IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
Charleston Division

DEREK CLEMENTS, *et al.*,	)	
	)	
Plaintiffs	)	
	)	
v.	)	Civil Action No.
	)	
LLOYD J. AUSTIN, III, *et al.*,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Plaintiffs, by and through counsel, respectfully submit this memorandum of points and authorities in support of their motion for both a Temporary Restraining Order and a Preliminary Injunction pursuant to Fed. R. Civ. P. 65 and LCvR 65.01. The Temporary Restraining Order is requested to temporarily enjoin Defendant Rear Admiral ("RADM") William G. Kelly, Superintendent, United States Coast Guard Academy ("USCGA"), from disenrolling five plaintiffs—Cadets A. Aime, T. Aime, S. Galdamez, D. Johnson, and J. Johnson—from the Academy prior to resolution of the motion for preliminary injunction; each of these Plaintiffs face permanent disenrollment from USCGA as early as Thursday, June 30, 2022.

Plaintiffs further request this Honorable Court preliminarily enjoin Defendants from taking any adverse action against Plaintiffs for failing to obtain the vaccine due to a sincerely held religious belief or for having prior immunity. Plaintiffs request this Court rule on the

Temporary Restraining Order absent a hearing, and further request this Court set an expedited oral hearing pursuant to LCvR 7.08 on the Preliminary Injunction.

I. INTRODUCTION AND STATEMENT OF FACTS

In response to a novel virus first detected in 2019—now referred to as COVID-19—a Gadarene rush ensued to develop and produce equally novel vaccines. Compl. at ¶ 40. The Pfizer-BioNTech vaccine, the Moderna vaccine, and the Johnson & Johnson Janssen vaccine were pressed into use in the United States under the auspices of the Food and Drug Administration's ("FDA") Emergency Use Authorization ("EUA") provision found at 21 U.S.C. § 360bbb-3.[1] *Id.* at ¶ 41. After the FDA's emergency authorization, the manufacturers continued their developing efforts using FDA's Biologics License Application ("BLA") process with the ultimate goal of getting approval for a licensed product.[2] *Id.* at ¶¶ 41-43.

On August 23, 2021, the FDA issued a BLA approval letter to BioNTech Manufacturing GmbH of Mainz, Germany, for one of its various formulas of the vaccine—BNT162b2.[3] *Id.* at ¶¶ 42-44. BioNTech, in conjunction with Pfizer, was permitted to label and market this licensed

[1] *See* Ctrs. for Disease Control & Prevention (CDC), How CDC is Making COVID-19 Vaccine Recommendations (2019), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html#:~:text=%E2%80%A2%20On%20Dec.%2011,of%20COVID%2D19 (last visited Oct. 13, 2021) (the Pfizer-BioNTech COVID-19 vaccine received EUA on December 11, 2020; the Moderna COVID-19 vaccine received EUA on December 18, 2020; and the Johnson & Johnson Janssen COVID-19 vaccine received EUA on February 27, 2021).

[2] *See* U.S Food & Drug Admin., Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry (2020), https://www.fda.gov/media/139638/download (last visited June 24, 2022).

[3] U.S Food & Drug Admin, Pfizer-BioNTech COVID-19 EUA LOA reissued August 23, 2021, (Aug. 23, 2021), https://www.fda.gov/media/151710/download (last visited June 24, 2022).

formula with the proprietary name "COMIRNATY."[4] *Id*.[5] Its distribution was prohibited until the manufacturer submitted a final container sample of the product and received a notification of release from FDA's Director of the Center for Biologics Evaluation and Research.[6] At the time of the FDA's issuance of the license, COMIRNATY was not being manufactured in the United States, nor would it be for the foreseeable future.[7] *Id.* at 47.

When it issued the BLA approval letter, the FDA simultaneously notified Pfizer that the Pfizer-BioNTech vaccine EUA was being extended because "[t]here [was] no adequate, approved, and available alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine." *Id.* at ¶¶ 43-45. The FDA's letter noted that although the two products had similar chemical compositions, they were legally distinct and had "certain differences"—with "certain differences" remaining undefined.[8] *Id.* at ¶ 44.

On November 18, 2021, Pfizer-BioNTech requested to supplement its BLA with a different vaccine formula. *Id.* at ¶ 46. Less than one month later, this request was approved, and the FDA permitted Pfizer-BioNTech to distribute this version of COMIRNATY with a gray cap and label—unlike the first version, which was supposed to have a purple cap and label, should it

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[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] U.S. Food & Drug Admin, Letter of Authorization – Pfizer-BioNTech (reissuing authorization) (Aug. 23, 2021), http://web.archive.org/web/20210823142928/https:/www.fda.gov/media/150386/download (last visited June 27, 2022).

have actually been manufactured and distributed.[9] *Id.* Notwithstanding the supplemental approval, the FDA has continued to reissue the EUA for the Pfizer-BioNTech vaccine, with the latest one issued on June 17, 2022.[10] *Id.* at ¶ 45. In other words, as of two weeks ago, the FDA still maintains there is no "adequate, approved, and available alternative to this product." *Id.* Indeed, on the FDA "Vaccine Finder" website, COMIRNATY is not available in the United States.[11]

Further clouding its already bizarre licensing and EUA decisions, at the time it licensed COMIRNATY, FDA opined that COMIRNATY and the Pfizer-BioNTech COVID vaccines could be used "interchangeably" for treatment purposes.[12] *Id.* at ¶ 61-63. Notably, the FDA's Purple Book, which lists all regulatory aspects of a drug or vaccine's licensing and status, shows there is *no* vaccine that is interchangeable with COMIRNATY.[13] More importantly, the designation of a vaccine as being interchangeable with another vaccine cannot happen with the stroke of some bureaucrat's pen on FDA letterhead. "Interchangeability" has very specific

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[9] U.S. Food & Drug Admin., BioNTech BLA Supplemental Approval (Dec. 16, 2021), https://www.fda.gov/media/154939/download (last visited June 21, 2022).

