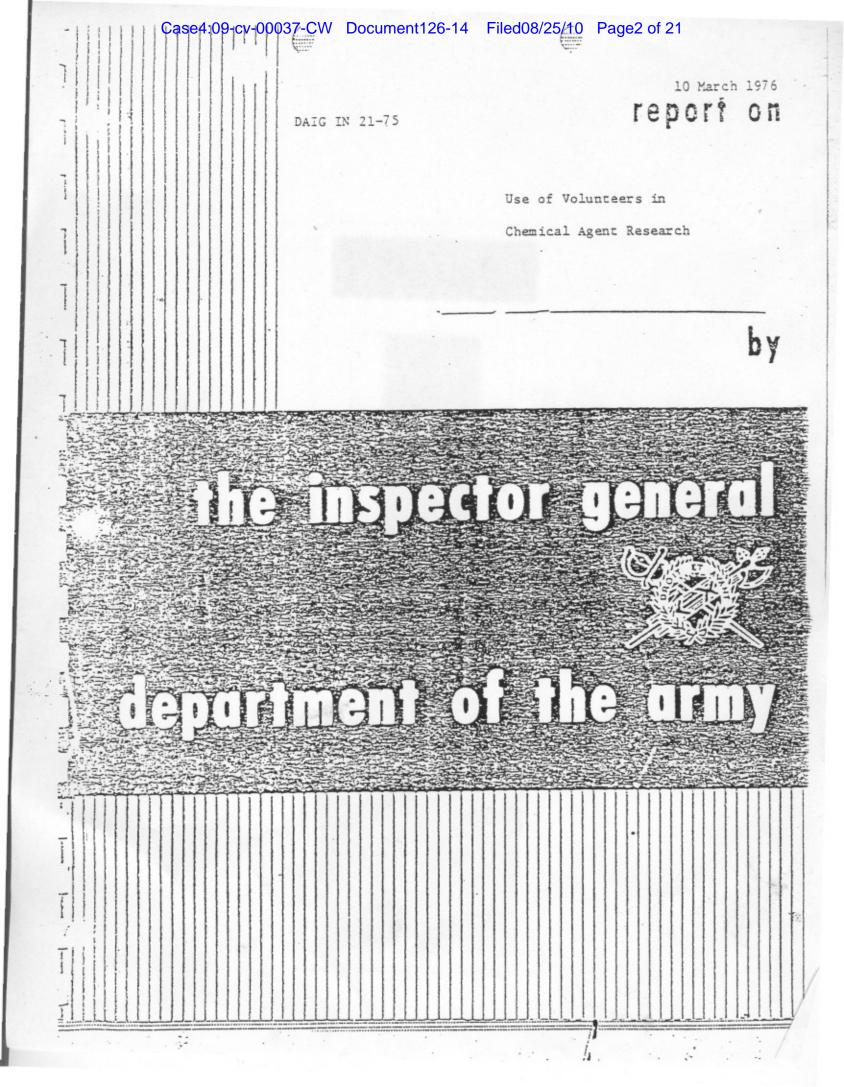
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Case4:09-cv-00037-CW Document126-14 Filed08/25/10 Page3 of 21

OFFRATIVENT OF THE ARMY
OFFICE OF THE PICAESTOR OFFICTS AND AUCTOR SETTEME
WASHINGTON, D.C. 20310

DAIG-IN 21-75

Use of Volunteers in Chemical Agent Research

MO MAR 19/6

CAUTION:

THIS INSPECTOR GENERAL REPORT CONTAINS PRIVILEGED INFORMATION AND WILL BE PROTECTED IN ACCORDANCE WITH THE PROVISIONS OF PARAGRAPHS 1-10 AND 1-11, AR 20-1. SPECIFICALLY, DISSEMBLATIVE OF THE REPORT WILL BE RESTRICTED TO THE ABSOLUTE MINIMUM COUNTY OF THE EFFECTIVE MANAGEMENT OF THE INTERNAL AFFAIRS OF THE ABOVE DISSEMBLATION OUTSIDE ANY OFFICE HAVING TEXTORARY CUSTODY OF REPORT, AND/OR REPRODUCTION OF ANY PORTION OF THE REPORT WILL BE MADE WITHOUT SPECIFIC FERMISSION OF THE INSPECTOR GENERAL.

