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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

VIETNAM VETERANS OF AMERICA, et al.,

Plaintiffs,

v.

CENTRAL INTELLIGENCE AGENCY, et al.,

Defendants.

Case No. CV 09-0037-CW (EDL)

DEFENDANTS' RESPONSE TO THE COURT'S ORDER REGARDING A PROPOSED HEALTH CARE INJUNCTION

INTRODUCTION

Pursuant to the Court's December 7, 2016 Order (ECF No. 588), the Army[1] respectfully submits this response to the Court's proposed injunction requiring the Army to effectuate its plan for providing medical care and reply to Plaintiffs' proposed modifications to the Court's proposed injunction.

In this action, Plaintiffs presented a claim under the Administrative Procedure Act (APA), and specifically § 706(1) of the APA, that the Army had unlawfully withheld the provision of healthcare to Plaintiffs pursuant to Army Regulation (AR) 70-25. AR 70-25 permits the provision of "all necessary medical care for injury or disease" to volunteer test participants "that is a proximate result of their participation in research." AR 70-25 at 3 (1990). As the sole source for the authority to provide medical care, and the sole basis for the claim before the Court, AR 70-25 defines both the source of the obligation to provide care and limits the authority of this Court to impose additional obligations beyond those specified in the regulation. As this Court has noted (*see* ECF No. 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 All.* (*SUWA*), 542 U.S. 55, 64 (2004)). Accordingly, as set forth further below, the power of this Court to craft a remedy is limited to the power to require the undertaking of a "discrete" action. Here, the "discrete" action found by the Court was that a duty existed under AR 70-25 to provide health care to the Plaintiffs in the face of the Army's contention that the provision imposed no such duty. The Court decided no other issue, such as how that duty is to be carried out. Thus, beyond ordering that the Army must carry out this discrete duty, other obligations imposed or proposed to be imposed by this Court would be improper. The appropriate remedy is not a detailed injunction, but a remand to the Army or simply an injunction to comply with AR 70-25 as it has been interpreted by this Court and the Ninth Circuit.

[1] The District Court granted summary judgment in favor of Defendants United States of America, the United States Attorney General, the Department of Defense, the Central Intelligence Agency and its Director, and the Veterans Administration and its Secretary. The Army is the sole remaining Defendant in this action.

To the extent the Court nonetheless intends to issue an injunction similar to the Court's Proposed Injunction, ECF No. 588-1, and without waiving the Army's right to seek further review, any such injunction should be limited to compliance with the source of the duty at issue: AR 70-25. Because AR 70-25 only requires the provision of care and does not specify in any detail how the Army must do so, much less in the specific terms set forth in the Army's implementation plan, any injunction should only order compliance with the duty to provide care under AR 70-25. *See* ECF No. 587-1, Army's Implementation Plan. In addition, while the Court's proposed injunction tracks much of the implementation plan the Army already has in place, it nonetheless would improperly limit the Army's discretion in fulfilling its self-imposed duty to provide medical care. Thus, to the extent the Court does issue an injunction along the lines it has proposed, the Army requests a few modifications, either to comport with governing law or for clarification, and also requests that the Court decline to implement several additional changes sought by Plaintiffs.

ARGUMENT

I. RESPONSE TO THE COURT'S PROPOSED INJUNCTION

A. The Court Lacks Authority to Direct the Army to Take Specific Acts to Carry Out its Obligation to Provide Medical Care.

Section 706(1) of the APA does not open the door for the Court to impose specific additional requirements on the agency's discretion in carrying out the discrete agency action found to be at issue here — the duty to provide "all necessary medical care for injury or disease" to volunteer test participants "that is a proximate result of their participation in research" — precisely because AR 70-25 requires nothing further. Rather, 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.

The Court's proposed injunction would improperly limit agency discretion by specifying the manner in which the Army will provide medical care, to include requiring the Army to provide private medical care if care is not available through military treatment facilities or VA facilities. This direction is outside any remedy the Court can provide under the APA. "If a reviewing court agrees that the agency misinterpreted the law," the agency's action must be set aside and the case

must be remanded "even though the agency . . . might later, in the exercise of its lawful discretion, reach the same result for a different reason." *FEC v. Akins*, 524 U.S. 11, 25 (1998). In such circumstances, the district court "ha[s] no jurisdiction to order specific relief." *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005); *see also Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 657–58 (2007) ("As an initial matter, we note that if the [agency's] action was arbitrary and capricious, as the Ninth Circuit held, the proper course would have been to remand to the agency for clarification of its reasons.") (citing *Gonzales v. Thomas*, 547 U.S. 183 (2006) (*per curiam*)). Indeed, even if an injunction were appropriate under the APA, it "would need to be limited only to vacating the unlawful action, not precluding future agency decisionmaking." *Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 46 n.1 (D.C. Cir. 2013).

