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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)

DEPARTMENT OF THE ARMY REPORT PURSUANT TO THE COURT'S NOVEMBER 19, 2013 INJUNCTION

Pursuant to paragraph 4 of the Court's November 19, 2013 injunction, dkt. 545, the Department of the Army, through undersigned counsel, hereby provides the following report.

BACKGROUND

On November 19, 2013, the Court entered final judgment in this case. Dkt. 546. The Court entered judgment for Plaintiffs on "their claim, pursuant to the Administrative Procedure Act (APA), that Defendant Department of the Army (Army) has an ongoing duty to warn class members of any information acquired after the last notice was provided, and in the future, that may affect their well-being, when that information becomes available (Notice Claim)." *Id.* The Court's judgment indicated that the basis for the imposition of the duty was Army Regulation 70-25. *Id.*

That same day, the Court entered an injunction over the objection of the Defendants. Dkt. 545. The Court's injunction requires the Army to provide a report which "describes the efforts it has undertaken to locate the Newly Acquired Information as of the Entry Date from the various sources of information it has available to it . . ." Dkt. 545 at ¶ 4.a.[1] The injunction further requires the Army to confirm "whether Newly Acquired Information has been found and describing generally its nature;" and to explain "the plan it has in its discretion developed for transmitting Newly Acquired Information to the class members entitled to notification, including the methods intended for notification . . . ." *Id.* at ¶ 4.b.-c. The injunction also requires the Army to commit to "transmit the Newly Acquired Information as of the Entry Date to those class members no later than one hundred twenty (120) days from the Entry Date, and outline[] its plan to do so." *Id.* at ¶ 4.d. Finally, the injunction requires that the Army's report "outline[] the plan and policies it has in its discretion developed for (i) periodically collecting and transmitting Newly Acquired Information that becomes available to it after the Entry Date and (ii) provide[] any necessary update reports to the Court regarding such future efforts." *Id.* at ¶ 4.e.

[1] The Court's injunction defines "Newly Acquired Information" as including (a) "[t]he nature, duration, and purpose of the testing undergone by that particular test subject;" (b) "[t]he method and means by which the testing was conducted;" (c) "[t]he inconveniences and hazards reasonably to be expected by that test subject as a result of participation in the testing;" and (d) "[t]he effects upon their health which may possibly come from such participation." *Id.* at ¶ 2.a.-d.

The Army describes its efforts to comply with the Court's injunction in the following sections of this report.[2]

DISCUSSION

I. DESCRIPTION OF EFFORTS UNDERTAKEN TO LOCATE "NEWLY ACQUIRED INFORMATION" AND WHETHER SUCH INFORMATION HAS BEEN FOUND.

Although the Army is uncertain precisely what information the Court intended to cover by the term "Newly Acquired Information," the Army interprets the term to generally cover two categories of information: (1) information concerning the participant's experience during his specific tests; and (2) information concerning long-term health effects that may affect the test participant's well-being.[3] Given that interpretation, the Army provides the following description of its efforts to locate "Newly Acquired Information."

A. Information Concerning The Test Program

As discussed below, the government has engaged in a reasonable, substantial effort to identify *all* class members and notify them about their participation in the test programs. Those

[2] The Army's efforts described below are designed to comply with the Court's injunction and should not be construed as a concession that AR 70-25 requires such compliance measures. In addition, the information contained in this report is supported by the Declaration of Lloyd Roberts, which is attached as Exhibit A to this report.

[3] Because the Court's injunction does not define the discrete elements contained in its definition of "Newly Acquired Information," such as, for example, what is meant by the "nature" of the tests or the "methods and means" by which the testing was conducted, the Army has had difficulty understanding the precise information that the injunction requires the Army to provide to class members. For example, interpreting what the Court means by "Newly Acquired Evidence" is complicated by the fact that the Court has taken most of the elements of its definition from the appendix to AR 70-25, entitled "Volunteer Agreement Affidavit," and which governs the information that is to be provided to clinical volunteers in order to obtain informed consent prior to participation in the clinical study. *See* SJ Ex. 49 at App. E. The 1990 version of AR 70-25 contains as an appendix a "Volunteer Agreement Affidavit." The "[p]rinciple [*sic*] [p]urpose" of this affidavit was "[t]o document voluntary participation in the Clinical Investigation and Research Program. SSN and home address will be used for identification and locating purposes." *Id.* The affidavit provides that "[t]he implications of my voluntary participation/consent as legal representative; duration and purpose of the research study; the methods and means by which it is to be conducted; and the hazards that may reasonably be expected have been explained to me by _____." *Id.* Accordingly, endeavoring to apply the information intended to obtain informed consent to research participants on a forward-looking basis raises substantial ambiguity in terms of compliance with the Court's injunction.

efforts have concluded, and the Army is unaware of any "Newly Acquired Information," as it interprets the Court's injunction, that would trigger the need to provide additional notice.