THIS REPORT WILL BE RETURNED TO THE OFFICE OF THE INEPECTOR OF DEPARTMENT OF THE ANIM, MASHINGTON, DC 20310 WHEN IT HAS SERVICED TO PURPOSE. (Para 1-7a(18), AR 20-1)



WASHINGTON, D.C. 20310

DAIG-IN

SUBJECT: Research Report Concerning the Use of Volunteers in Chemical Agent Research

This research report was prepared by Colonel James R. Taylor and Major William N. Johnson, Inspectors General, Office of The Inspector General, Beadquarters, Department of the Army, pursuant to the Vice Chief of Staff Letter of Instruction, dated 21 July 1975.

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Investigations Division

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APPROVED BY:

ieutemant General USA

The Inspector General

and Auditor General

USE OF VOLUNTEERS

IN

CHEMICAL AGENT RESEARCH

FOREWORD

During the 1975 hearings conducted by the Senate Select Committee to study Governmental Operations with Respect to Intelligence Activities, the U.S. Army's role in research and experimentation with hallucinogenic drugs became a matter of interest and concern to the Committee and the public. The coupling of Army efforts in chemical agent research and actions involving the Intelligence community resulted in a spate of publicity both factual and speculative.

During the same general timeframe, the ongoing joint hearings of the Senate Labor and Public Welfare Committee, Subcommittee on Health, and the Senate Judiciary, Subcommittee on Administrative Practice and Procedure, asked questions of the Army about the Human Volunteer Program, the quality of "informed consent" as related to research volunteers, and the adequacy of medical follow-up on those who had volunteered to take part in research projects over the years.

As a result of the several congressional hearings and subsequent publicity, numerous requests for information were received by the Department of Defense from congressional committees, individual members of Congress, private citizens and the media. The nature of the inquiries reflected the different interests involved and resulted in several different staff agencies within Department of the Army being tasked to provide the requested information.

The lack of factual information available to quickly respond to the inquiries illustrated an inadequacy of the Army's institutional memory on this subject area. This inadequacy was aggravated by inconsistencies in the limited data which was available.

These shortcomings in responding fully, accurately, and rapidly, particularly at a time when Governmental agency actions and programs were already suspect, placed an additional strain on the public's faith in the credibility of the U.S. Army.

To assure that requests for information concerning the Army's role in hallucinogenic drug research were answered factually, the Secretary of the Army directed that a research effort be made to determine what had been done in chemical agent research. Accordingly, The Inspector General and Auditor General, Headquarters, Department of the Army, was directed to conduct the necessary research to determine the Army's role in drug testing. A verbatim text of the Letter of Instruction which directed the research effort is reprinted below:

21 Jul 1975

SUBJECT: Letter of Instruction

The Inspector General and Auditor General Department of the Army Washington, D.C. 20310

- 1. Recent public and Congressional interest in the Army's use and testing of hallucinogenic drugs has generated numerous requests from the news media for information concerning these activities. Records currently available to the Army Staff indicate that these tests were conducted during the period from the early 1950's through the late 1960's at various locations in the United States and overseas. However, due to the lengthy time span involved in the testing program, many of the supervisory personnel involved in the program and the records and reports pertaining to the planning, conduct, and results of the tests have been retired. This situation places the Army in a position of not being able to reply quickly and factually to requests for information from various news and Congressional agencies.
- 2. You are directed to conduct the necessary research to establish the historical facts and circumstances surrounding the U.S. Army's participation in the testing of hallucinogenic drugs. Specifically, your research will be in sufficient detail to provide, at a minimum, the following information: a clear reconstruction of the programs and projects involved with particular emphasis on the rationale used as a basis for their initiation; appropriate mandates and authorizations upon which the testing programs and projects were initiated, examination of extent of volunteers, the use of subjects without subjects' knowledge; and the costs of such projects and programs funded by the Department of the Army to include the total cost of operation of the Special Operations Division, Fort Detrick, MD.
- 3. The Surgeon General and the Assistant Chief of Staff for Intelligence will provide technical assistance as required and will provide access to and copies of any reports pertaining to the testing of hallucinogenic drugs by the Army which are required to complete your research. The Commander, U.S. Army

Materiel Commend, will provide essistance required by your research teams in gaining access to installations, testing facilities, and records storage facilities. The research teams are authorized access to all records, files, facilities, and information which they consider necessary to accomplish this tasking.

