sincerely held religious beliefs; and (iii) Defendants shall not refuse to accept for commissioning or enlistment any inductee or appointee due to their refusal to get vaccinated for COVID-19 due to their sincerely held religious beliefs. Further, Members who submitted requests for religious accommodation may cancel or amend previous voluntary retirement or separation requests or requests to transfer to the Air Force Reserve. Nothing in this Order precludes the Department of the Air Force from considering vaccination status in making deployment, assignment, and other operational decisions.

7. Conclusion

This Court asked Defendants to identify why this Court should not grant a class-wide preliminary injunction. In response, Defendants made the case for why this Court *should* do so; in any event Defendants failed to bring to the Court's attention any changed circumstances despite this Court's specific request. Instead, things are the same. There is no evidence Defendants have abandoned their policy of denying every religious accommodation request, except for those at the end of their term of service. Defendants have not demonstrated that they ceased favoring medical and administrative exemptions, which would make the questions closer. Instead, Defendants inform the Court they have judged their vaccine mandate to be lawful, so they can continue to violate the United States Constitution and federal statutory law.

Preliminary class injunctive relief should be granted.

¹⁰ Plaintiffs do not believe that there are any such actions at this time.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that I have served a copy of the foregoing by CM/ECF, this 25 day of July, 2022.

/s/ Christopher Wiest_____

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DECLARATION OF WENDY COX

Pursuant to 28 U.S.C. §1746, the undersigned, Wendy Cox, makes the following declaration, under penalty of perjury under the laws of the United States of America, that the facts contained herein are true and correct to the best of my knowledge and belief and that such facts are made based on my personal knowledge:

- 1. My name is Wendy Cox, and I am one of the class counsel for *Doster v. Kendall*.
- 2. On July 25, 2022, in the course of my responsibilities, I received the following true and accurate documents that are public records and records kept in the ordinary course of government business from the Department of the Air Force:
 - a. COVID Vaccine Exemptions Guidance for AFMS Medical Personnel (Exhibit 1)
 - b. COVID19 mRNA Vaccine Provider Medical Exemption Guidance

11SEP2021 (*Exhibit 2*)

Pursuant to 28 U.S.C. §1746, I declare under penalties of perjury under the laws of the United States of America that the foregoing Declaration is true and correct to the best of my knowledge and belief and that such facts are made based on my personal knowledge.

Executed on July 25, 2022.

Wendy Cox Wendy cox

On 23 August 2021, the US Food and Drug Administration (FDA) approved the Pfizer-BioNTech mRNA COVID-19 vaccine, now marketed as COMIRNATY[®], for prevention of COVID-19 disease in individuals 16 years of age and older. Following the FDA news release, the Secretary of Defense <u>announced</u> that the COVID-19 vaccine would be a mandatory requirement for all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard.

This product is intended to guide medical providers through interactions they have with patients who request exemption from the COVID-19 vaccine. IAW <u>AFI 48-110</u>, <u>AFPD 52-2</u>, and <u>DAFI 52-201</u>, members may request exemption from vaccine requirements for either religious or medical reasons. Both exemption packages require a medical appointment. While the member's request is being processed, they are on hold from the vaccine requirement until a final disposition is determined by the appropriate approving authority.

All medical providers must review the Department of the Air Force Plan (*when available*), your local COVID-19 Vaccine Immunization Program (CVIP) plan, and all current information as it pertains to the COMIRNATY[®] vaccine. Prior to meeting with members requesting exemptions, all staff should:

- Have appropriate knowledge and expertise to counsel patients about risks for disease and implications for health management, based on medical and scientific standards and information.
- Be familiar with the requesting individual's medical history and be prepared to consult with other health care professionals as necessary.
- Medical staff should review with patients that:
 - The vaccine is safe and effective.
 - Vaccination offers a layer of protection, in addition to non-pharmaceutical interventions such as: hand washing, use of cloth face masks, social distancing, and tele-working.
- Adhere to standards of nondirective counseling and avoid imposing personal moral values or judgment on the patient.
- Refer to additional resources related to vaccine specifics and vaccine hesitancy.
 - Vaccines for COVID-19 | CDC
 - o <u>Clinical Care Considerations for COVID-19 Vaccination | CDC</u>
 - o Group: DAF COVID-19 Vaccine Confidence Working ... |milBook Home (milsuite.mil)
 - o Workbook: Breakthrough and VAERS (health.mil)

RELIGIOUS EXEMPTIONS:

- IAW <u>DAFI 52-201</u> members requesting a religious exemption require counseling by a military medical provider.
- This appointment is administrative in nature focusing on specific education points.
- Providers must cover at a minimum:
 - Specific information about COVID-19.
 - Specific vaccine information including product constituents, benefits, and risks.
 - Potential risks of infection incurred by unimmunized individuals. For example:
 - An estimated 20-30% of unvaccinated patients who get COVID-19 may develop longterm symptoms.
 - Unvaccinated persons are >2x more likely than vaccinated individuals to get COVID-19 a second time.
 - Full vaccination decreases the risk & severity of complications.
 - Full Vaccination decreases chance of hospitalization >96% and risk of death >99%
- Medical provider will produce a MFR addressed to the member's commander which will be included in the religious exemption packet.
 - Medical provider will document this counseling in the EMR.
 - Medical provider will document the exemption in the IMR.
 - Will only use one either ASIMS or MHSG, not both.
 - Document in ASIMS:
 - Immunization Exemption: "administrative refusal"
 - Reschedule date to 90 days pending decision from chain of command.
 - Coordinate with medical provider assigned to the Religious Resolution Team (RRT) for final decision.
 - Document in MHSG:
 - Not Given Type: "Refused"
 - Not Given Reason: "Postpone due to refusal"
 - Do not click "cancel series and stop forecasting"
 - Reschedule date to 90 days pending decision from chain of command.
 - Coordinate with medical provider assigned to the RRT for final decision.

MEDICAL EXEMPTIONS:

- IAW <u>AFI 48-110</u>, members requesting a medical exemption require a medical evaluation to determine if there are any appropriate contraindications to warrant the exemption.
- Those with previous COVID-19 infection are not considered fully vaccinated.
 - Evidence is emerging that people get better protection being fully vaccinated compared with having had COVID-19. Unvaccinated people who already had COVID-19 are >2x as likely as fully vaccinated people to get COVID-19 again.
- Providers must counsel on the below items:
 - Specific information about the diseases concerned.
 - Specific vaccine information including product constituents, benefits, and risks.
 - Potential risks of infection incurred by unimmunized individuals.
 - An estimated 20-30% of unvaccinated patients who get COVID-19 may develop long-term symptoms.

- Unvaccinated persons are >2x more likely than vaccinated individuals to get COVID-19 a second time.
- Vaccination decreases the risk & severity of complications.
- Full vaccination decreases chance of hospitalization >96% and risk of death >99%
- The benefits of vaccination in pregnancy against COVID-19 outweigh the risks. https://www.cdc.gov/media/releases/2021/s0811-vaccine-safe-pregnant.html
 - The CDC has <u>released new data</u> on the safety of the COVID-19 vaccines in pregnant people against COVID-19.
 - Analysis did not find an increased risk of miscarriage among nearly 2,500 pregnant women who received an mRNA COVID-19 vaccine before 20 weeks of pregnancy.
 - Previous data did not find any safety concerns for pregnant people who were vaccinated late in pregnancy or for their babies.
 - Pregnant and recently pregnant people are more likely to get severely ill with COVID-19 compared with non-pregnant people.
- Providers Medical Exemption Screening: Screen for Contraindications and Precautions.
 - Conditions that qualify vaccine candidates for exemption:
 - Treatment with monoclonal antibodies or convalescent plasma, under "people who previously received passive antibody therapy". <u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-</u> us.html. Authorize 90 day temporary exemption.
 - Multisystem Inflammatory Syndrome in Adults (MIS-A): Until cleared by patient's specialty care team. Authorize 60 day temporary exemption, then review.
 - Acute SARS-CoV-2 infection (confirmed), and until the member has met criteria to discontinue isolation. Authorize 30 day temporary exemption.
 - Pregnancy (confirmed)
 - Pregnant people should be encouraged to take the vaccination.
 - Data and the known severe risks of COVID-19 during pregnancy demonstrate that the benefits of receiving a COVID-19 vaccine for pregnant people outweigh any known or potential risks.
 - Myocarditis or pericarditis following first dose or current unresolved myocarditis / pericarditis.
 - Prior anaphylaxis to COMIRNATY[®] or a component of COMIRNATY[®] (<u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C)</u>
 - Defined as: Onset within no more than 4 hours
 - o **Urticaria**
 - Wheezing/Dyspnea
 - o Vomiting/Diarrhea
 - Hypotension
 - Angioedema
 - Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the COVID-19 vaccine
 - Reaction to vaccines that share ingredients see Table 1.
 - History/symptoms that **DO NOT** fit immediate allergic reaction exemption:

- Onset of symptoms >4hr from exposure
- o Malaise
- o Fever
- Report of contracting COVID-19 from the vaccine
- o Isolated throat tightness that self-resolves
- Vasovagal reaction
- Reaction to foods, stinging insects, and medications that do not contain shared ingredients