Once the Army undertakes its obligation to provide medical care by establishing a system to adjudicate claims and to provide medical care to those eligible under AR 70-25, the challenged agency action is no longer being unlawfully withheld. It remains within the Army's discretion to determine how such care will be provided in accordance with its own regulations and requirements, including deciding whether a particular applicant meets the proximate result requirement of the regulation. Accordingly, the Court should limit its order to simply require the Army to carry out the "enforceable duty" it determined the Army owed to the Plaintiffs under AR 70-25 and nothing more.

The Army's submitted plan sets forth the approach the Army intends to take in implementing this duty. *See* Army's Implementation Plan, ECF No. 587-1. But conversion of the Army's plan into an injunction would go beyond the scope of the Court's power under § 706(1) and improperly limit the Army's flexibility in implementing the duty to provide medical care. There is no legitimate concern that the Army will not duly undertake its obligations, and it should be presumed that the Army will proceed in good faith. *County of Del Norte v. United States*, 732 F.2d 1462, 1468 (9th Cir.1984) ("In the absence of clear evidence to the contrary, courts presume that public officers properly discharge their duties....") (citing 3 K. Davis, Administrative Law Treatise § 17.6 (2d ed. 1980) (quoting *United States v. Chemical Foundation, Inc.*, 272 U.S. 1, 14–15 (1926))). Plaintiffs contend that Army's good-faith defense of its prior interpretation of the

regulation somehow demonstrates the likelihood that the Army will not comply going forward. *See* ECF No. 591 at 4. That argument is entirely conjectural, and mischaracterizes disagreements on questions of law about the scope of an obligation with a purported intent not to comply with a court order. *See Chemical Foundation*, 272 U.S. at 14–15 ("The presumption of regularity supports the official acts of public officers, and, in the absence of clear evidence to the contrary, courts presume that they have properly discharged their official duties."). The Army, along with the Department of Defense and the Veterans Administration, has long sought to meet the needs of test participant class members, *see* ECF No. 495 at 2–10 (describing decades-long outreach efforts), just not through the mechanism of AR 70-25 as it now is interpreted, and will continue to do so.

Specifically, after taking in and adjudicating claims, the Army intends to provide medical care for injuries proximately caused by research participation in military treatment facilities using the Secretarial Designee Authority and, where such care is inconvenient for the veteran or unavailable through military treatment facilities, to coordinate with the VA to provide care in VA facilities. In carrying out its plan, the Army will not be withholding medical care that the Court found was owed under AR 70-25. However, as long as the Army is carrying out its duty to apply AR 70-25 to Plaintiffs who qualify for such care under that provision, the Court should not dictate the manner for carrying out the provision, including deciding whether or not a person's injury or disease is a proximate result of their participation in research or how such care is provided. At most, the appropriate response at this stage would be an injunction limited to the terms of AR 70-25 that preserves Army's discretion under governing law to implement the regulation as it is now being interpreted by the Court and according to the plan Army has developed. *N. Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012) ("When a district court reverses agency action and determines that the agency acted unlawfully, ordinarily the appropriate course is simply to identify a legal error and then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal.").

B. The Army's Authority To Provide Medical Care Is Limited To Military Treatment Facilities.

Beyond the question of whether any injunction to enforce AR 70-25 would be proper, and the appropriate scope of any such injunction, the Court's proposed injunction raises certain specific concerns, including directing the provision of health care by private providers outside of Military Treatment Facilities. Cognizant of this concern, the Court has invited the parties to "address in their filings the Army's argument that it lacks authority to pay for medical care provided outside of its network of Military Treatment Facilities." ECF No. 588 at 2.

As an initial matter, the likelihood that a veteran deemed by the Army to require care for injuries proximately caused by participation in Army research will not also be deemed by the VA to be eligible for service-connected VA care (which employs a lower standard of proof), is practically nil. Therefore, the Court should not stretch its limited authority in this context to cover such an unlikely situation. In any event, as the Army has argued, Army funding of *private* physician care is not authorized by AR 70-25 or any other law. *See* ECF No. 587. In arguing to the contrary, Plaintiffs conflate this Court's determination that the Secretary of the Army had the authority to create an "enforceable right" *via* AR 70-25 to medical care with the manner in which the Secretary must implement the duty to provide such care. Whether the Secretary of the Army has authority to provide health care generally is different from whether there is authority to pay for particular kinds of health care services (for example, from private providers).

The authority to pay for health care services is controlled by principles of fiscal law, and the only fiscal authority that exists for the Army to provide medical care to former research participants is 10 U.S.C. §1074(c). Plaintiffs assert that "[t]he statute does not restrict how those 'appropriated funds' must be used." ECF No. 591 at 6. Plaintiffs, however, neglect to consider (or even quote) the statute's language in its entirety. Specifically, 10 U.S.C. § 1074(c) states, "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, <u>including the provision of such care (other than elective private treatment) in private facilities for members of the uniformed services</u>." 10 U.S.C. § 1074(c)(1) (emphasis added). Therefore, contrary to Plaintiffs' argument, the statute

does, in fact, restrict how funds may be used — only allowing care in private facilities for members of the uniformed services.