4. Your report will be submitted to the Chief of Staff as expeditiously as possible consistent with the requirement to insure that the information provided is complete, factual, and accurate.

S/ WALTER T. KERWIN, JR. General, United States Army Vice Chief of Staff

This mission was unlike the usual directive for inquiry or investigation normally assigned to The Inspector General for action. Instead of determining the facts and circumstances of a specific wrong(s) or allegation(s), the mission was to conduct a form of historical research; research which would determine exactly what the Army had done in chemical agent testing during the period 1950-1975. A period which probably had as many changes, programs, and problems as any comparable period in history: post-World War II; the Korean War; the Cold War; reorganization of Department of Defense; reorganizations of Department of the Army; the war in Vietnam; and major advances in medicine, the sciences, nuclear weapons, missiles, and aircraft. The sheer volume and frequency of change alone provided some indication of the magnitude of the task to be performed. From the outset, the research effort proved to be difficult and cumbersome.

The research was not to include any activities or arrangements between Department of Defense and the Central Intelligence Agency concerning biological/chemical agents and weapons systems for delivery, but was to be limited to the Army's participation in the testing of d-lysergic acid diethylamide (LSD) with emphasis on the rationale used as a basis for test initiation; authorizations upon which the testing programs and projects were initiated; and the costs of such projects funded by Department of the Army. An exception was made to the limitation on the research as it concerned DOD/CIA and biological agents, in that the total cost of operating the Special Operations Division (SOD), Fort Detrick, MD, from 1953 to 1971 was to be determined.

The research scope eventually was enlarged to include drugs other than LSD. Initially, the term hallucinogenic was used as a means of describing the extent of the research, however, as more accurate information was received, the inaccuracy and inadequacy of the term became apparent. Ultimately, the study was to include LSD and also other drugs generally classified as chemical incapacitating agents, to include benzilates and glycolates. All drugs investigated or tested during the period were not included in the research, however, those which figured prominently in the Human Volunteer Program were reviewed.

The search for records was to prove particularly difficult. Current records posed no particular problem, since records handling policies made them reasonably available; however, the majority of the records involved were not current. Most of the research effort, particularly on LSD, occurred during the 1950s and early 1960s; these records had long since been retired and in some cases destroyed in accord with normal destruction schedules. The frequent changes in the U.S. Army organizational structure resulted in many changes in unit designations and locations, resulting in records being retired, destroyed, or relocated without adequate concern for proper disposition of records with historical significance.

Where records were not available or where information gaps existed, plans were developed to interview the personnel involved, both the scientist and the subject volunteer. Since the research spanned a 25-year period, man of the personnel actively involved in the research programs were retired, quite elderly, moved to new locations, or deceased.

The history of the Human Volunteer Program was examined in considerable detail. The use of humans in chemical agent research was examined from the earliest days of the Chemical Warfare Service during World War I through the publication of the Secretary of Defense (Wilson) memorandum in 1953; and then tracing the development of the formal volunteer program in use today. The selection of volunteers, to include the pre- and post test medical examinations, care during the experiments, and most important, the quality of informed consent was examined critically by reviewing medical records maintained on volunteers and in limited cases interviewing the volunteers.

The thoroughness of the research effort is indicated by the following statistical data:

a. Interviews of 65 witnesses were conducted in 32 cities, in 17 states, and the District of Columbia and involved traveling in excess of 160,000 passenger miles.



b. Tens of thousands of pages of documents were reviewed at various locations to include the National Archives; the National Records Center. Suitland, MD; the Army Records Center, St. Louis, MD; the Army War College Library, Carlisle Barracks, PA; Edgewood Arsenal, Edgewood MD; Aberdeen Proving Grounds, Aberdeen, MD; Fort Detrick, MD; Fort McClellan, AL; and the files of the various staff agencies, commands, or units which might have been involved, no matter how peripherally, with the chemical research program. Additionally, witnesses were requested to provide any documents or evidence which might have come into their possession.