There have been a variety of studies over the years assessing the health of test participants, and a number of those studies have involved outreach efforts to the test participants. For example, in March 1972, the Army conducted a medical follow-up of certain Edgewood test participants, referred to as EA Technical Report, *Long-Term Followup of Medical* Volunteers (March 1972). In that study, a total of 40 subjects were examined over a 10-month period, from June 1970 to April 1971. In addition, in 1980, the Army's Medical Command published a report on its follow-up study on the Cold War-era test participants exposed to LSD during the testing. The study researchers responsible for the 1980 LSD Follow-On Study "attempted to contact every individual for whom present addresses could be obtained and invite them to enter one of three Army medical centers for evaluation." Of the original 686 veterans identified as LSD recipients at Edgewood Arsenal, 220 veterans were examined directly, and an additional 100 had returned completed medical history questionnaires. Of the remaining 366 veterans, 24 were known to have died before the follow-up study, 193 were unable to be located, and 149 declined to respond to the contact letters or to the request to complete a medical questionnaire.

Working under an Army contract, the Army provided to the National Research Council ("NRC") a list of 6,720 test participants so that the NRC could contact them and provide them with a health survey, and 4,085 test participants responded to that survey. The results of that investigation are found in the three-volume NRC study, entitled *Possible Long-Term Health Effects of Short-Term Exposure to Chemical Agents*. In connection with the NRC's three-volume study assessing the health effects of all Cold War-era chemical test participants, the NRC sent a survey to 4,996 locatable individuals, of which 4,085 test participants responded. In 2003, the NRC, working under an Army contract, conducted a review of the three-volume 1985 report with respect to for sarin and other anticholinesterase agents. The report is entitled "Long-Term Health Effects of Exposure to Sarin and Other Anticholinesterase Chemical Warfare Agents," and in connection with the study, 4,022 locatable test subjects were sent health surveys.

In connection with the Army's follow-on study of the biological test participants, a total of 358 former biological test participants agreed to complete a self-administered questionnaire that inquired about, among other things, their health status, ongoing clinical symptoms, and signs. The researchers published the results of this study in "An Assessment of Health Status at Fort Detrick, Maryland," by Colonel Phillip R. Pittman, *et al*., in 2005. This study was a follow-on to a 1991-1992 questionnaire provided by the Army which was completed by approximately 200 biological test participants.

With respect to the WWII-era test program, in 1991, at the Department of Veterans Affairs' ("VA") request, the Institute of Medicine ("IOM") initiated a study regarding the WWII-era test program, which culminated in the January 1993 publication entitled *Veterans at Risk: The Health Effects of Mustard Gas and Lewisite* ("*Veterans at Risk*"). The purpose of the report was "to survey the medical and scientific literature on mustard agents and Lewisite, assess the strength of association between exposure to these agents and the development of specific diseases, identify gaps in the literature, and recommend strategies and approaches to deal with any gaps found." The VA sent announcements to each individual who had a claim pending with the VA for alleged injuries from exposure to mustard agents or Lewisite. Twenty veterans appeared in person to present statements about their experiences, and others provided statements through the mail or by telephone. Press coverage generated by the hearing resulted in statements being provided by additional veterans. In total, 257 veterans provided information about their experience as test subjects and health effects.

Beyond the efforts described above, DoD also contracted with Battelle Memorial Institute to assist in the collection of mustard gas and Lewisite documents so that it could provide information to VA so that VA could provide notice to test participants. DoD asked Battelle to provide any information that they could find, including the names of test participants, from a variety of sites where mustard agents or Lewisite was tested, produced, transported or stored. DoD and Battelle went to a number of locations to search for WWII-era test documents, including, among other places, the records center in Suitland, Maryland, National Archives, the

National Archives complex in Chicago which contained records from the Great Lakes naval training center, Edgewood Arsenal and Dugway Proving Ground. Names were obtained from, among other sources, lab notebooks maintained by the Naval Research Laboratory. The names that were collected were placed into an Access database that DoD create in 1995, and those search efforts have been completed. DoD developed the database to create an organized list of personnel that could be shared with the VA, which in turn, could enable VA to contact veterans and to facilitate veterans' ability to make claims for VA benefits.

