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INTRODUCTION

This Court's determination, made pursuant to the Administrative Procedure Act (APA), that Army Regulation (AR) 70-25 imposes a duty on the Army to provide medical care to Plaintiffs was affirmed by the Ninth Circuit in Vietnam Veterans of America v. Central Intelligence Agency, 811 F.3d 1068 (9th Cir. 2016), but the Court of Appeals reversed this Court's determination that an injunction was not warranted in light of the availability of health care from the Department of Veteran's Affairs (VA). See Nov. 19, 2013, SJ Order, ECF 544 at 47-51. On remand, the Court ordered the parties to meet and confer, and to submit either a stipulated injunction, or competing proposed injunctions along with a brief supporting the party's proposal and explaining why it objects to the other party's proposal. Feb. 8, 2016 Order, ECF 572. This is Defendant's¹ submission in response to that Order.

As a threshold matter, Defendant preserves its position that there is no basis for the issuance of any injunction in this case. While this Court was reversed for "categorically" denying injunctive relief given the availability of VA medical care, the Court of Appeals did not address whether and in what manner this Court might nonetheless take into account, in formulating any injunction, whether "the medical care available from the VA would be equal in scope and quality to the medical care that Plaintiffs claim is owed to them by the Army." See VVA, 811 F.3d at 1082. Accordingly, it appears to remain open for this Court to consider the scope and quality of VA care as compared to the medical care that could be provided by the Army in deciding whether an injunction is warranted. As set forth below, when considering the respective missions, number and scope of facilities, and range of services provided, the VA health care system provides more comprehensive care than would be provided directly by the Army through military Medical Treatment Facilities (MTFs). See Declaration of COL Brian A. Hughes, U.S. Army Medical Command.

¹ The District Court granted summary judgment in favor of Defendants United States of America, the U.S. Attorney General, DoD, the Central Intelligence Agency and its Director, and the VA and its Secretary. The Army is the sole remaining Defendant in this action. NO. C 09-37 CW DEFENDANTS' RESPONSE TO THE COURT'S ORDER REGARDING A PROPOSED HEALTH CARE INJUNCTION

If, however, the Court determines an injunction is necessary, it should enter an injunction that simply directs the Army to provide medical care in accord with AR 70-25 to Plaintiffs and any class members who apply for such care for a medical condition that the Army determines was the proximate result of the testing programs at issue. The Army has set forth a specific plan for carrying out such an injunction. *See* Hughes Decl. ¶ 9. The Court should reject Plaintiffs' proposed injunction which substantially exceeds the relief available under the APA, and otherwise would impose unreasonable and improper requirements on the Army.

BACKGROUND

Plaintiffs' Fourth Amended Complaint raised four constitutional and APA claims against several federal agencies arising out of the use of military and civilian volunteers in conducting chemical and biological research during World War II and the Cold War. *See* ECF 486. The only remaining issue is that the certified class is entitled to receive medical care from the Army pursuant to AR 70-25(k), which provides, in part: "Volunteers are authorized all necessary medical care for injury or disease that is a proximate result of their participation in research."

This Court previously held that AR 70-25 imposes a duty on the Army to provide medical care to eligible volunteers but declined to impose an injunction on the Army because the VA is charged by Congress with providing health care to veterans and has created a comprehensive VA Health Care System to do so:

The DVA, through its Veterans Health Administration, is charged with providing "a complete medical and hospital service for the medical care and treatment of veterans." 38 U.S.C. § 7301(b). Congress has mandated that it provide hospital care and medical services "to any veteran for a service-connected disability." 38 U.S.C. § 1710. Thus, a "veteran who has a service-connected disability will receive VA care provided for in the 'medical benefits package' . . . for that service-connected disability," even if that veteran is "not enrolled in the VA healthcare system." 38 C.F.R. § 17.37(b). When receiving care for service-connected disabilities, veterans are not subject to any copayment or income eligibility requirements. 38 C.F.R. §§ 17.108(d)(1), (e)(1), 17.111(f)(1), (3).

ECF 544 at 48-49. The Court considered, and rejected, Plaintiffs' argument that the care owed by

DoD was different in scope and quality from that offered by the VA. Id. The Ninth Circuit

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DISCUSSION

I. AN INJUNCTION IS NOT APPROPRIATE BECAUSE THE MEDICAL CARE AVAILABLE FROM THE VA IS BROADER IN SCOPE THAN CARE AVAILABLE FROM MILITARY TREATMENT FACILITIES.