Certain events which occurred during the course of the research effort added to the complexity of the effort and served to stretch out the time required to complete the project. First, there were the allegations aired publicly on TV and other media reflecting on the fitness of the Chief of the Medical Research Division, Biomedical Laboratory, Edgewood Arsenal. The person involved was in charge of the drug testing program. An investigation concerning this matter was conducted and reported separately. Then, during the course of records and file searches it was learned that a civilian patient in a New York psychiatric hospital had died in 1953 after receiving an experimental drug which had been provided the hospital by the U.S. Army (Chemical Corps) as part of a research project conducted by the hospital under an Army contract. An investigation of this incident was also conducted and reported separately. Finally, during the course of the research information was received indicating that the U.S. Army Intelligence Center/School had conducted jointly, with the Chemical Corps, a series of research projects involving LSD at Edgewood Arsenal, U.S. Army, Europe, and the U.S. Army, Pacific. A report of those tests is included herein.

It is in this vein that the research was conducted. Every effort was made to obtain and review pertinent data. Where records did not exist, the testimony of witnesses was solicited to fill in the gaps. Where neither documentary or testimonial evidence was available, then license was taken by drawing logical conclusions or assumptions based on evidence available. past performance, or other indicators. Where this occurred, efforts to clearly identify such license is made.



CHAPTER X

CONTRACTS WITH CIVILIAN INSTITUTIONS

General

The purpose of this chapter is to provide an overview of the contracts awarded to civilian institutions by the U.S. Army Chemical Corps during the period 1950 to 1971 and to briefly discuss the rationale, scope and cost of these contracts. The discussions in this chapter were limited to contracts for which actual contracts or contract progress reports were available.

Contracts with civilian medical, penal and educational institutions were an important and integral part of the Army's Chemical Corps medical research program. The contracts were executed for a wide variety of purposes, ranging from analysis of chemical compounds to the use of volunteers and patients in psychotropic drug experimentation.

Due to the passage of time and the routine records destruction requirements, many of the contracts executed in conjunction with the Chemical Corps medical research program were not located, nor was a determination made as to the actual number of contracts awarded, their cost, or how many volunteers or patients were used by contractors. Although thousands of pages of documents from contracts, contract reports, and conference notes were reviewed, it was recognized that additional information may exist at sources and locations not explored during the research effort. However, the information presented was considered to be based on the most accurate data available.

Available records indicated that the Chemical Corps Medical Research Laboratories entered into numerous contracts with chemical companies, medical schools and hospitals prior to 1950. However, the earliest evidence of a contract or report of a contract relevant to this research effort was dated 18 May 1950. That contract was with the University of Maryland for "Psychological Studies of the Effects of Chemical Warfare Agents." The available reports regarding the contract indicate that - human subjects were not involved. In all, 54 contracts or report of contracts were discovered and reviewed during the research effort. The chart at the end of this chapter provides a breakout of 48 of the 54 . contracts, to include: contractor, dates of contract, estimated cost, contract number, purpose of contract and the number of volunteers used, as indicated in the available reports. Six contracts for which reports were located were not included on the chart because they did not involve human subjects, drugs, chemical agents or matters related to the research effort. It should be noted, that the contract data, to include

3

contract dates, cost, and number of human subjects, presented in this chapter may differ from similar type data presented elsewhere in this report. This is not to say that one is more accurate or complete than others, rather the difference lies in the sources from which the information was obtained. An example of such a difference can be found in a comparison of the cost figures presented in Chapter XI regarding the contractual costs. The figures for this chapter were derived from contracts and progress reports which were in many cases incomplete; while in Chapter XI the figures were based primarily on accounting records and available procurement reports. Since neither source can substantiate the figures with absolute certainty, it seemed more appropriate to present the figures as they were determined from the various records rather than use a single data source. Additionally, the total number of volunteers actually used by the contractors may be greater than the number reflected on the chart, however, a higher figure could not be supported by the available records.