In late 2004, VA received the database from DoD containing 2,800 full-body mustard agent exposures and 1,750 partial body exposures. Ultimately, DoD identified 6,400 service members and civilians who were exposed to mustard agents and other chemical substances during WWII. Approximately 4,000 of those names relate to individuals exposed to mustard agents and Lewisite. The remainder of the names in the database involved exposures to agents such as chlorine gas, nerve agents, and antidotes such as atropine. Upon obtaining whatever current contact information it could through the use of matches against VA's databases and the Internal Revenue Service, VA began sending WWII-era test participant notice letters in March 2005. VA has sent notice letters to every WWII-era class member for whom it could reasonably locate contact information.

With respect to Cold War-era class members, in February 2004, DoD began developing plans to implement the requirement of section 709 of the National Defense Authorization Act for Fiscal Year 2003 (also known as the Bob Stump Act),[4] as well as a suggestion in a May 2004 GAO Report that DoD expand its search efforts for test participants beyond Project 112/SHAD, a test program that is not at issue in this case. DoD once again utilized the services of Battelle to engage in a comprehensive search for information concerning the Cold War-era test program. DoD had meetings with Battelle to brainstorm possible locations where records may have been stored. Battelle visited various sites and collected information, including names, concerning the

[4] That Act required DoD to take efforts to identify, rather than notify, individuals who participated in test programs beyond Project 112/SHAD.

tests. Battelle collected data that it transmitted to DoD, which then transmitted the information to VA. Battelle has completed its work on the Cold War-era test program project.

Once DoD verified the data received from Battelle, DoD placed the data into the database and provided updates of the database to VA. The database includes, where available, among other things, identifying information about the test participant, the substance(s) the participant was exposed to, the dose(s) received, and the mode(s) of administration. The information in the database comes primarily from the test participant files for each veteran. A typical service member test file includes (1) the individual's unit of origin; (2) a consent to audiovisual use of the individual's image by the Army; (3) a consent to testing form; (4) a summary sheet of the test plans and agent which the individual was administered, if any; (5) psychological test information; (6) medical treatment information or lab results, to the extent those were generated while the individual was on post; (7) a test plan summary providing information about the tests; and (8) oftentimes a writing by the individual describing his experiences after the testing.

DoD also provides the test participant records to VA. The database is set up for DoD to provide VA with as much information as DoD has about an individual test participant, including the location of the test; the tests in which the veteran may have participated; the chemical substances the individual may have been exposed to; the duration of the tests; and any birth date, rank, service number, or social security number to the extent the information is available.

VA began sending notice letters to veterans who participated in the Cold War-era tests on June 30, 2006. VA has sent a notice letter to every test participant for whom it could obtain accurate contact information.

In addition, DoD currently maintains a toll-free number where veterans could call to obtain information regarding their participation in the Edgewood test program. A large number of veterans have utilized DoD's 1-800 number. For a period of time during the mid-2000s, DoD received calls to the DoD call-in center several times a week from veterans who want to know if they are in the DoD database. If they are in the database, DoD refers them to VA for follow-up, and DoD asks for the veteran's address, which it provides to VA, so that the veteran can receive a

notice letter. When veterans call the hotline, they are referred to the Army FOIA officer to enable them to access their test records. DoD hired Northrop Grumman employees to staff the hotline because they were former investigators and would be especially capable of assimilating a lot of information and making sure veterans who called DoD were pointed in the right direction. Those answering the phones at the call-in center have access to the database and can answer questions about participation. In addition, those that worked in the call center can assist veterans in obtaining their test files. The call center also refers callers to a DoD website that contains information about the test program. That public website is located at http://mcm.fhpr.osd.mil/cb_exposures/cb_exposures_home.aspx. The DoD website contains information about both the WWII-era tests and the Cold War-era chemical and biological tests, including copies of, among other things, GAO reports, IOM reports, congressional testimony, and DoD briefings and reports. The DoD website also contains the following reports concerning potential health effects associated with the test programs: (1) Bullman & Kang, A Fifty Year Mortality Follow-Up Study of Veterans Exposed to Low-Level Chemical Warfare Agents (2000); (2) the 1980 LSD Follow-Up Study Report; (3) William Page, Long Term Health Effects of Exposure to Sarin and Other Anticholinesterase Chemical Warfare Agents (2003); (4) Pittman, An Assessment of Health Status Among Medical Research Volunteers who Served in the Project Whitecoat Program at Ft. Detrick, Maryland (2005); (5) the three-volume National Research Council report entitled Possible Long-Term Health Effects of Short-Term Exposure to Chemical Agents (1982-1985); and (6) Supplement to Institute of Medicine Study: Long-Term Health Effects of Participation in Project SHAD, "Health Effects of Perceived Exposure to Biochemical Warfare Agents" (2004). http://mcm.fhpr.osd.mil/cb_exposures/briefings_reports.aspx. The DoD website also contains frequently asked questions on a number of topics, and provides both a phone number and address so that veterans may verify or obtain information about their participation in the tests, including obtaining a copy of their test file. Test participants may also obtain their service member test files through the DoD website. Since 2006, the Army has