Congress appropriates funds for specified medical care each year. The funding for medical care derives from Congress's appropriation to the Defense Health Program.[2] The use of these funds is constrained to what has been authorized by Congress, placing limitations on the manner in which funds are expended. *United States v. Maccollom*, 426 U.S. 317, 321 (1976) ("The established rule is that the expenditure of public funds is proper only when authorized by Congress, not that public funds may be expended unless prohibited by Congress."). Chapter 55 of Title 10 prescribes the use of those funds for medical care to members of the armed forces, their dependents, and retirees, with one limited exception — Secretarial Designees (10 U.S.C. § 1074(c)). And, as noted, section 1074(c) does not authorize payment for private medical care for former service members.[3]

Plaintiffs incorrectly suggest that the Court has already rejected the Government's argument that it lacks fiscal authority to provide the contemplated medical care outside of MTFs.

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[2] For instance, for Fiscal Year 2016, Congress including the following in their Omnibus Appropriations Act, "DEFENSE HEALTH PROGRAM – For expenses, not otherwise provided for, for medical and health care programs of the Department of Defense as authorized by law, $32,329,490,000; of which $29,842,167,000 shall be for operation and maintenance, of which not to exceed one percent shall remain available for obligation until September 30, 2017, and of which up to $14,579,612,000 may be available for contracts entered into under the TRICARE program; of which $365,390,000, to remain available for obligation until September 30, 2018, shall be for procurement; and of which $2,121,933,000, to remain available for obligation until September 30, 2017, shall be for research, development, test and evaluation: *Provided*, That, notwithstanding any other provision of law, of the amount made available under this heading for research, development, test and evaluation, not less than $8,000,000 shall be available for HIV prevention educational activities undertaken in connection with United States military training, exercises, and humanitarian assistance activities conducted primarily in African nations: *Provided further*, That of the funds provided under this heading for research, development, test and evaluation, not less than $943,300,000 shall be made available to the United States Army Medical Research and Materiel Command to carry out the congressionally directed medical research programs." Pub. L. No. 114-113, 129 Stat. 2242 (2015).

[3] The Army's implementing regulations affirm this restriction. The controlling Defense Department regulation implementing Section 1074(c) explicitly allows medical care to be provided to research volunteers only "during the pendency of the volunteer's involvement in the research." 32 C.F.R. § 108.4(i).

Setting aside the Court's express invitation to address this unresolved issue, the Army's previous arguments concerned the authority to mandate medical care for former service members in the first instance, not whether or not funds may be expended to pay for private physician care as a matter of fiscal law. *See* ECF No. 495 at 32-34. In addressing those prior issues, the Court found that the Secretary's authority under housekeeping statutes was sufficient to adopt a regulation "promising to provide volunteers with medical treatment," thereby creating a "substantive rule . . .sufficient to create enforceable rights." ECF No. 544 at 27. The Court did not say that the adoption of the regulation, in and of itself, was sufficient fiscal authority to provide that medical care *in a particular manner*, much less outside the bounds of applicable law. *Id*.

Rather, to the extent this Court has found that 10 U.S.C. §§ 3013 and now-repealed 4503 authorized the Secretary to create an enforceable right to medical care to veterans no longer connected with the Army, the Secretary's authority to satisfy this obligation is confined to his authority to fund the medical care. And the only possible authority to expend funds for health care to satisfy the obligations of AR 70-25 is 10 U.S.C. § 1074(c). Thus, the Court's ruling necessarily must take account of the authority available under that statute to provide medical care. To hold otherwise would amount to a holding that the Secretary's unilateral announcement of an obligation to provide health care through the issuance of a regulation authorizes the Department to expend appropriated funds not authorized by Congress — a clear *ultra vires* action by any agency head or cabinet secretary.[4]

Because the Army may act only pursuant to its lawful authority to spend appropriated funds, it may not, through Secretarial Designee authority, or pursuant to housekeeping authority, or by regulatory happenstance *via* AR 70-25, authorize itself to pay for private medical care. The

[4] Nor do DoD regulations provide the Army with the authority to provide medical care outside of medical treatment facilities, as Plaintiffs suggest. While DoD regulations allow the Army to supplement Secretarial Designee procedure, such supplements must be "consistent with applicable authority." DoD Instructions No. 3216.02, Enclosure 3, ¶ 10.b (Nov. 8, 2011), http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdfv (last visited March 1, 2017). As explained above, neither 10 U.S.C. sections 3103, 4503, nor 1074(c) give the Secretary of the Army the authority to use funding in a way otherwise prohibited by statute.

only care authorized by AR 70-25 to class members is through MTFs. For this reason, the draft injunction language providing to the contrary should be deleted.

C. The Court Lacks Authority to Create Jurisdiction Over Individual Agency Decisions.

The Court's proposed injunction also provides that "[a]ny disputes regarding the denial of medical care may be presented to the Court as a motion to enforce the injunction." Proposed Injunction ¶ 7. The Government respectfully submits that this aspect of the proposed injunction is improper for two distinct reasons. First, it is not narrowly tailored to remedy the § 706(1) violation identified by the Court. Second, claimants wishing to challenge a future denial of medical care already have an existing remedy at law: they can (and, indeed, must) bring a separate lawsuit under the standards of review set forth in § 706(2) of the APA.