[10] U.S. Food & Drug Admin., Letter of Authorization – Pfizer-BioNTech (reissuing authorization) (June 17, 2022), https://www.fda.gov/media/150386/download (last visited Jun. 21, 2022).

[11] *See* Ctrs. for Disease Control and Prevention, https://www.vaccines.gov/search/, (last visited June 27, 2022).

[12] U.S. Food & Drug Admin., Letter of Authorization – Pfizer-BioNTech (reissuing authorization) (Aug. 23, 2021), http://web.archive.org/web/20210823142928/https:/www.fda.gov/media/150386/download (last visited June 27, 2022).

[13] *See Purple Book Database of Licensed Biological Products*, U.S. Food & Drug Admin., https://purplebooksearch.fda.gov/results?query=COVID-19%20Vaccine,%20mRNA&title=Comirnaty (last visited June 24, 2022).

requirements with respect to evaluation of the vaccines involved. *Id.* at ¶¶ 61-63. Not one of those requirements has been met with respect to either of these vaccines, and there is no legal basis for the FDA to make such a designation. *Id.*

This confusing licensing decision by FDA changed nothing about how vaccinations in the United States were administered, with one notable (and apparently deliberate) exception—it has been widely reported by the press and generally assumed by the public at large that the Pfizer-BioNTech vaccine now being administered has been fully licensed by FDA. But it has not. Until recently, every vial of vaccine used in the United States (regardless of manufacturer) contains a label clearly stating that it is "For use under Emergency Use Authorization." *Id.* at ¶ 47.

On August 9, 2021, Defendant Secretary of Defense Austin issued a memorandum notifying the entire Department of Defense (DoD) that the President had asked him "to consider how and when [DoD] might add the coronavirus disease 2019 (COVID-19) vaccines to the list of those required for all Service members."[14] *Id.* at ¶ 48. Defendant Secretary of Defense Austin stated that he would mandate involuntary inoculation with a COVID-19 vaccine by either seeking the President's approval to use unlicensed, EUA vaccines no later than mid-September, or upon approval by the FDA, whichever occurred first.[15] *Id.*

Defendant Secretary of Defense Austin wasted no time in issuing the mandate once the FDA "licensed" COMIRNATY on August 23, 2021. The very next day, August 24, 2021, he mandated all service members receive "full vaccination" against COVID-19, using only fully

[14] Sec'y of Def., Memorandum For All Department Of Defense Employees (Aug. 9, 2021), https://media.defense.gov/2021/Aug/09/2002826254/-1/-1/0/MESSAGE-TO-THE-FORCE-MEMO-VACCINE.PDF (last visited June 21, 2022).

[15] *Id.*

licensed vaccines. [16] *Id.* at ¶ 49. The various services and academies, including the United States Coast Guard and USCGA, began to carry out the mandate faithfully.[17] Per Defendant Secretary of Defense Austin, Service members with prior COVID-19 infection would not be considered fully vaccinated.[18] *Id.* at ¶¶ 49-50.

Each of the armed services and the Coast Guard issued implementation guidance that requires either individual compliance with Defendant Austin's order or disciplinary action, including involuntary separation from the service with a stigmatizing, less than honorable characterization of service. *Id.* at ¶¶ 49-52.

In carrying out this mandatory vaccine program, the military has categorically denied religious accommodation requests, despite stating it would take such requests seriously. *Id*. at ¶¶ 68-74. For example, as of June 13, 2022, Defendant Secretary of the Air Force has received 13,376 requests, and subsequent appeals, for religious accommodation and has only approved

[16] Sec'y of Def., Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members (Aug. 24, 2021), https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF (last visited June 21, 2022).

[17] Then-Commandant of the Coast Guard Admiral Schultz issued a Coast Guard order on August 26, 2021, wholly adopting Defendant Secretary of Defense's August 24 memorandum. *See* ALCOAST 305/21 (Aug. 26, 2021).

[18] Sec'y of Def., Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members, (Aug. 24, 2021), https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF (last visited June 21, 2022).

118. [19] *Id*. at ¶ 71. In the meantime, the Air Force has granted 979 administrative exemptions and 709 medical exemptions—although, it has failed to state how many of these requests were submitted or whether any of those requests were combined with religious accommodation requests, and appears to now be deflating its data on these two accommodations.[20] *Id.* Although neither the Coast Guard nor the Army are publishing their numbers like the Air Force (despite concern the Air Force is now providing false data), upon best information and belief, the Coast Guard has granted only approximately 4 religious accommodation requests out of approximately 1,300 and the Army has granted just one religious accommodation request out of 3,760. *Id.* at ¶¶ 73-74.

Consequently, because they object to taking the vaccine, Plaintiffs are being subjected to disciplinary action, including threats of separation and active steps toward disenrollment from

[19] *DAF COVID-19 Statistics - June 2022*, U.S.A.F. (June 14, 2022) https://www.amc.af.mil/News/Article-Display/Article/3055214/daf-covid-19-statistics-june-14-2022/ (last visited June 28, 2022).

[20] *Id.* It necessitates noting that the Air Force seems to have deflated its number of medical and administrative accommodations granted over the past several months. For example, in February 2022, the Air Force said it had granted 1,393 medical accommodation requests, and 1,705 administrative accommodation requests. Despite the religious accommodation request numbers remaining fairly steady with previous representations, the numbers of overall approved administrative and medical accommodation requests are now significantly less than what was previously reported. To be clear, these are not monthly approvals; they are total number of approvals since the mandate was issued. Similar lawsuits challenging the legality of the Air Forces' denial of religious accommodations have been pending for months, and there exists honest concern that the Air Force is now manipulating its numbers in response to these lawsuits. *See DAF COVID-19 Statistics - February 2022*, U.S.A.F. (Feb. 22, 2022) https://www.af.mil/News/Article-Display/Article/2919591/daf-covid-19-statistics-february-2022/ (last visited Jun. 28, 2022).

the academies. Id. at ¶ 75. Numerous Plaintiffs have received Letters of Reprimand, and the USCGA cadets have already been served their disenrollment orders. *Id.* at ¶¶ 20-24.