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https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-
19-vaccines-us.html#Appendix-C
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- If an individual's clinical case is not readily definable, provider should seek consultation from MTF Allergist or the DHA Immunization Healthcare Division, 1-877-Get-Vacc (1-877-438-8222), DSN 761-4245, <u>https://www.health.mil/Military-Health-Topics/Health-</u><u>Readiness/Immunization-Healthcare/Clinical-Consultation-Services</u>
- Disposition:
 - <u>Approved Exemption</u>: Clearly document in EMR covering requirements above, rationale for exemption, and time frame.
 - Because additional COVID-19 immunization products may yet become approved and recommended, permanent medical exemptions are not permitted at this time.
 - Medical provider will document the exemption in the IMR.
 - Will only use one either ASIMS or MHSG, not both.
 - Document in ASIMS:
 - Medical Temporary Exemption
 - Only use "MT" or "Medical, Temporary" medical exemption code
 - Document in MHSG:
 - Not Given Type: "Contraindicated"
 - Not Given Reason: "Temporary contraindication Reschedule" or "Patient Currently Pregnant"
 - Do not clinic "cancel series and stop forecasting"
 - Reschedule date to 365 days for chronic illness, 90 days for patients treated with monoclonal antibodies or convalescent plasma, 60 days placeholder (and until cleared by specialty care team) for MIS-A, 30 days for Acute SARS-CoV-2 infection (and until the member has met criteria to discontinue isolation) and Estimated Date of Delivery for those with pregnancy.
 - <u>Denied Exemption</u>: Clearly document in EMR covering requirements above, rationale for disapproval.
 - No documentation required in IMR. Member will remain in yellow/red status.

| Vaccines | with | Shared | Ingredients |
|----------|------|--------|-------------|
|----------|------|--------|-------------|

- Fluad (influenza)

- Infanrix (DTaP)

- Havrix (Hepatitis A)

- Prevnar 13 (pneumococcal)

- Vaxelis (DTaP+IPV+Hep B+Hib)

- Flublock (influenza)
- Flulaval quad (influenza)
- Heplisav-B (hepatitis B)
- Pediarix (DTaP+IPV+Hep B)
- Trumenba (meningococcal)

- Fluarix quad (influenza)
 - Twinrix (hepatitis A&B)
 - JE-Vax (Japanese encephalitis)
 - Quadracel (DTaP + IPV)
- Flucelvax quad (influenza) - Gardasil (HPV)
- Kinrix (DTaP + IPV) - Shingrix (zoster)
- - source: Banerji, et al, J Allergy Clin Immunol Pract, 2021

Table 1. Vaccines with Shared Ingredients

FREQUENTLY ASKED QUESTIONS:

- 1. If a Service Member received the first vaccination of Moderna, but not the second vaccination, can they receive the Pfizer COVID-19 vaccine? Should it be one or two doses?
 - In exceptional situations in which the mRNA vaccine product given for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time. Such persons are considered fully vaccinated against COVID-19 \geq 2 weeks after receipt of the second dose of an mRNA vaccine. As COMIRNATY[®] is the only BLA product on the market, it is the only one required for Force Health Protection.
 - o In this case, the Service Member would complete their full vaccination with one dose of COMIRNATY[®].
- 2. What should the MTF do if a Service Member refuses to get the Pfizer COVID-19 vaccine the MTF has in their inventory which was on hand prior to Pfizer receiving FDA approval and only agrees to receive the COMIRNATY® vaccine.
 - Educate the member that both are the same product.
- 3. If a Service Member is seeking a vaccination medical exemption and does not agree with the medical provider's decision to deny a medical exemption, can the member be evaluated in a second opinion?
 - Yes, all patients have the right for a second opinion. This second evaluation must be with another military medical provider credentialed in the MTF. It can be with another military medical provider in the same clinic.
 - If the second evaluation also denies a medical exemption, the provider should then document this denial as the final medical exemption disposition in the IMR and EMR.
 - If the medical evaluations do not concur, then notify the SGH and consider further 0 consultation from MTF Allergist or the DHA Immunization Healthcare Division,1-877-Get-Vacc (1-877-438-8222), DSN 761-4245, https://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Clinical-Consultation-Services.

HOW TO ENGAGE A PATIENT ABOUT THEIR REQUESTED EXEMPTION:

- Understand there may be hesitancy present.
- Utilize motivation interview techniques:
 - A client-centered yet direct approach for facilitating change by helping people to resolve ambivalence and find intrinsic reasons for making needed behavior change. Originally designed for people with substance use disorders, motivational interviewing is now broadly applied in health care, psychotherapy, correctional, and counseling settings. It is particularly applicable when low intrinsic motivation for change is an obstacle. Rather than advocating for and suggesting methods for change, this approach seeks to elicit the client's own goals, values, and motivation for change and to negotiate appropriate methods for achieving it. See also "motivational enhancement therapy."
 - Step 1: Embrace an attitude of empathy and collaboration
 - Be compassionate, show empathy, and be genuinely curious about the reasons why the patient feels the way they do.
 - Be sensitive to culture, family dynamics, and circumstances that may influence how patients view vaccines.
 - Remember: Arguing and debating do not work. Taking a strong initial stand may also backfire, especially with people who have concerns about vaccines.
 - Step 2: Motivational interviewing
 - Ask the patient a scaled question. For example, "On a scale of 1 to 10, how likely are you to get a COVID-19 vaccine?" (1 = never; 10 = already have an appointment to get vaccinated). Then explore both sides of whatever number is given.
 - Example: Let's assume someone says 4. This is where curiosity comes in. You can say, "Okay, why 4? And why not a lower number?" Let them answer, and ask a follow-up question like, "What would help you move to a 5 or 6?"
 - The goal is to help the patient become more open to moving toward higher numbers—in other words, getting vaccinated.
 - You want them to talk about this out loud because talking actually changes how they process their choices and can develop forward momentum.
 - People hesitant about vaccines usually have more practice explaining why they haven't gotten vaccinated, so it's good to reverse that. Ask them to express their vaccination benefits out loud.
 - Be compassionate and curious about the patient's mixed feelings, both the part of them that wants to trust that getting a vaccine is important and safe and the other part that feels hesitant. It is important to show support for the patient to incorporate their personal values and the health needs of their family and community as they make their decision.
 - Step 3: Respond to questions about vaccines, health, or mental health
 - If a patient asks a question about vaccine safety, vaccine risks, or their health or mental health, respond within the boundaries of your competence, ethics, and scope of practice.
 - Provide scientific information as needed.

COVID-19 mRNA Vaccine Provider Medical Exemption Guidance 11SEP2021

Permanent Medical Exemption

- Documented anaphylaxis after receipt of first COVID-19 vaccination or symptoms less than 4 hours after vaccination including hives/swelling, wheezing/shortness of breath, vomiting/diarrhea, hypotension. Can be vaccinated under guidance of Allergist, if available.
- Diagnosed with myocarditis / pericarditis after first COVID-19 vaccination or infection including ST elevation and/or enzymes.
- Temporal association of Stevens-Johnson Syndrome (SJS) or Guillain Barre Syndrome (GBS) that cannot be attributed to another underlying cause
- Thrombosis with Thrombocytopenia Syndrome (TTS)

Temporary Medical Exemption

- Currently in isolation / quarantine for COVID-19. Recommend they get vaccinated as soon as off isolation / quarantine.
- Pregnancy, although strongly recommend vaccination per ACOG / CDC guidance
- Monoclonal antibody administration against COVID-19 (90 days). Renewal of temporary medical exemption will be required every 30 days.
- If required for travel to be vaccinated in hospital Immunizations Clinic under guidance of Allergist
- If required to gather more information regarding special medical considerations on limited basis

Definitely Vaccinate

- Symptoms following first COVID-19 vaccination more than 4 hours after shot including malaise, fever, report of contracting COVID-19 from the vaccine, isolated throat tightness selfresolved, vasovagal reaction
- Currently breastfeeding
- Personally immunocompromised
- Concerns regarding infertility
- Concerns regarding medically vulnerable family members
- Reaction to other vaccines / medications / allergens that do not contain shared ingredients
- Allergic reaction to any foods, including eggs and gelatin, latex, preservatives, antibiotics, or metals including iron, nickel, cobalt, lithium, rare earth alloys

Refer questions to: DHA Global Teleconsultation Portal: <u>https://help.nmcp.med.navy.mil/path/user/</u> ViewLogin.action or https://path.tamc.amedd.army.mil/path/user/ViewLogin.action

IN THE UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF OHIO – Cincinnati Division

| HUNTER DOSTER, et. al. | : | Case No.: 1:22-cv-00084 |
|-----------------------------|---|-------------------------|
| Plaintiff | : | |
| v. | : | |
| Hon. FRANK KENDALL, et. al. | : | |
| Defendants | : | |

DECLARATION OF CHRISTOPHER WIEST

Pursuant to 28 U.S.C. §1746, the undersigned, Christopher Wiest, makes the following declaration, under penalty of perjury under the laws of the United States of America, that the facts contained herein are true and correct to the best of my knowledge and belief and that such facts are made based on my personal knowledge:

- 1. My name is Christopher Wiest, and I am one of the Class Counsel in this matter.
- 2. Certain Air Force members have sent us, over the past three weeks, certain granted religious accommodations by the Surgeon General or MAJCOM commander. All of them that we reviewed were for members at the end of their service, and there is no evidence that we have that the policy of granted religious accommodations only for end-of-service personnel has changed from January through April.

Pursuant to 28 U.S.C. §1746, I declare under penalties of perjury under the laws of the United States of America that the foregoing Declaration is true and correct to the best of my knowledge and belief and that such facts are made based on my personal knowledge.

Executed on July 25, 2022.

Christopher Wiest