As this Court and others have recognized, Congress has mandated that the VA establish a program for providing veterans with medical care. *See* ECF 544; *Preminger v. Sec'y of Veterans Affairs*, 517 F.3d 1299, 1314 (Fed. Cir. 2008); *White v. Principi*, 243 F.3d 1378, 1381 (Fed. Cir. 2001); and *Jaffee v. United States*, 663 F.2d 1226, 1236 (3d Cir. 1981).

Since the filing of this lawsuit and the Court's summary judgment decision three years ago, the VA has broadened its health care program. Most notably, in 2014 Congress established the Veterans Choice Program which *inter alia* increases VA funding to hire more physicians and staff, and allows the VA to authorize care for veterans outside the VA health care system if they meet certain criteria. *See* PL 113-146 as amended by PL 113-75, 113-235, 114-19, 114-41. The VA currently has Congressional appropriations of over \$59 billion, and provides care to more than 9.2 million veterans in 168 hospitals and 1,221 outpatient clinics, located throughout the United States. *See* Hughes Decl. ¶ 7. The VA's "medical benefits package" consists of all necessary inpatient hospital care and outpatient services to promote, preserve or restore veterans' health. *Id.* VA

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medical facilities provide a wide range of services. *Id.*; 38 C.F.R. § 17.38. Importantly, the VA medical benefits package includes some long-term care services such as a VA nursing home program, domiciliary care, medical foster home, and State Veterans Homes, as well as "geriatric and extended care services for veterans who are elderly and have complex needs, and to veterans of any age who need daily support and assistance." *Id.* Veterans who are service-connected for disabilities due to participation in military testing are eligible for health care from the VA for those service-connected disabilities at no cost, and have access to VA facilities for any other health care needs, though there may be a co-pay. *See* 38 C.F.R. §§ 17.37, 17.38, 17.108, 17.110, 17.111; ECF 517. In sum, the VA health care system is specifically set up for the express purpose of providing a wide-range of medical care to veterans, including for service-connected conditions and disabilities.

The Army's legal authority to provide health care must come from Congress. *See Bell v. United States*, 366 U.S. 393, 401 (1961); *see also Schism v. United States*, 316 F.3d 1259, 1272 (Fed. Cir. 2002) (citing Supreme Court authority that benefits for retired military personnel depend upon the exercise of legislative grace). In contrast to VA care, the only available health care that the Army is Congressionally-authorized to provide to the plaintiff class would be at MTFs, pursuant to its authority under 10 U.S.C. § 1074. In accord with that statutory authority, a "member of a uniformed service" is "entitled to medical and dental care in *any facility of any uniformed service*," *i.e.*, in an MTF. *Id.* § 1074(a)(1) (emphasis added). Plaintiffs are veterans, not members of the uniformed services. Under § 1074(c)(1), the Secretary of Defense and the Secretaries of the service branches have discretionary authority to promulgate regulations establishing eligibility for health care not otherwise created by statute:

Funds appropriated to a military department . . . may be used to provide medical and dental care to persons entitled to such care by law or regulations, including the provision of such care (other than elective private treatment) in private facilities for members of the uniformed services.

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Id. § 1074(c)(1). Beyond certain other narrow categories of eligibility, there is no other statutory 1 authority for the provision of health care to non-retiree veterans.² Accordingly, pursuant to 2 3 § 1074(c), DoD published regulations to create the "Secretarial Designee" or "SECDES" program 4 through which medical care could be provided directly by the Army in MTFs: 5 Secretarial Designee Program. The program established under section 1074(c) to create by regulation an eligibility for health care services in military medical 6 treatment facilities (MTFs) as well as dental treatment facilities for individuals who 7 have no such eligibility under 10 U.S.C. chapter 55. 8 32 C.F.R. § 108.3 (emphasis added). Notably, the SECDES policy makes clear that MTF care is 9 available to Plaintiffs who were research subject volunteers:

(i) Research Subject Volunteers. Research subjects are eligible for health care services from MTFs to the extent DoD Components are required by DoD Directive 3216.02 to establish procedures to protect subjects from medical expenses that are a direct result of participation in the research.