All five USCGA Cadets in this case, Cadet N. Aime, Cadet T. Aime, Cadet Galdamez, Cadet D. Johnson, and Cadet J. Johnson have been subjected to two negative "Page 7" counselings. *Id*. at ¶¶ 20-24. Each received a second Page 7 on June 13, 2022, directing the cadet to take the first of two COVID-19 vaccines within five (5) business days—or June 21, 2022. *Id.* Each was then notified on June 23 by Defendant RADM Kelly of their immediate disenrollment from the Academy for failing to comply with the second Page 7. *Id.* Each cadet has until June 30, 2022, to submit an appeal. *Id.* This appeal will be expedited so as to disenroll the cadets as quickly as possible.

Technical Sergeant ("TSgt") Clements has already received a Letter of Admonishment and Letter of Reprimand for his violation of a "lawful order," Article 92, Uniform Code of Military Justice ("UCMJ"), for not taking the vaccine. *Id.* at ¶ 1. He faces further adverse disciplinary action, including involuntary separation with a less than honorable characterization of service. *Id.*

Senior Airman ("SrA") Kloster has been ordered to receive a COVID-19 vaccine by June 27, 2022, or face separation with a less than honorable characterization of service. *Id.* at ¶ 2. Lieutenant Colonel ("Lt Col") Babcock, Captain ("Capt") Pokrant, and SrA Vasiliu face adverse disciplinary action for vaccine refusal, including potential separation with a less than honorable characterization of service. *Id.* at ¶¶ 3-5.

Major ("Maj") Baumann has already received a Letter of Reprimand and has been told he faces separation from the Reserves. He has been informed that the paperwork for transferring

him to the Individual Ready Reserve, from which he will be administratively discharged without a chance for appeal, has already been prepared. *Id.* at ¶ 6.

TSgt Carey was ordered to initiate a vaccination "regimen" within 5 calendar days, or face initiation of involuntary separation with a less than honorable characterization of service. Adding to this punishment is the fact his selection for promotion to Master Sergeant in October 2022 will be unrealized. *Id.* at ¶ 7.

Col Hall's retirement request, which she filed following denial of her religious accommodation request, was disapproved; she has been ordered to be fully vaccinated by July 22, 2022, or else face adverse disciplinary and punitive action under the UCMJ. *Id.* at ¶ 8. If involuntarily separated, she faces substantial recoupment of service bonuses, and the possibility of reduction to a much lower rank, thereby resulting a potential near 40% reduction in anticipated retirement pay. *Id.*

Capt Wilburn's travel as a pilot has been substantially restricted, thereby denying his access to training and hindering his ability to progress in his career. *Id.* at ¶ 9. He faces further adverse disciplinary action for vaccine refusal, including potential separation with a less than honorable characterization of service. *Id.* As a graduate of the USAFA, Capt Wilburn also has a year left on his service academy commitment and 8 years left on his Active Duty Service Commitment, meaning that he could be subjected to forced recoupment if he is discharged with less than honorable characterization of service. *Id.*

USAFA Cadet Beggs received a Letter of Reprimand on May 9, 2022, and has been told that unless he begins a COVID-19 vaccine regimen by August 1, 2022, he will be disenrolled effective that date. *Id*. at ¶ 10.

USAFA Cadets Paul, Pym, and Shaffer face adverse disciplinary action for vaccine refusal, including potential disenrollment. Id. at ¶¶ 13-15. Moreover, on April 2, 2022, Cadet Shaffer was ordered to receive the COVID-19 vaccine or face certain disciplinary action and processing for involuntary dismissal from the Academy. *Id.* at ¶ 15. Because she has "committed" to the Air Force and served in excess of two years at the Academy, she will also be subjected to recoupment of her educational costs. *Id.*

USAFA Cadet Staiger has been allowed to enter the Academy due to a temporary medical waiver; if the waiver is revoked, he faces disenrollment. *Id.* at ¶ 16. Similarly, Cadet Cass has a temporary medical waiver but is subject to disenrollment once the medical waiver is no longer valid. *Id.* at ¶ 11.

USAFA Cadet Suess was permitted to graduate and obtain his degree, but his commission is being withheld, he was placed into no-pay post-graduation status, and he now faces dismissal from the Academy and forced recoupment of his educational costs. *Id.* at ¶ 17.

Both West Point Cadets, Cadet Penney and Cadet Wojtkow, face adverse disciplinary action for vaccine refusal, including potential disenrollment. *Id.* at ¶¶ 18-19.

Because the vaccines currently available in the United States remain under EUA, Plaintiffs are required to be vaccinated with unlicensed vaccines. The requirements for deployment of an EUA drug or biologic are laid out in 21 U.S.C. § 360bbb-3 of the Food, Drug, and Cosmetics Act ("FDCA"). In addition, there are specific requirements that apply to the use of an EUA vaccine on service members. *See* 10 U.S.C. § 1107a. In short, that statute prohibits the use of an EUA vaccine as part of a mandatory vaccination program for service members without either the service member's informed consent—without consequence for refusal—or a presidential waiver of the informed consent requirement. From the very inception of this ill-

conceived vaccine mandate, Defendants have willfully ignored the requirements of 10 U.S.C. § 1107a. Compl. at ¶¶ 46-52; *Cf.*, *Doe v. Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004).

In addition to the requirements attached to EUA vaccines, Defendants have also circumvented regulations that require evaluation of a service member's natural immunity derived from previous infection. *See* Army Regulation 40-562, "Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases" (Oct. 7, 2013) ("AR 40-562"); Compl. at ¶¶ 53-55.[21] This regulation, applicable to each of the Service Defendants, has been directly contravened, because Defendants have not conducted any sort of analysis or evaluation of Plaintiffs' natural immunity to COVID-19. Cadet N. Aime, Cadet T. Aime, Lt Col Babcock, Maj Baumann, Cadet Beggs, TSgt Carey, Cadet Cass, Cadet Ford, Cadet Galdamez, Cadet D. Johnson, SrA Kloster, Cadet Paul, Capt Pokrant, Cadet Pym, Cadet Shaffer, Cadet Staiger, Cadet Suess, SrA Vasiliu, and Cadet Wojtkow all have natural immunity, as confirmed by previous infection and/or positive antibody tests. Compl. at ¶¶ 2-7, 10-17, 19-22.