1. While a "district court has considerable discretion in fashioning suitable relief and defining the terms of an injunction," *Lamb-Weston, Inc. v. McCain Foods, Ltd.*, 941 F.2d 970, 974 (9th Cir. 1991), there "are limitations on this discretion; an injunction must be narrowly tailored to give only the relief to which plaintiffs are entitled." *Orantes-Hernandez v. Thornburgh*, 919 F.2d 549, 558 (9th Cir. 1990). As this Court has recognized (ECF No. 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*, 568 F.3d at 766 (quoting *SUWA*, 542 U.S. at 64). Here, the Court has determined that the discrete action the Army has a duty to undertake under AR 70-25 is the provision of medical care to volunteer participants who were proximately injured as a result of their participation in research. The Court's injunction must therefore be limited to remedying this particular § 706(1) violation. *See Church of the Holy Light of the Queen v. Holder*, 443 F. App'x 302, 303 (9th Cir. 2011) (injunctive relief "must be tailored to remedy the specific harm alleged. An overbroad injunction is an abuse of discretion").

Plaintiffs have not alleged (nor could they) that AR 70-25 imposes a duty enforceable under § 706(1) of the APA to find that a *particular claimant* was proximately injured as a result of his participation in past research. Such determinations must be made on an individualized basis based on the medical evidence presented to the Army and the professional evaluations of Army medical personnel (and, as discussed below, would be subject to review under § 706(2) of the APA). But

such individualized assessments of medical proximate causation cannot be challenged as a failure to undertake a discrete, required agency action under § 706(1) of the APA in this context.

For this reason, the Court's retention of jurisdiction to review the merits of each individual future proximate cause determination by the Army is well outside the scope of Plaintiffs' complaint, the scope of the litigation leading to final judgment, and the legal injury identified by the Court.[5] Put simply, the question of whether class members have been proximately injured by the Army, which could not have been brought in the form of a § 706(1) claim, has never been at issue in this case and should not be a subject of the Court's injunction. *See Church of the Holy Light of the Queen*, 443 F. App'x at 303 (while a ban on the importation of Daime tea by church violated the Religious Freedom Restoration Act, the Ninth Circuit reversed the district court's injunction enjoining portions of the Controlled Substances Act and associated regulations as "overly broad because it reaches beyond the scope of the complaint and enjoins government regulations that were explicitly never challenged or litigated").

2. Moreover, claimants wishing to challenge the Army's denial of medical care already have an existing remedy at law that will be governed by the arbitrary and capricious standard of review set forth in § 706(2) of the APA, which undercuts the need and justification for an injunction in which the court retains jurisdiction to resolve disputes over medical causation. *See O'Shea v. Littleton*, 414 U.S. 488, 502 (1974) (plaintiff must demonstrate "the inadequacy of remedies at law" to support entry of injunction); *Califano v. Yamasaki*, 442 U.S. 682, 705 (1979) (same).

For example, district courts routinely review determinations made by the Army Board for Correction of Military Records (ABCMR), including decisions resulting in the denial of military benefits, under § 706(2) of the APA[6]. *See Joslyn v. United States*, 110 Fed. Cl. 372, 386-87 (Fed.

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[5] As set forth above, once the Army undertakes its obligation to establish a system to adjudicate claims and to provide medical care, its duty to take "discrete" agency action under AR 70-25 is no longer unlawfully withheld. Furthermore, AR 70-25 leaves to the Army's discretion how that care is to be provided, including how proximate cause is to be determined.

[6] The Secretary of the Army may act through a civilian board to correct any Army record when he "considers it necessary to correct an error or remove an injustice." 10 U.S.C. § 1552(a)(1).

Cl. 2013) (ABCMR decision resulting in the denial of retirement benefits reviewed under § 706(2)); *Coburn v. McHugh*, 77 F. Supp. 3d. 24, 27-29 (D.D.C. 2014) (ABCMR decision upholding plaintiff's discharge from the Army reviewed under § 706(2)). Under § 706(2) of the APA, a court will overturn an agency decision only if it is "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Burns v. Marsh*, 820 F.2d 1108, 1110 (9th Cir. 1987) (reviewing ABCMR decision under arbitrary and capricious standard); *McHugh*, 77 F. Supp. 3d. at 29 (same). "An agency action is arbitrary and capricious if the agency has failed to follow procedures required by law or if it has entirely failed to consider an important aspect of the issue." *Motor Vehicle Mfrs. Ass'n v. State Farm Auto Ins. Co.*, 463 US. 29, 43 (1983). Under this standard, a court will not disturb the decision of an agency that has "examined the relevant data and articulated a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id*. at 43. In addition, the agency's decision here is subject to a presumption of regularity. *Escobedo v. Green*, 602 F. Supp. 2d 244, 248 (D.D.C. 2009) (citing *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), abrogated on other grounds by *Califano v. Sanders*, 430 U.S. 99, (1977)). Given the existence of an alternative and adequate remedy at law that will be governed by the arbitrary and capricious standard of § 706(2) of the APA to challenge the denial of medical care, this Court should not enter an injunction creating a separate (and potentially conflicting) mechanism to challenge any future denials of medical care by the Army. *See O'Shea*, 414 U.S. at 502 (plaintiff must demonstrate "the inadequacy of remedies at law" to support entry of injunction).