Id. § 108.4(i). In addition, AR 70-25, which underlies this Court's holding that the Army must

provide medical care to Plaintiffs, contemplates that medical care be provided through MTFs:

k. Volunteers are authorized all necessary medical care for injury or disease that is a proximate result of their participation in research.

(2) Medical care costs for all other categories of personnel, who under the provisions of AR 40–3 are routinely authorized care in a military MTF will be waived for the volunteer while in the hospital, if the volunteer would not normally enter the hospital for treatment but is requested to do so to facilitate the research. This also applies to a volunteer's extension of time in a hospital for research when the volunteer is already in the hospital.

In short, the relevant provisions of the United States Code, the Code of Federal Regulations, and the Army's Regulations, make clear that Defendant is limited to providing Plaintiffs medical care through MTFs by using the SECDES authority.

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The mission and scope of care available from MTFs differs from the comprehensive health

care available from the VA. See Hughes Decl. ¶¶ 6-8. In comparison to health care services at

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² The final clause in the pertinent provision in § 1074(c) -- "including the provision of such care . . . in private facilities for members of the uniformed services" -- makes clear that the care is through MTFs except if a special provision is made for members of the uniformed services. NO. C 09-37 CW

MTFs, the VA health care system is designed to provide more comprehensive health care services to a smaller and older population through a greater number of facilities nationwide that receive greater funding. *Id.* While military medical centers and certain hospitals in the Military Health System provide comprehensive health care services comparable to the VA, the Military Health System overall is focused on serving the health care needs of current military service members and their dependents, and is not designed to serve an aging veteran population across all regions of the United States in the comprehensive manner provided by the VHA. *Id.*

For these reasons, the Court can again find that an injunction is not warranted, not as a categorical legal matter—which the Ninth Circuit rejected—but based on the fact that these are two separate, distinct, and markedly different systems, and VA care is designed, intended, and better suited to treat the class plaintiffs nationwide.

II. ALTERNATIVELY, THE COURT SHOULD ENTER AN INJUNCTION LIMITED TO DIRECTING THE ARMY TO PROVIDE HEALTH CARE TO PLAINTIFFS.

If the Court determines that an injunction is necessary, the injunction should simply direct the Army to fulfill its obligations under AR 70-25 to provide medical care to plaintiff class members who were exposed to a chemical or biological substance as part of their participation in research, for any "injury or disease that is a proximate result of their participation in the research" (AR 70-25). Defendant has submitted a proposed form of order which provides this relief, and has set forth a plan for how the Army will carry out such an injunction. See Hughes Decl. ¶ 9. But the Court should decline Plaintiffs' invitation to impose particular detailed requirements for how the Army must carry out this mandate. The claim at issue is whether the Army violated § 706 of the APA by failing to provide health care to Plaintiffs. See Fourth Amended Compl. ¶ 22, 128, 189(c). As this Court has noted (see ECF 544 at 21), a "claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a discrete agency action that it is required to take." Sea Hawk Seafoods, Inc. v. Locke, 568 F.3d 757, 766 (9th Cir. 2009) (quoting Norton v. S. Utah Wilderness Alliance (SUWA), 542 U.S. 55, 64 (2004)). Plaintiffs prevailed on their claim that the provision of health care under AR 70-25 was required by § 706(1), and that is the NO. C 09-37 CW DEFENDANTS' RESPONSE TO THE COURT'S ORDER REGARDING A PROPOSED HEALTH CARE INJUNCTION

appropriate, limited scope of what the Court may order. Section 706 does not otherwise open the door for the Court to impose specific additional requirements on the agency's discretion in carrying out that discrete agency obligation, precisely because AR 70-25 only requires the provision of care. AR 70-25 leaves to the Army's discretion how that care is to be provided, how proximate cause is to be determined, and how any other particulars relating to that care are to be undertaken by the Army. Because the regulation itself is limited in scope, the Court's injunction necessarily must be so limited. *SUWA*, 524 U.S. at 64.