The service members and cadets are generally facing a Hobson's Choice of either being victimized by an illegal program that requires them to be injected with an unlicensed vaccine (that comes with its own set of risks and uncertainties) and violates their sincerely held religious

[21] AR 40-562 at ¶1-1; ¶1-4.*c.*(4) ("Medical commanders, commanding officers, and command surgeons: Ensure patients are evaluated for preexisiting immunity, screened for administrative and medical exemptions, and/or evaluated for the need for medical exemptions to immunizations or chemoprophylaxis medications."); 2-6.*a.*(1)(*b*) (a medical exemption is warranted with "[e]vidence of immunity based on serologic tests, documented infection, or similar circumstances."); 3-1.*a.*(2) "(Immunize if the primary series is incomplete, if a booster immunization is needed, or if the Service personnel has no serologic or documented evidence of immunity."); 3-1.*a.*(3) ("Before immunizing, conduct serologic testing where available."); and 3.1.*e.* ("Upon accession, screen commissioned and warrant officers for immunization *or immunity status* and vaccinate as required.").

beliefs or be disciplined and face the loss of their professional careers because of their refusal to be inoculated. Litigation will be lengthy; absent preliminary injunction by this Court, each Plaintiff faces certain involuntary separation from the service.

II. ARGUMENT

The undisputed facts before the Court, even at this early stage, demonstrate that Plaintiffs are likely to succeed in this litigation and are sufficient to sustain a preliminary injunction. The details of this mandatory vaccination program reveal direct and straightforward violations of laws designed to protect service members from forced submission to experimental vaccines.

The service branches have employed blanket denials of Plaintiffs' religious exemption requests, despite there being clearly existing alternatives and less restrictive means for achieving the purported goals of the military. The program also runs roughshod over patient rights enshrined in regulations governing vaccination and inoculation of service members, namely the right to refuse inoculation with an unapproved and unlicensed vaccine and the need to evaluate previous infection and individualized medical circumstances. Plaintiffs are currently being irreparably harmed by Defendants' swift efforts to discipline, separate, and disenroll them, and Plaintiffs face further irreparable damage in the immediate future if this program is not stopped. Injunctive relief is the only way to prevent further harm to their interests.

A. Standard of review for motions for preliminary injunctive relief.

This Court may issue preliminary injunctive relief when the movant demonstrates the following:

> (1) they are likely to succeed on the merits, (2) they are likely to suffer irreparable harm, (3) the balance of hardships tips in their favor, and (4) the injunction is in the public interest.

Pashby v. Delia, 709 F.3d 307, 320–21 (4th Cir. 2013) (citing *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 129 S.Ct. 365 (2008)). "[C]ourts considering whether to impose preliminary injunctions must separately consider each Winter factor." *Id.* (citing *The Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 347 (4th Cir. 2009), *vacated on other grounds*, *Citizens United v. FEC*, 558 U.S. 310, 130 S.Ct. 876 (2010), *aff'd*, *The Real Truth About Obama, Inc. v. FEC*, 607 F.3d 355 (4th Cir. 2010) (per curiam)). Nonetheless, courts can assign different weight to these factors, and a strong showing in one factor may be used in evaluating the others. *See id.* at 330 (finding that the likelihood of success undoubtably contributed to whether the injunction is in the public interest and noting that likelihood of success could satisfy the public interest factors). Any injunction that a court issues must be carefully circumscribed and tailored to remedy the harm shown. *See* Fed. R. Civ. P. 65(d); *Pashby*, 709 F.3d at 331 (citing *Schmidt v. Lessard*, 414 U.S. 473, 476, 94 S.Ct. 713 (1974)).

B. The undisputed facts show that Plaintiffs are likely to succeed on their RFRA and APA claims because the services' enforcement of the DoD Vaccine Mandate violates the RFRA, 10 U.S.C. § 1107a, and the services' own regulations

The vaccine mandate issued by DoD, the implementing orders issued by the various service branches, and the policies implemented across the board of denying religious accommodation requests contravene federal statutes, DoD regulations, and service branch regulations. These violations are properly addressed under the framework established by the Administrative Procedures Act, 5 U.S.C. § 702.

The APA permits Federal District Courts to hold unlawful and set aside agency action, findings, and conclusions found to be—

> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

> (B) contrary to constitutional right, power, privilege, or immunity;
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
>
> (D) without observance of procedure required by law;

5 U.S.C. § 702.

The Federal District Courts have authority to review final agency actions under the APA. *Id.* A military action is justiciable when: (1) the action violates a constitutional right or the military has acted in violation of applicable statutes or its own regulations; and (2) the plaintiff has exhausted all available intraservice corrective measures. *Roe v. Dep't of Defense*, 947 F.3d 207, 218 (4th Cir. 2020). The exhaustion requirement is not absolute, though. Such exhaustion need not include an appeal to the Service's board for correction of military records, when the boards themselves are unable to adjudicate claims regarding the unlawful or unconstitutional nature of a military regulation, and there is no categorical requirement in this circuit that constitutional and facial claims be administratively exhausted prior to judicial review. *Roe v. Shanahan*, 359 F. Supp. 3d 382, 403 (E.D. Va. 2019) (referencing *Nationsbank Corp. v. Herman*, 174 F.3d 424, 429 (4th Cir. 1999)). Furthermore, exhaustion is unnecessary when it would be futile. *Id.* (quoting *McDonald v. Centra, Inc*., 946 F.2d 1059, 1063 (4th Cir. 1991); *see also Shalala v. Ill. Council on Long Term Care, Inc*., 529 U.S. 1, 12-13, 120 S.Ct. 1084, 146 L.Ed.2d 1 (2000) ("Doctrines of 'ripeness' and 'exhaustion' contain exceptions, however, which exceptions permit early review when, for example, the legal question is fit for resolution and delay means hardship, ... or when exhaustion would prove futile" (internal quotation marks and citations omitted)).