In sum, an injunction requiring this Court to review future proximate cause determinations by the Army, which have not been at issue in this case, is an improper means to remedy the § 706(1) violation found in this case with respect to the scope of AR 70-25. Having decided a narrower question — whether there is a duty to provide health care under AR 70-25 to persons that may be eligible for such care under that regulation — a single federal district court is not thereby empowered under a theory of enforcement jurisdiction, to the exclusion of any other court, to review all individualized claims that might arise under that provision. Instead, claimants must challenge any future denials of medical care by filing a new challenge governed by § 706(2) of the

APA. For this reason, the Army respectfully requests that, should the court enter any injunction, it provide simply (as set forth in the Army's original implementation plan, *see* ECF No. 587-1) that any final decision by the Army with respect to an application for the provision of health care would be reviewable under applicable law and in the appropriate forum established by law.[7]

II. RESPONSES TO PLAINTIFFS' MODIFICATIONS TO THE COURT'S PROPOSED INJUNCTION

Plaintiffs offered several modifications to the Court's proposed plan, arguing such changes would "ensure the injunction reflect[ed] a fair and equitable implementation of the Army's legal duties under AR 70-25." ECF No. 591 at 2. As explained below, Plaintiffs' modifications create obligations beyond what the Court found the Army was required to provide, create undue burdens, and are otherwise unwarranted.

A. Reporting Requirement

Plaintiffs request that the Court include a reporting requirement in its medical care injunction. Plaintiffs argue this reporting requirement need not be an "intrusive" obligation, yet Plaintiffs request substantial obligations beyond the Army's duty of proving medical care. Specifically, Plaintiffs request a quarterly reporting requirement consisting of not only the number of applications received and considered, but also the locations of available treatment facilities, and the frequency of visits by individual test subjects — information which is not relevant to ensuring the Army is complying with the Court's injunction. Generally speaking, ongoing reporting obligations are not proper in the context of APA remedies. *See* Part I.A, *supra*. To the extent the Court incorporates such a requirement, the Army is amenable to reasonable reporting obligations, but Plaintiffs' requests are unnecessary, overly burdensome, and unnecessarily intrusive.

First, there is no reason to require reporting of individualized reasons for application denials. Individual applicants will receive written notification of the basis for any denial decision. As discussed above, should an applicant be dissatisfied with those reasons, there already exists a

[7] While the Government believes the Court would lack jurisdiction to resolve future adverse proximate cause determinations, should the Court choose to do so, it should, at a minimum, incorporate the standards of review set forth in section 706(2) of the APA in any injunction. *See supra*.

remedy to challenge such an agency action under the standards of review of § 706(2) of the APA (regardless of whether or not this court retains jurisdiction over such claims). Furthermore, while Plaintiffs' counsel represented the class for the purpose of enforcing the Army's duty to provide medical care, it is not apparent that such representation extends to every individual application denial, and thus it is questionable whether Plaintiffs' counsel are entitled to personal health care information for every person whose application may be denied. And if the current Plaintiffs' counsel do represent every individual who applies for health care under AR 70-25, they should be in a position to make arrangements to obtain whatever decision may be issued from their clients.

Second, pursuant to 32 C.F.R. § 108.4(p), military treatment facilities of all branches will be available to individuals who are provided Secretarial Designee ("SECDES") status. 32 C.F.R. § 108.4(p). The Army has already provided notice of the location of such facilities. ECF No. 587-1 at 8, 10, 12. To require the Army to provide a list of all available facilities every quarter is excessive and unnecessary.

Finally, Plaintiffs' request for notice of the number of visits by individual test subjects following *approval* for healthcare has no apparent probative value concerning the Army's compliance with the Court's injunction. Additionally, information pertaining to individual receipt of medical care would be protected by other privacy statutes. *See e.g.*, Health Insurance Portability and Accountability Act, Pub. L. No. 104-101, 110 Stat. 49 (1996). Further, once individual applications are approved, it is completely within the applicant's discretion whether and how often they use the care the Army provides. As long as access is provided, it is no longer the Army's duty to ensure an individual actually seeks care from the Army. Additionally, frequency of medical visits are related to other factors beyond whether the Army is making care available (e.g., whether an individual's testing related issue is symptomatic). Ultimately, this is personal information between a patient and physician that is not maintained by the Army. The lack of probative value of such information, coupled with the burden that would result in having to compile such information, as well as privacy interests individuals have in their personal health information, make Plaintiffs' request for individual medical care information unreasonable.