Accordingly, if the Court intends to enter an injunction, it should do no more than enter the straightforward proposed form of order Defendant has submitted, and not otherwise restrict the Army's discretion to carry out this mandate. The Army has created a Plan for implementing such an injunction. *See* Hughes Decl., Attachment 5 (Army Plan). Under the Army's Plan, a class member would submit an application explaining why he and his treating physician believe the injury or illness is caused by the exposure, as well as documentation supporting the applicant's claim, including relevant medical records, Army personnel records, and any VA service connection decisions. *See id.* The Army will establish a Benefits Application Panel to review completed applications and determine whether the "proximate result" standard set forth in AR 70-25 has been met.³ The Panel will consist of at least three medical professionals who will consider relevant evidence and factors as per ¶ 4 of the Army's Plan.

If the Panel determines the proximate result test has been met, the Panel will request SECDES status for the applicant so he can receive medical care for the research related medical condition. If the Secretary of the Army grants the request for SECDES status, the applicant will be provided with an access ID card entitling him to receive treatment for the approved condition at the MTF closest to his residence with the capability to treat that condition. The applicant will

³ Both this Court and the Ninth Circuit acknowledged the significance of the proximate result standard. *See* ECF No. 544 at 47 (Plaintiffs are entitled to "medical care for disabilities, injuries or illnesses caused by their participation in government experiments."); *VVA*, 811 F.3d at 1080 ("[T]est subjects must show they suffer from diseases that are a proximate result of their participation in government experiments.") NO. C 09-37 CW

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not have any co-pay or any charge for his care at the MTF. If the Panel denies a class member's application, that would be a final agency decision that is subject to judicial review.

The Army's proposed plan is an appropriate exercise of agency discretion that is entitled to deference. *See VVA*, 811 F.3d at 1080; *Firebaugh Canal Co. v. United States*, 203 F.3d 568, 578 (9th Cir. 2000). Section 706 of the APA does not permit "broad programmatic attacks" under the rubric of reviewing discrete agency action. *SUWA*, 542 U.S. at 64-66 (rejecting APA challenge where a statute provided a mandatory object to be achieved, but also provided the agency with "a great deal of discretion in deciding how to achieve it"). Here, the Court has held that a mandate to provide medical care exists, and can so order that, but should not otherwise impose particular non-discrete obligations on the Army in carrying out that mandate.

III. PLAINTIFFS' PROPOSED INJUNCTION IS NOT APPROPRIATE

To the extent the Court intends to issue a more specific injunction than the form Defendant has proposed, it should at least hew to the approach set forth in the Army's Plan in doing so. In no event should the Court adopt the terms of Plaintiffs' proposed injunction, which not only exceed the relief allowable under the APA but would impose unnecessary, onerous, and inappropriate requirements on the Army.⁴

Most notably, contrary to the controlling regulations and the law of the case, **Plaintiffs'** ¶ **2** attempts to substitute a "diagnosed as or plausibly associated with" standard for the AR 70-25 standard of "proximate result," the core governing standard in the regulation at issue, in flat contravention of what this Court and the Ninth Circuit recognized would apply.

Plaintiffs' ¶ **6** seeks to have the Army do physical examinations of all test subjects to determine eligibility for medical care. But such a requirement is nowhere apparent in AR 70-25, and is not the kind of discrete agency action that can or should be compelled by a court. The Army intends to undertake an administrative process in which the relevant evidence will be collected of

⁴ Plaintiffs' proposal begins with eight "Whereas" clauses that are unnecessary, beyond the necessary scope of any injunction, argumentative, and contested. Their inclusion in any injunction alone risks further litigation. NO. C 09-37 CW

a person's participation in the research at issue, medical diagnosis, and whether a medical condition was the proximate result of the exposure at issue. *See* Army Plan \P 3. This is the proper approach to determining whether particular individuals are eligible for health care.

Plaintiffs' ¶ 3 seeks the appointment of a special master to oversee the Army's compliance with an injunction, and Plaintiffs' ¶ 7 purports to give a special master the power to overrule an Army decision on eligibility for medical care or make that decision in the first instance if the Army has not issued a decision within 45 days, make that decision final and binding on the Army, and impose court monitoring of that process. These proposed provisions are unwarranted and contrary to law. Most notably, any further judicial review of individual adjudications of a person's eligibility for health care should proceed in the normal course under applicable law (which would be APA review) and in an appropriate forum. While this Court could oversee whether its injunction is being carried out, such individual adjudications would be different claims, on individualized records, rather than the broad policy claims this Court has reviewed.