The APA mandates that "[a] court *must* set aside agency action it finds to be 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Marshall v.*

Purcell, Civil No. 2:12–84–RMG–BHH, 2012 WL 613819, at *2 (D.S.C. Nov. 6, 2012) (quoting 5 U.S.C. § 706(2)(A); *Tourus Records, Inc. v. Drug Enforcement Admin.*, 259 F.3d 731, 736 (D.C. Cir. 2001)) (emphasis added); *see also Roe v. Dep't of Defense*, 947 F.3d 207, 218-220 (4th Cir. 2020) (noting the application of the APA to the military).

1. Plaintiffs have exhausted their administrative remedies, and to the extent any further administrative remedies exist, exhaustion would be unnecessary or futile.

Plaintiffs' challenges in this case can be broken into two categories: (1) challenging the lawfulness of the mandates as they impede the right to religious freedom; and (2) challenging the lawfulness of the mandates as they were purposefully enacted, in violation of statute and service regulations. In the first instance, many of Plaintiffs' initial requests and subsequent appeals have been denied; and, in the case of all USCGA cadets, they are facing immediate disenrollment. A handful of the remaining Plaintiffs are awaiting final decision on their appeals, but to the extent the decisions are consistent with previous denials, they too are very likely to be denied. To that end, further exhaustion is futile. And, if Plaintiffs were to then appeal to their respective service's board for correction of military records, the very individual who set in motion the guidance on denying the religious accommodations—the Service Secretary—would be the one subsequently denying any such correction board decision. *See Roe*, 359 F. Supp. 3d at 403-04 (finding an appeal to the Air Force Board of Correction of Military Records futile when the same individual who made the decision to separate the plaintiffs from the Air Force in the first instance, would be the same decision maker on the Board's decision on any subsequent appeal).

With respect to the mandates being issued in direct violation of statute and service regulations, there is no adequate relief available through the Services' correction boards. The vaccine mandate was issued in violation of 10 U.S.C. § 1107a—knowing there were no FDA

licensed vaccines available in the United States—and AR 40-562—disregarding immunity from prior infections. But as recognized in *Roe*, the correction boards "cannot adjudicate a claim that the [military's] policies and regulations themselves are unconstitutional or otherwise unlawful." *Roe*, 359 F. Supp. 3d at 403 (emphasis in original). With no automatic requirement for administrative exhaustion of such claims, this Court—like the *Roe* court—should also find Plaintiffs' challenge to the lawfulness of the mandate, absent further appeal to the correction boards, justiciable.

2. The DoD and services violate the RFRA by not implementing the least restrictive means available to achieve its purported compelling interest.

A court may grant appropriate relief against the government when an individual's religious exercise has been burdened in violation of the RFRA. 42 U.S.C. § 2000bb-1(c); *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 693, 134 S.Ct. 2751, 189 L.Ed.2d 675 (2014). Indeed, "[b]y enacting RFRA, Congress went far beyond what [the Supreme Court] has held is constitutionally required." *Id.* at 706, 134 S.Ct. 2751. RFRA, per its plain text, applies to the military. *See* 42 U.S.C. § 2000bb-1.

In RFRA cases, the court must address whether: (1) Plaintiffs' sincerely held religious beliefs are being substantially burdened by Defendants; (2) the substantial burden is in furtherance of the Government's compelling interest; and (3) the substantial burden is the least restrictive means of furthering Defendants' compelling interests. *See, e.g., Doster v. Kendall*, No. 1:22-CV-84, 2022 WL 982299, at *11 (S.D. Ohio Mar. 31, 2022). Moreover, "The substantial-burden test asks whether the Government is effectively forcing plaintiffs to choose between engaging in conduct that violates sincerely held religious beliefs and facing a serious consequence." *New Doe Child #1 v. Cong. of United States*, 891 F.3d 578, 589 (6th Cir. 2018).

Indeed, "the Government substantially burdens an exercise of religion when it places substantial pressure on an adherent to modify his behavior and to violate his beliefs or effectively bars his sincere faith-based conduct." *Id.*

First, Defendants' orders have clearly and substantially burdened Plaintiffs' religious beliefs. Compliance with the mandate comes at the direct cost of causing Plaintiffs to violate their sincerely held religious beliefs.

Second, while the backdrop of this tragic disease may allow Defendants to argue they have a compelling interest for the vaccine mandate, Defendants' denials of religious accommodation requests are clearly not the least restrictive means for achieving this compelling interest. This is evident for one simple reason: other, less restrictive means have been utilized effectively to mitigate the effects of the pandemic.

To this point, each service branch has been effectively dealing with the pandemic for well over two years, and there are clearly established means for mitigating any perceived risk effectively. There is no better evidence of this than the Air Force's own reported numbers: of the 102,515 known cases of COVID-19 in the Air Force, there have been only 11 hospitalizations and 16 deaths (although, the data does not reveal the health status of these individuals, or whether there were any comorbidities).[22] Further, there are thousands of other service members who remain unvaccinated but have been allowed to remain on duty with their vaccinated peers because of medical or administrative exemptions, thus demonstrating less restrictive means exist.

[22] *DAF COVID-19 Statistics - June 2022*, U.S.A.F. (June 14, 2022) https://www.amc.af.mil/News/Article-Display/Article/3055214/daf-covid-19-statistics-june-14-2022/ (last visited June 28, 2022).

Compared to these other, less restrictive measures used to mitigate the effects of the now endemic COVID-19, Defendants' near-complete exclusion of religious objectors is incompatible with the assertion that Defendants are utilizing the least restrictive means to protect the force. *See Poffenbarger v. Kendall,* No. 3:22-cv-1, 2022 WL 594810, at *9 (S.D. Ohio Feb. 28, 2022).