responded to approximately 110 FOIA requests from Edgewood test participants. Approximately 400 individuals have requested their test files from the Army in total.

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) maintains records for approximately 2,300 volunteers who participated in over 150 Army tests of potential biological agents, vaccines, and antibiotics, from 1954 to 1973, in Operation Whitecoat. USAMRIID receives on average several inquiries per year from volunteers, regarding tests performed and whether these have any bearing on their present medical condition. USAMRIID provides the research medical record and a physician's explanation whether or not the subject's present condition has a relationship to these tests.

A follow-up study was done on members of Operation Whitecoat between 1998 and 2002 to assess long-term effects on the health of the subjects of their involvement in the research. Between 2007 and 2010, Loma Linda University conducted a second follow-up study of this group, and future such studies may be conducted by Loma Linda University. The lead Loma Linda University researcher presented his findings to the Operation Whitecoat subjects at a 2011 reunion, concluding that there was no statistical difference in current health status between those who were exposed to either an agent or a vaccine and those who were not.

In sum, because the Army has completed its efforts to identify test participants, transmitted that information to the VA, and the VA has notified all test participants for whom contact information could be found, the Army is unaware of any "Newly Acquired Information" concerning the conduct of the test program to be provided to class members.

B. Information Concerning Long-Term Health Effects

As described in the previous section, there have been a number of studies conducted concerning the test program, and the results of those studies have been made known to test participants both through direct mailings of the results of certain of those studies, the placement of those studies on the DoD website, and the provision of certain studies to test participants who have contacted DoD and requested the studies. As one example, class member Bruce Price has

requested from the Army the LSD follow-on study discussed above, and the Army has provided that study to him.

Beyond studies that directly relate to the test program, there are other studies that have been conducted by the IOM that analyze some of the same substances that were used during the test programs. For example, in the early 2000s, the VA contracted with the IOM to prepare a multi-volume series of studies concerning exposures to service members in the Gulf War to a variety of substances, including certain pesticides, sarin, and pyridostigmine bromide (PB), which were used during the test programs at issue in this case. With respect to the volume that analyzed sarin and PB, the IOM considered, among other things, the literature concerning the test participants in this case. The IOM concluded that "there is inadequate/insufficient evidence to determine whether an association does or does not exist between PB and long-term adverse health effects." And with respect to sarin, the IOM concluded that there was only "limited/suggestive evidence of an association between exposure to sarin at doses sufficient to cause acute cholinergic signs and symptoms and subsequent long-term health effects."

Accordingly, the Army is currently unaware of any information concerning the long-term health effects that may affect the class members' well-being that has not been made available to them. Nevertheless, because the Army construes the Court's injunction as requiring the Army to affirmatively investigate potential health effects – despite the numerous studies that have already been conducted – the Army intends to conduct, potentially with the assistance of other governmental agencies and contractors, scientific literature searches pertaining to chemical and biological substances at issue. This effort will involve a multi-step process described below.

First, the Army currently is undertaking measures to determine the magnitude of the project. Utilizing Dr. Pittman and Lloyd Roberts, the Army will conduct literature searches on a sample of the substances used during the test programs to estimate the potential overall universe of the literature that may need to be searched. These searches will include, as appropriate, Internet database searches (such as PubMed), and appropriate searches of internal governmental databases. Depending on the results of these searches, the search terms used may need to be

refined and new searches conducted to ensure that an accurate sampling has been conducted. The Army estimates that this initial scoping of the project will take several weeks.