Plaintiffs' special master proposal has other significant flaws. Federal Rule of Civil Procedure 53, "Masters," does not permit an appointed master to issue final, binding decisions that are not reviewable in district court. The types of individual agency determinations that will be at issue are subject to APA review by a judicial officer only. In addition, imposing a time limit after which a non-judicial officer could grant eligibility to health care is particularly inappropriate given the potential size of the class, potential delays in obtaining a complete record and then issuing a final agency decision on the matter.⁵ Moreover, to the extent delay in obtaining decisions on eligibility is a concern, the APA provides for this contingency too -- the applicant has the right to move to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1). The Army's Plan establishes a panel of medical experts with the appropriate expertise to determine whether the applicant's exposure was the proximate cause of his medical condition. *See* Army

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⁵ Plaintiffs argued in their motion for class certification that "the Proposed Class has at least tens of thousands of members." *See* Order, ECF 485. DoD identified 6,400 service members and civilians who were exposed to mustard agents and other chemical substances during WWII and approximately 7,000 service members who were Cold War-era test participants. NO. C 09-37 CW

Plan ¶¶ 4, 7. A non-judicial officer cannot override this process simply because it takes more than 45 days or at any point.

Plaintiffs' ¶ 7(a) seeks to define the scope of the applicable administrative record available to the special master, which is the province of the administrative agency to assemble and present to a reviewing court. **Plaintiffs'** \P 4(a), (b) and \P 5 would have the Army provide status reports to the Court every three months that are not required by AR 70-25, and are well beyond what is necessary or appropriate. Plaintiffs' ¶ 4(c), (d), (e) would have the Army describe how it will determine eligibility for care, notify the class, and provide care – but the Army has already provided a plan doing all those things. See Army Plan ¶¶ 1, 4-6. As to Plaintiffs' ¶ 8, the parties are in agreement that the medical care offered by the Army is in addition to the medical care available to the class through the VA (see Army Plan FN 1). However, Plaintiffs would add in a clause that "the Army should provide referrals to DVA facilities and/or private physicians for free medical care." But Plaintiffs are fully aware that the VA is no longer a defendant in this litigation and cannot be compelled to provide medical care; they appealed this Court's sensible determination that VA care was already available to them; and, in any event, the Army cannot be compelled to ensure that another agency's health care system will be available to the plaintiff class. Nor does the Army have any statutory authority to pay private physicians to provide medical care to Plaintiffs. See supra Section I (care to be provided at MTFs); 10 U.S.C. § 1074; 32 C.F.R. §§ 108.3, 108.4; AR 70-25. Plaintiffs have sued to obtain health care directly from the Army, and that is all the relief the Court has discretion under existing statutory and regulatory authority to afford them. For all these reasons, Plaintiffs' proposed injunction provides no reasonable guideposts for the Court to follow should it decide to issue an injunction.

CONCLUSION

For the reasons set forth above, no medical care injunction is appropriate, but if one is entered, the Court should issue a limited order as Defendant proposes and defer to the Army's proposed implementation plan.

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Dated: November 15, 2016 Respectfully submitted, 1 2 **BENJAMIN C. MIZER** Principal Deputy Assistant Attorney General 3 BRIAN STRETCH United States Attorney 4 ANTHONY J. COPPOLINO Deputy Director, Federal Programs Branch 5 6 /s/ Susan K. Ullman SUSAN K. ULLMAN 7 District of Columbia Bar No. 426874 Senior Trial Counsel 8 Civil Division, Federal Programs Branch U.S. Department of Justice 9 20 Massachusetts Ave., NW Washington, D.C. 20530 10 Telephone: (202) 616-0680 E-mail: susan.ullman@usdoj.gov 11 12 Attorneys for Defendants 13 14 15 16 17 18 19 20 21 22 23 24 25 26 NO. C 09-37 CW DEFENDANTS' RESPONSE TO THE COURT'S ORDER REGARDING A PROPOSED HEALTH CARE INJUNCTION

Attestation Pursuant to Civil Local Rule 5-1

I, Susan K. Ullman, am the ECF User whose ID and password are being used to file this document.

Date: November 15, 2016

/s/ Susan K. Ullman Susan K. Ullman