Instead, it is apparent that something else is at play with respect to the religious objectors. In the case of the Air Force, for example, there is evidence of a high-level meeting involving Defendant Kendall and other commanders, where the Air Force Chief of Chaplains was ordered from the room and Defendants finalized a policy to deny religious exemptions. A formal ban on nearly *all* religious accommodation requests while approving others in a situation involving a contagious disease is precisely the type of interference with religious observance that the RFRA was enacted to prevent. *See, e.g., Air Force Officer v. Austin*, No. 5:22-cv-009, 2022 WL 468799, at *10 (M.D. Ga. Feb. 15, 2022) ("With such a marked record disfavoring religious accommodation requests, the Court easily finds that the Air Force's process to protect religious rights is both illusory and insincere. In short, it's just 'theater.'").

Plaintiffs are able to provide a clear roadmap for succeeding in this case, based on Defendants' denial of Plaintiffs' religious accommodations as contrasted by other, less restrictive means for achieving Defendants' mission. The above facts and applicable law show that Plaintiffs can establish a compelling argument against Defendants on an RFRA violation, meaning that Plaintiffs can establish a substantial likelihood of success. Plaintiffs more than satisfy this initial factor needed for a court to grant a preliminary injunction.

3. The DoD and services' orders violate federal statute and DoD regulations by not following vaccination consent requirements.

Plaintiffs will also likely succeed in showing that Defendants' mandates were issued in violation of 10 U.S.C. § 1107a and DoD Instruction (DoDI) 6200.02, as the mandates require their respective military personnel to submit to an unlicensed vaccination without providing personnel the opportunity to refuse without consequence.

The DOD may only override service members' informed consent rights if it complies with the requirements of 10 U.S.C. § 1107a (the applicable statute for EUA products). *See* DoD Instruction (DoDI) 6200.02 at ¶¶ 5.2.2, 5.2.3. 10 U.S.C. § 1107a stipulates that "In the case of the administration of a product authorized for emergency use […] to members of the armed forces, the condition […] designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security." 10 U.S.C. § 1107a(a)(1).

At the time of the DoD mandatory vaccination memorandum, President Biden had not issued any such order authorizing the waiver of consent requirements necessary for EUA vaccines. Nor has he issued any such order at the time of this case's filing.

Not one single vaccine available in the United States at the time of the DoD's mandate was FDA-licensed.[23] At the time the order was issued (and as is overwhelmingly still the case),

[23] Notably, the FDA's grant of an EUA is also subject to informed consent requirements to "ensure that individuals to whom the product is administered are informed" that they have "the option to accept or refuse administration of the product." FDCA § 564(e)(1)(A)(ii)(III); 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). In granting each of the three COVID-19 vaccines their respective EUA status, the FDA included a consent condition as described in Section 564(e)(1)(A)(ii)(III), requiring that the FDA's "Fact Sheet for Recipients and Caregivers" be

only EUA vaccines were available in any identifiable quantity in the United States. In fact, both DoD and various service branches were acutely aware of this complete lack of licensed vaccine stock, going so far as to direct personnel to order nominal amounts of FDA-licensed COMIRNATY vaccine once available in an attempt to avoid liability and to disguise the fact that the vaccines available in the United States (and thus to service members) were not FDA-licensed.

By requiring each service member or cadet to receive an unlicensed vaccine that has been authorized for emergency use only, the mandates simply bypassed this critical statutory and regulatory requirement. *See* 10 U.S.C. § 1107a; DoDI 6200.02 at ¶¶ 5.2.2, 5.2.3.

Defendants' actions will not survive the arbitrary and capricious review, which looks to Defendants' decision-making process at the time action was taken. The Court's arbitrary and capricious standard of review, while narrow, "does not reduce judicial review to a rubber stamp of agency action." *Ergo-W. Va., Inc. v. EPA*, 896 F.3d 600, 609 (4th Cir. 2018). In order to survive this review, Defendants "must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Sierra Club v. Dep't of the Interior*, 899 F.3d 260, 293 (4th Cir. 2018) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Agency action is arbitrary and capricious when "then agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so

made available to every potential vaccine recipient. Each Fact Sheet stipulates that it is each recipient's choice whether to receive the vaccine or not.

implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

In conducting this review, the Court must "consider the record made before the agency at the time the agency acted," so "post-hoc rationalizations … have 'traditionally been found to be an inadequate basis for review.'" *Dow AgroSciences LLC v. Nat'l Marine Fisheries Srv.*, 707 F.3d 462, 467-68 (4th Cir. 2013). Further, the Court may not supply a reasoned basis for the agency's actions that the agency itself did not consider. *Bowman v. Transp., Inc. v. Arkansas-Best Freight Sys., Inc.,* 419 U.S. 281, 285-86 (1974).

In issuing a mandate to receive a federally licensed vaccine, knowing full well no such vaccine existed—nor would it exist—and, without seeking the President's written approval to use an EUA vaccine—as Defendant Secretary of Defense Austin was required to do per his own service regulation and federal law—Defendants have acted in a manner that belies statutory and regulatory requirements, and therefore, their actions are unequivocally arbitrary and capricious. And, to date, Defendants' mandates remain in violation of statute and regulation. As such, Plaintiffs' case is clearly likely to be successful, thereby providing this honorable Court another basis for finding that a preliminary injunction is appropriate and warranted.

4. The DoD and services' orders contravene regulations that require vaccination and inoculation programs take into consideration an individual's previous infection.

Plaintiffs can also show a likelihood of success in showing an APA violation of Defendants' own promulgated regulations, not just federal statutes. Defendants' regulations, including AR 40-562, stipulate that vaccination cannot occur without proper consideration being given on a person-to-person basis, as determined by each individual's own medical circumstances and condition.

Defendants each issued an order to all military personnel under their respective commands, mandating that all personnel should receive the COVID-19 vaccination. These orders purposefully excluded consideration of natural immunity. This purposeful exclusion is a direct afront to Defendants' own regulations and also fails to account for the fact that a substantial number of Plaintiffs in this case has proven that they still retain natural immunity after previously contracting a COVID-19 infection. This includes Plaintiffs who were infected by COVID-19 in early 2021, and who still possess positive antibodies when tested in 2022.