If the Court wishes to include reporting requirements, less extensive requirements would be appropriate. Specifically, the Army could provide a status update on its implementation plan and notice 180 days after the Court enters the injunction. Thereafter, the Army could provide status reports annually, notifying the Court of the number of complete applications the Army has received and the number of applications that have been considered, including the number on which a decision has been rendered, until a set time in the future (for example, 3 years).

Regardless of whether the Court creates a reporting requirement, Plaintiffs' request for the Court to create a separate reporting requirement for the Army regarding creation of a volunteer database (provided for in AR 70-25) is entirely outside the scope of this injunction. The Army's duties imposed by AR 70-25 were thoroughly and heavily litigated in this Court, and at no time did Plaintiffs prevail on any issue related to AR 70-25's volunteer database requirements, with which the Army has long-ago complied. Indeed, Plaintiffs withdrew their contentions about such a database. *See* ECF No. 513-1 at 8–9 (discussing volunteer database provision of AR 70-25). Plaintiffs are attempting to re-litigate issues on which they never prevailed, in the context of an injunction concerning an entirely separate aspect of the regulation: the provision of health care. This is inappropriate. At most, these demands go to the provision of notice, not medical care. And that issue has been fully and finally litigated. *See* ECF No. 545, 570.

B. Decision Timelines

Plaintiffs also request the Court impose a 45-day decision timeline on all completed applications. (ECF No. 591 at 3). Plaintiffs further suggest the Court permit individual claimants to come to seek court enforcement following the expiration of that timeline. These requests impose clearly unreasonable expectations on the Army, especially considering the Army is establishing a new review procedure and the exact size of the potential class of applicants as well as the potential complexity of each case is unknown.[8] Until individuals actually file applications, it is unrealistic to put in place such a stringent timeline. Further, to allow immediate court intervention only creates the potential for unnecessary court involvement in the midst of ongoing administrative

[8] It is estimated that there were more than 60,000 chemical and biological testing participants during World War II, and an additional 9,000 used during testing programs from 1955 until 1975. *See* ECF No. 544 at 3–4; 570 at 7–8.

review. While the Army may create a timeliness provision in implementing its plan after the Army has assessed the volume of applications and its ability to process them, imposing deadlines, particularly such drastically short deadlines as Plaintiffs propose *ex ante* is imprudent and would be highly disruptive of the administrative process.

By way of reference, analogous military administrative panel decisions take far longer than 45 days. For instance, the Army Board for Correction of Military Records ("ABCMR") is the highest level of administrative review within the Department of the Army.[9] Congress recognized that fair and thorough review takes time and has directed all the military service Boards for Correction of Military Records to complete 90 percent of all applications received in a fiscal year within 10 months and 100 percent within 18 months. *See* 10 U.S.C. 1557(a)-(b) (2016). The ABCMR processes applications in the order they are received, but it can still take substantial processing time, on average twelve months, for a decision to be made.[10] Similarly, the Integrated Disability Evaluation System ("IDES"), whereby the Department of Defense ("DoD") "determines whether wounded, ill, or injured Service members are fit for continued military service" takes far longer than forty-five days. U.S. Dep't of Def., 1332.18, Disability Evaluation System (DES) Manual: Integrated Disability Evaluation System (IDES), encl. 3, para. 1 (Aug. 5, 2014). The processing goal established by DoD and Veterans Affairs for service members referred into the IDES system is to complete 80 percent of active duty cases within 295 days and reserve component cases within 305 days. *Id.* at encl. 7, para. 2.a; 3.a; and encl. 8 IDES Timeline (Aug. 5, 2014). Any time requirements — and none should be entered — should at most be comparable to these deadlines, rather than Plaintiffs' unreasonable ones.

[9] Army Review Board Agency, The Army Board for Correction of Military Records: Mission Statement, *available at* http://arba.army.pentagon.mil/abcmr-overview.cfm (last visited Feb. 28, 2017).

[10] Army Review Board Agency, The Army Board for Correction of Military Records: Frequently Asked Questions, How Long Should It Take To Process My Application, *available at* http://arba.army.pentagon.mil/abcmr-faq.cfm (last visited Feb. 28, 2017).

If the Court determines to incorporate a timeliness requirement for processing applications, it should consist of a requirement that the Army notify the Court of the timeliness requirement it intends to self-impose after eighteen months of developing the assessment program.

C. Factors To Be Considered in Deciding Application

Plaintiffs also request the Court require the Army to consider several equitable factors in the proposed injunction in deciding whether an applicant's diagnosed condition was the proximate result of his participation in the specific research program. Plaintiffs' request attempts to improperly reduce the standard of proof required by the regulation and removes the Army's discretion in deciding how to implement its duty under the regulation.

The Court found that AR 70-25 requires the Army to provide medical care for illnesses and injuries that were the proximate result of testing participation. ECF 544 at 27. The decision on whether an application meets the scientific standard to qualify for care is withheld to agency discretion, subject only to the APA's arbitrary and capricious standard. Section 706(1) does not grant the Court authority to substitute its discretion for that of the agency, even where the Court has found that the agency has unlawfully withheld action in the past. *See AARP v. EEOC*, 823 F.2d 600, 605 (D.C. Cir. 1987). If the equitable factors the Army drafted are enshrined in injunction form, the original language from the Army's implementation plan, which expressly preserves the Army's scientific discretion to assess all relevant factors, should be restored. *See* Army Plan at 4.