Second, based upon the results of this initial sampling, a Performance Work Statement (PWS) will be developed. The PWS is a document describing the needs of the Army to initiate the contracting process. The US Army Medical Command (MEDCOM), the Army component tasked with responsibility for this project, has directed the development of the PWS. The PWS will include, as appropriate, databases to be searched, date ranges of publication, and keywords (*e.g.*, substances). The PWS will include both the literature searches and the application of the results of those searches to the specific circumstances of the test program. It is anticipated that the PWS should be completed within several weeks of the completion of the initial scoping of the project. The PWS will be provided to the MEDCOM contracting office.

Third, if the PWS suggests that a relatively small universe of literature would need to be searched, the MEDCOM Chief of Staff may decide to conduct all or part of the project in-house. However, in the event that the PWS reflects a relatively large universe of literature searches, MEDCOM may decide to contract for such searches to be completed.

Fourth, if MEDCOM decides to contract for these efforts, in accordance with procedures established in the Federal Acquisition Regulation, the appropriate contracting procedures will be used, including, among other things, conducting market research on potential responsive contractors who could do the work, making a decision as to whether to sole source the contract or solicit a request for proposals, and making a determination of funding. Appropriate timelines for solicitation of requests for proposals and awarding the contract will be followed. For example, if a decision is made to competitively award the project, the solicitation must be posted online for at least thirty days. An evaluation of those proposals would then take place, and it is estimated that such an evaluation may take several weeks from the date the proposals are received. Alternatively, if a decision is made to sole source the contract, the contracting officer would need to create a justification for sole sourcing, a review of the justification must take place through both the MEDCOM Office of the Staff Judge Advocate and the competition advocate, and the

decision must be approved. It is estimated that this process could be completed between several weeks and one month from the date the sole source justification is developed.

Fifth, whether conducted in-house or through contract, after the results of the research have been analyzed, an assessment will be made to determine whether the new and pertinent information may affect the well-being of class members. As previously discussed in the Declaration of Dee Dodson Morris, in order to assess whether any new literature is pertinent to the well-being of class members, a comparison must be made between the conclusions in the literature and the specific circumstances of the test programs at issue in this case. The long-term health effects associated with exposure to a particular substance typically turn upon such factors as the substance(s) exposed to, the dose(s) administered, and the mode(s) of administration. Accordingly, the Army will need to compare the circumstances discussed in the literature to the specific circumstances of the test participants to determine, on an individualized basis, whether there is an increased risk of adverse health effects. The scope and timing of this assessment will necessarily be driven by the results of the research efforts described above.

This plan constitutes the Army's initial approach to making these assessments. Should circumstances warrant a changed approach, the Army will modify its plan as circumstances may warrant.

II. DESCRIPTION OF PLAN TO TRANSMIT "NEWLY ACQUIRED INFORMATION" TO CLASS MEMBERS.

If "Newly Acquired Information" is located, the next step is to transmit such information in a responsible manner to class members. The Army, with the possible assistance of other governmental agencies, such as the VA, or contractors, intends to use existing websites to transmit newly acquired information, but only if such information is appropriate for wide dissemination. One such website is located at http://mcm.fhpr.osd.mil/cb_exposures/cb_exposures_home.aspx. As for newly acquired information that may warrant dissemination other than via internet websites, the Army intends to transmit or have other governmental agencies or contractors transmit that information by mail. Additionally, the Army and/or other governmental agencies or contractors will continue to

respond to direct inquiries from individual test subjects. Key Army leaders within the U.S. Army Medical Command will be tasked to inform the Army Surgeon General or his/her designee(s) of any Newly Acquired Information within their commands and areas of responsibility. The Army Surgeon General's Office or designee(s) will ensure that such information is transmitted by online notice. Also, a toll-free telephone number is, and will be, prominently displayed on the current website so that interested parties may call to seek additional guidance.

III. THE ARMY'S PLAN FOR FUTURE COLLECTION AND NOTIFICATION EFFORTS AND UPDATES TO THE COURT.

The Army will continue to respond to direct inquiries from individual class members. Key Army leaders within Army Medical Command will be tasked to inform the Army Surgeon General or his/her designee(s) of "Newly Acquired Information" within their commands and area of responsibility. The Army Surgeon General's Office or the designee(s) will ensure that such information is transmitted by online notice, mail, and/or toll-free telephone number that interested parties may call. The Army will notify the Court every seven years, or, at the Army's discretion and as circumstances may warrant (such as a significant change in outcomes or approaches), at intervals shorter than seven years, with regard to its efforts and with regard to any "Newly Acquired Information" it has located and disseminated since the previous report.

March 6, 2014

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