This Circuit has never held reservations about "directing the military to comply with its own regulations where it has been shown that a regulation was not followed, and there has been a prima facie showing that a member of the military has been prejudiced thereby," to include cases of medical compliance. *Bluth v. Laird*, 435 F.2d 1065, 1071 (4th Cir. 1970); *see also Roe*, 947 F.3d at 218-220 (finding that individualized assessment was required in discharging servicemembers who were HIV positive); *United States ex rel. Brooks v. Clifford*, 409 F.2d 700 (4th Cir. 1969). "[W]hen the sovereign has established rules to govern its own conduct it will be held to the self-imposed limitations on its own authority, departure from which denies procedural due process of law." *Bluth*, 435 F.2d at 1071 (citing *United States v. Heffner*, 420 F.2d 809 (4th Cir. 1969)). "[I]n exercising its discretion, the military *will* be held to the positive commands it has imposed on itself as to what procedures and steps are to be followed in exercising its discretion." *Id.* (emphasis added).

As early as June 2021, Defendants recognized their own regulations required consideration of one's natural and prior immunity before requiring involuntary inoculation. For instance, the Army's Director of Healthcare Operations, Colonel ("COL") Dubray Kinney, Sr., and the Army Medical Command's Deputy Chief of Staff overseeing planning and operations,

Brigadier General Wendy Harter, authored an information paper titled, "Vaccine Refusal and Exemption Procedures."[24] In this paper, COL Kinney summarized AR 40-562, and noted that general medical exemptions from the vaccine mandate included evidence of natural immunity.[25] And yet, just two short months later, this regulatory requirement was summarily disregarded.

Defendants are obligated to follow their own regulations, and in cases where they refuse to, this Court has absolute authority to direct compliance. Accordingly, given Defendants' straightforward violation of its own regulations requiring testing for natural immunity prior to involuntary inoculation, Plaintiffs will have no difficulty in proving its case on this point.

C. The unusual circumstances of these mandates will, by their very nature, create irreparable harm.

In addition to demonstrating likelihood of success, Plaintiffs need also establish that they are subject to irreparable harm absent a preliminary injunction. The irreparable harm typically needs to be of such imminence that there is a clear and present need for equitable relief—in other words, later action or monetary award will not suffice. *See Di Biase v. SPX Corp.*, 872 F.3d 224, 230 (4th Cir. 2017); *Hughes Network Sys., Inc. v. InterDigital Commc'ns Corp.*, 17 F.3d 691, 693 (4th Cir. 1994).[26]

"[A] deprivation of a constitutional right, 'for even minimal periods of time, unquestionably constitutes irreparable injury.'" *Miranda v. Garland*, 34 F.4th 338, 365 (4th Cir.

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[24] Davis Winkie, *Here's the Army rule for vaccine refusals, which service leaders brushed up on this summer*, Army Times (Aug. 25, 2021), https://www.armytimes.com/news/pentagon-congress/2021/08/25/heres-the-army-rule-for-vaccine-refusals-which-service-leaders-brushed-up-on-this-summer/.

[25] *Id.*

[26] Notably, preliminary injunctions on behalf of military personnel against the military have long been established. *See Yahr v. Resor*, 431 F.2d 690, 690 (4th Cir. 1970).

2022) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). Two constitutional rights are at play in this case: Plaintiffs' First Amendment right to free exercise of religion and Plaintiffs' Fifth Amendment right to procedural due process. Both are being violated by the mandates.

At this stage, there is sufficient evidence before this Court to establish that Defendants' outright denial of Plaintiffs' religious accommodation requests and appeals is a violation of their right to free exercise of religion. A violation of this explicit right has been found by this Circuit to constitute per se irreparable harm. *See, e.g., Johnson v. Bergland*, 586 F.2d 993, 995 (4th Cir. 1978) (finding that "Violations of first amendment rights constitute per se irreparable injury" and reversing lower court denial of a preliminary injunction). Sister courts have also extended this strict standard to violations of the RFRA. *Poffenbarger*, 2022 WL 594810, at *9.

Pertinent to Plaintiffs' case at hand, other federal district courts have repeatedly granted preliminary injunctions in cases brought by military plaintiffs over the very same issues, finding that "the substantial pressure on a religious objecting service member to obey the COVID-19 vaccination order and violate a sincerely held religious belief constitutes an irreparable injury redressable by a preliminary injunction." *Navy Seal 1 v. Austin*, No. 8:21-cv-2429, 2022 WL 534459, at *19 (M.D. Fla. Feb. 18, 2022); *see also Doster v. Kendall*, No. 1:22-CV-84, 2022 WL 982299, at *33-34 (S.D. Ohio Mar. 31, 2022); *Air Force Officer*, 2022 WL 468799, at *12 (finding that the plaintiff established irreparable injury because her religious exemption request was denied by the Air Force and such denial "essentially infringed upon the free exercise of her religion"); *U.S. Navy SEALs 1-26 v. Biden*, No. 4:21-cv-01235, 2022 WL 34443, at *3 (N.D. Tex. Jan. 3, 2022) ("But because these injuries are inextricably intertwined with Plaintiffs' loss of constitutional rights, this Court must conclude that Plaintiffs have suffered irreparable harm").

Moreover, this Circuit has long held that when the military violates its own regulations, the aggrieved service member is denied procedural due process. *Bluth*, 435 F.2d at 1071. The Supreme Court has further clarified that the "Due Process Clause is implicated [when] an individual has reasonably relied on agency regulations promulgated for his guidance or benefit and has suffered substantially because of their violation by the agency." *United States v. Caceres*, 440 U.S. 741, 752-53 (1979). In addition to refusing the vaccine on religious grounds, many of the Plaintiffs in this case have continued refusal because they have acquired natural immunity, and they stand firm that Defendants' regulations must afford them relief from involuntary receipt of the COVID-19 vaccine because of this natural immunity. In addition, despite Defendants' conflation and obfuscation efforts, the mandated vaccines are not licensed (and are still EUA vaccines), nor has there been the requisite Presidential waiver required by DoDI 6200.02 (and 10 U.S.C. § 1107a), meaning that Defendants are violating regulatory and statutory protections which require that Plaintiffs be presented the choice to provide or withhold informed consent. Their reliance on Defendants' own regulations is now to their own detriment and harm, as each one of these Plaintiffs faces involuntary separation from the service.