III. ADDITIONAL REVISIONS

The Army respectfully submits additional revisions to the Court's proposed injunction, as follows and as reflected in the concurrently filed redline. See Army's Redline to Court's Proposed Injunction (attached hereto as Exhibit A).

1. Plaintiffs' changes to paragraph 1 are acceptable to Army.
2. "Whether" and "or otherwise" in paragraph 1 should be deleted because the Secretarial Designee (SECDES) statutory authority is the only source of authority for DoD to provide health care to plaintiffs at a MTF.
3. Applications should include any relevant VA records (¶ 3).

4. Initial medical examinations are already available through the VA, pursuant to 38 C.F.R. § 3.326. *See also* ECF No. 495 at 9 (discussing availability of VA examination for Edgewood test participants, as described in notice letters sent to participants). Rather than requiring the Army to "arrange" for any needed examination, it should be sufficient for the Army to provide information advising the potential applicant how to obtain the examination that is already available to them through the VA.

5. The Court should reject Plaintiffs' deletions to subparagraph 4(e) and proposed additions to subparagraph 4(d), and retain the original language the Court included in these subparagraphs, which made clear that the Benefits Application Panel is not required to affirmatively search and weigh information from external voluminous databases (such as the CBRNIAC and DTIC databases), but instead that the Panel will consider such information from these external databases when the information has been provided by the applicant.

CONCLUSION

For the foregoing reasons, the Court should not enter the proposed injunction but, instead, either remand the matter to the Army or enter a limited injunction as proposed by the Army (ECF No. 587-2) and defer to the Army's proposed implementation plan. If the Court does enter an injunction, the Army requests that the proposed injunction be revised as discussed above and as set forth in the concurrently filed "redline" from the Army. *See* Exhibit. A.

Dated: March 1, 2017

Respectfully submitted,

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Attestation Pursuant to Civil Local Rule 5-1

I, Nicholas Cartier, am the ECF User whose ID and password are being used to file this document.

Date: March 1, 2017 /s/ Nicholas P. Cartier
Nicholas P. Cartier

Exhibit A

Army Redline of Court's Proposed Plan
Additions in Blue; Deletions in Red

Proposed Plan for Implementing the Provision of Medical Care Pursuant to Army Regulation 70-25

To fulfill the obligations under Army Regulation 70-25 (AR 70-25) to provide medical care to former members of the armed forces who participated as research subjects in the Army's chemical or biological substance testing programs, ~~the Army exposed to a chemical or biological substance as part of their participation in research,~~ for any injury or disease that is the proximate result of their participation in the research, medical care will be provided to requesting class members as set forth below.

If the class member is determined, under the process set forth below, to have any health condition having a sufficiently strong causal link such that a reasonable person could find that the injury or disease was caused by testing exposure or participation in research, the Army will provide the requisite health care at Department of Defense (DoD) medical treatment facilities (MTFs)~~, whether~~ by using the Secretarial Designee (SECDES) statutory authority, *see, e.g.*, 10 U.S.C. § 1074(c), DoD Instruction 6025.23, AR 40-400.~~,~~[1] ~~or otherwise.~~

A. The Army will implement the following process to determine eligibility for medical care:

[1] The health care provided through this plan is supplemental to the comprehensive care a plaintiff is entitled to receive through the Department of Veterans Affairs (VA) based on his status as a veteran. *See* 38 CFR 17.36(b). This plan will have no bearing and has no effect on the provision of care or benefits independently performed by the VA under its own statutory and regulatory requirements, separate from this plan.

1. Notice to the Class. The Army will notify individuals who may qualify for research related medical care of the potential availability of Army provided medical care and the process to apply for such care. The Army will provide individual notification via first class mail to those class members for whom the Army has contact information. The Army will also provide notice via public media and outreach to the VA and to veteran's service organizations.

2. The Army will use a previously established DoD toll-free number for veterans who believe they may qualify for research related medical care to obtain additional information about potential eligibility for medical care and the process for applying for such care. The Army will make reasonable efforts to assist veterans in determining whether they participated in the relevant research programs by providing internet and toll-free contact information to obtain records of participation in the relevant research programs, to obtain medical records from the VA concerning a diagnosis (the veteran does not have to use a diagnosis from the VA), and to obtain a VA determination concerning service connected disability. The Army will also provide application information to veterans eligible for enrollment in the VA's comprehensive healthcare system. Once a veteran obtains records substantiating research participation, a diagnosis, and any pending or complete VA service connection determination, the veteran may apply (electronically or through the mail) for medical treatment in a military treatment facility.