In short, Defendants' violations of Plaintiffs' First and Fifth Amendment rights constitute per se irreparable harm, which more than satisfies the irreparable harm factor needed to grant a preliminary injunction. Accordingly, Plaintiffs ask that this Honorable Court follow the growing number of federal courts that have analyzed the very same kind of violations, and grant Plaintiffs' motion for a preliminary injunction.

D. An injunction is in the best interest of Defendant Agencies, Plaintiffs, and the public, as it upholds the rule of law.

After establishing a likelihood of success and the likelihood of harm, Plaintiffs must also demonstrate that a preliminary injunction is in the best interests of the public. Here, Plaintiffs can demonstrate that such injunction is clearly in the best interests of the public, given the likelihood of success, the need to ensure regulatory propriety, and the need to retain trained and qualified service members and cadets at their posts.

First, Plaintiffs likelihood of success, as established in the preceding sections of this memorandum, is a factor that substantially weighs in favor of finding that the public's best interests will be served by granting this preliminary injunction. *See Pashby*, 709 F.3d at 320–21; *The Real Truth About Obama*, 575 F.3d at 347 (overturned on other grounds).

Second, the preservation of regulatory propriety is of considerable public interest. To this point, in cases involving an injunction against a mandatory vaccine program in the military, federal courts have previously held that, "[T]he right to bodily integrity and the importance of complying with legal requirements, even in the face of requirements that may potentially be inconvenient or burdensome, are among the highest public policy concerns one could articulate." *Doe v. Rumsfeld*, 297 F. Supp. 2d 119, 134 (D.D.C. 2003). As in *Doe*, Plaintiffs note that the best interests of the DoD, military, and Plaintiffs coincide in having government follow the law. Indeed, this is all that Plaintiffs seek in this injunction.

Third, the vaccine mandate and implementing orders would remove qualified service members from their posts. Without an injunction, these illegal orders will still be used to remove valuable assets from their posts before Plaintiffs can fully litigate and demonstrate the arbitrary, capricious, and unsupported nature of the orders. This would create considerable economic and

institutional waste for the American taxpayer in the form of sunk training costs, sunk educational costs, and losing decades upon decades of invaluable institutional experience. For these reasons, this Court should find this factor in favor of Plaintiffs and grant the requested preliminary injunction.

E. The requested injunctive relief is tailored to the injury.

Finally, Plaintiffs can satisfy that the requested relief is tailored to the injury addressed above. *See Di Biase*, 872 F.3d at 231; *Pashby*, 709 F.3d at 319. All Plaintiffs ask for in this motion is to return the relationships between Defendants and Plaintiffs to the status quo ante, before the implementation of the unlawful vaccine mandate and subsequent implementation orders. *Id.* The injunctive relief does not seek to undo any actions already undertaken by the parties, but rather stops the implementation of the orders to prevent further violations of federal law and service regulations.[27] The requests are limited and reasonably related to correct APA and RFRA violations detailed above.[28]

[27] Alternatively, should any Plaintiffs be disenrolled or separated prior to a decision on this motion, this Court does in fact have the authority to issue a restorative preliminary injunction. *See Di Biase*, 872 F.3d at 231 ("But a preliminary injunction can also act to restore, rather than merely preserve, the status quo, even when the nonmoving party has disturbed it") (citing *Aggarao v. MOL Ship Management Co., Ltd.*, 675 F.3d 355, 378 (4th Cir. 2012)); *see also Savoie v. Merchants Bank*, 84 F.3d 52, 59 (2d Cir. 1996). The reach of this restorative injunctive authority would inherently extend to the military, as while there are only a few limited areas in which a court can order injunctive relief against the military, restoring a service member to their previous position following the improper application of separation procedures is squarely within the court's authority and discretion. *See, e.g., Hoskins v. United States*, 40 Fed. Cl. 259 (1998); *Poole v. Rouke*, 779 F. Supp. 1546 (E.D. Cal. 1991).

[28] It should be noted that tailored relief may permissibly extend to non-Plaintiffs. *See Evans v. Harnett County Bd. of Educ.*, 684 F.2d 304 (4th Cir.1982); *see also Lujan v. National Wildlife Federation*, 497 U.S. 871, 913, 110 S.Ct. 3177, 111 L.Ed.2d 695 (1990) (implying agreement); *National Mining Ass'n, et. al., v. U.S. Army Corps of Engineers, et. al.*, 145 F.3d 1399

III. CONCLUSION

For these reasons, Plaintiffs request this Honorable Court temporarily restrain Defendant RADM Kelly from disenrolling Cadets A. Aime, T. Aime, S. Galdamez, D. Johnson, and J. Johnson from USCGA prior to resolution of the motion for preliminary injunction, and further preliminarily enjoin Defendants from taking any adverse action against Plaintiffs for failing to obtain the vaccine due to a sincerely held religious belief or for having prior immunity pending final resolution of this case.

Respectfully submitted,

/s/ Michael T. Rose
Michael T. Rose (S.C. Bar No. 0004910)
Mike Rose Law Firm, PC
409 Central Ave.
Summerville, SC 29483
Telephone: (843) 871-1821
mike@mikeroselawfirm.com
Local Counsel

/s/ Carol A. Thompson
Carol A. Thompson
Federal Practice Group
1750 K Street N.W., Suite 900
Washington, D.C. 20006
Telephone: (202) 862-4360
Facsimile: (888) 899-6053
cthompson@fedpractice.com
Application for Special Admission Pending

(D.C.Cir.1998); *Bresgal v. Brock*, 843 F.2d 1163 (9th Cir.1987); *Meyer v. Brown & Root Construction Co.*, 661 F.2d 369 (5th Cir.1981).

/s/ John J. Michels, Jr.
John J. Michels, Jr.
Federal Practice Group
1750 K Street N.W., Suite 900
Washington, D.C. 20006
Telephone: (202) 862-4360
Facsimile: (888) 899-6053
lmichels@fedpractice.com
Application for Special Admission Pending

Counsel for Plaintiffs