3. Application: To apply for medical care, an applicant will submit an application to the Army. The application for medical care will consist of a form to be completed by the applicant and treating physician, and documentation to support the

applicant's claim, including: any civilian, VA, or Army medical records showing a diagnosis the applicant believes is proximately caused by exposure during research, Army personnel records relating to research participation,[2] any VA service connection decisions,[3] ~~,~~ and a short statement about why the physician believes the injury or illness is caused by the exposure or participation during research. Complete applications will include (1) records of participation in relevant research; (2) a medical diagnosis believed caused by research participation; and (3) any VA service connection decision (if applicable). In the event a class member is unable to pay for a medical examination ~~for purposes of obtaining a diagnosis to support an application, the Army will arrange for the class member to be examined at no cost at the nearest DoD MTF or VA facility.~~ of a potentially service connected illness or injury, the Army will provide information for the applicant to seek an examination from the VA, pursuant to 38 C.F.R. § 3.326. Upon receipt of a complete application, the Army will make the determination required in para. 4 below.

4. Review of Application: Complete applications will be reviewed by the Benefits Application Panel. This Panel will be established by the Army Medical Command (MEDCOM). The panel will consist of at least three medical professionals

[2] To the extent that former research participants do not have records to show participation, the Army will inform applicants how to apply to the Army Board for the Correction of Military Records (ABCMR). Applicants must then provide the ABCMR will sufficient information to prove research participation in order to have their records corrected to validate their participation in the medical research programs. Upon record correction to indicate research participation, a Veteran can apply for ~~SECDES~~ medical care under this plan.

[3] The Army will make independent proximate result determinations and will be informed by but not bound to any VA service connection decision.

from either the US Army Medical Research Institute of Chemical Defense (for chemical exposure cases) or the US Army Medical Research Institute of Infectious Disease (for biological exposure cases) and may include additional specialty members based on the type of illness or injury being considered. The panel will conduct a record review of the application, extrinsic medical evidence, VA records, and Army records and will determine, by a preponderance of the evidence, whether the applicant's diagnosed condition was a proximate result of his or her participation in the specific research program.

The Panel's decision will be based on a majority vote. A "proximate result" is defined as a sufficiently strong causal link such that a reasonable person could find that the injury or disease was caused by the research. In evaluating medical care claims under this standard, the Panel will reasonably weigh the following evidence:

(a) the nature of the applicant's participation in the research, to include the type of substance, means of administration, dosage, and frequency of exposure;

(b) the applicant's health condition during and after his research participation, including timing and severity of the onset of symptoms of medical illness, disease, or injury, as supported by the applicant's medical evidence and available records from the DoD and VA;

(c) the nature of the applicant's current medical condition, as supported by the applicant's submitted medical evidence and available records from the DoD and VA;

(d) available scientific evidence concerning the long term health effects of the chemical or biological substance to which the applicant was exposed; and

(e) all information provided by the applicant, to include documents obtained from Defendants during discovery pertaining to the Chem-Bio Database, the Mustard Gas Database, the Chemical, Biological, Radiological & Nuclear Defense Information Analysis Center ("CBRNIAC") Database and other related databases created in conjunction with Battelle Memorial Institute, and the Defense Technical Information Center ("DTIC") repository.

In making its determination the Panel, in its discretion, may equitably weigh the following:

(a) the medical research occurred over 40 years ago;

(b) records concerning the research may be limited or incomplete;

(c) scientific studies on the long-term health effects of certain chemical or biological substances may be limited or incomplete; and

(d) evidence related to the precise proximate cause of a particular diagnosed medical condition may not be definitive.

5. If the Panel determines there is a sufficiently strong causal link such that a reasonable person could find the applicant's condition was caused by participation in the specific research program claimed, the Panel will submit a recommendation to provide the applicant with necessary medical care for the research related medical condition to the Secretary of the Army or his designee.

6. The Secretary of the Army or his designee will review the Panel's recommendation in accordance with the criteria specified in 32 C.F.R. 108 and DoDI 6025.23 and the Court's orders. If medical care is granted to the applicant, the applicant will be provided with information for the nearest DoD MTF with the capability to treat

the approved condition and given a limited access ID card, as necessary, entitling him to receive treatment at the MTF for the specific medical condition, injury, or disease determined to be the proximate result of the research. If the nearest MTF is more than fifty (50) miles from the applicant's home, or in situations where necessary treatment is not available through a MTF, the Army will assist the applicant in requesting health care from the VA. ~~If the necessary treatment is also not available from the VA, the Army will arrange for treatment by and payment of a private medical provider.~~

7. Final Agency Action: When an application to the Army for medical care is denied, it is a final decision by the Army subject to judicial review in whatever manner such agency action would ordinarily be reviewable under applicable law and in the appropriate forum established by law. ~~the Army shall inform class counsel. Any disputes regarding the denial of medical care may be presented to the Court as a motion to enforce the injunction~~

B. Reporting and Jurisdiction.

1. Within 180 days of the date of entry of this Injunction, the Army shall file with the Court a report describing its implementation of policies and procedures to facilitate its compliance with this Injunction.

2. After this initial report, the Army shall file status reports annually, for the next three subsequent years, to update the Court on how many applications have been received and considered, including the number of applications on which a final decision has been issued.