Early Contracts

Very little evidence was found regarding contracts or the authority for the Chemical Corps Medical Laboratories to enter into contracts prior to 1953. However, it appeared that authority to enter into contracts was inherent in the missions and responsibilities assigned to the Chemical Corps. That is to say they were assigned the mission for development of "nerve agents" and were permitted to contract for . matters related to that mission which could be better accomplished by other agencies. Evidence of this was found in a report of the Medical Committee of the Chemical Corps Advisory Council's 1954 meeting. 2 At that meeting it was pointed out that the Medical Laboratories were having considerable difficulty procuring support for the Entomology Branch to study insecticides and insect repellants. In order to compensate for their lack of expertise in the entomology field, the Laboratories reported that they had contracted with two colleges that were prominent in the field (Johns Hopkins and Tufts). It was also reported at the same meeting that much of the clinical research of the Medical Laboratories was under contract to other colleges, universitites, and hospitals. The list included: Illinois College of Medicine, University of Colorado, University of Utah, Galesburg State Hospital, Montifiore 'Hospital, University of Louisiana, University of Pennsylvania, Massachusetts General Hospital, University of Wisconsin, University of Indiana, and Howard University. No other details of those contracts were reported; however, they were presented in a light that indicated each contract provided for a service that the contractors were better qualified to perform than the Medical Laboratories at Edgewood. It was apparently in that light that the New York State Psychiatric Institute was granted the first known contract to conduct research in the psychochemical drug

field. In fact, at the "First Psychochemical Conference" (12 May 1954) the principal Research Psychiatrist at New York Psychiatric Institute was introduced as "a pioneer in the field of correlating experimental pharmacology and clinical psychiatry." That institution had recently completed three Chemical Corpe contracts to determine psychological effects of psychological chemical agents on human subjects. Those contracts are reflected on the chart at the end of this chapter and were also discussed in a separate report regarding the death of a patient during one of the experiments conducted at the New York State Psychiatric Institute. Experiments conducted under those contracts involved testing of human subjects with derivatives of LSD and mescaline.

Post-1953 Contractual Efforts

As discussed earlier in this report, centralized approval authority for use of humans in research was initiated in February 1953 with the "Wilson Memorandum." It was apparently the intent, if not the wording, of that and later Department of the Army directives that the principles governing the use of humans be applied to the Army contractual efforts as well as its own experimental research.

That intent was also apparently understood, as evidenced by the first known request for permission to use volunteers in research. The final paragraph of that request from the Medical Research Laboratories (24 July 1953) stated: "Authority is also requested to use volunteer subjects for accomplishing those studies which for various reasons cannot be carried out in these Laboratories." Moreover, the Secretary of the Army noted in his approval of the request that: "Special care and attention will be given to those portions of the approved investigations which are to be accomplished by contract, to insure that the same basic principles and safeguards applicable to Department of the Army laboratories are observed by the contractor." 5

Of the 54 contracts, for which varying reports were available, there were only 14 actual contracts found. The 14 contracts were initiated after publication of the Army's basic policy for "Use of Volunteers in Research" in 1953 (CS:385) and in each case the contract included provisions to require the contractor to observe the Army policies regarding the use of volunteer subjects. Typical of those provisions was the one included in a 1961 contract with Hahnemann Medical College: "The contractor will be required to adhere fully to the provisions set forth in Appendix A entitled Policy to be Followed by the Contractor Where the Use of Human Subjects is Involved, attached hereto, in the use of any human subject in the work under this contract. The contractor further agrees to obtain prior approval of the Commanding Officer, U.S. Army Chemical R&D Laboratories before commencing any research hereunder on human subjects."

Nerve Agent Studies

The majority of the contracts reviewed during the inquiry involved studies other than psychochemical drugs in humans. Ten contracts, reflected on the chart, were awarded to four universities for studies of nerve agents and treatment of accidental exposures to nerve agents. Three of the ten contracts were awarded to the University of Colorado School of Medicine for investigation and treatment of nerve agent casualties and evaluation of therapy and antidotes for those casualties. A review of 21 reports submitted by the contractor reflected that 356 accidental nerve agent exposures, which occurred at Rocky Mountain Arsenal, were investigated, treated or evaluated under the terms of those contracts. There was no evidence that the contractor used drugs or volunteers in connection with his work. Two of the contracts were awarded to the University of Utah to study effects of nerve agents on personnel at Dugway Proving Ground, Utah. The two reports available regarding those contracts indicated that the contractor performed experimental research in animals, investigated accidental exposures at Dugway Proving Ground, and provided emergency hospital treatment for Dugway nerve agent casualties prior to the establishment of a military hospital at Dugway. No volunteer work was conducted under the terms of those contracts and drugs used were those recognized in the treatment of nerve gas exposure. Four similar contracts were awarded to Johns Hopkins University. A review of eight reports regarding those contracts revealed that there were three objectives of the contracts. The first was to conduct studies of the electroencephalogram (EEG) as an aid in the evaluation of drugs; no humans were involved in those studies. The second was a study of "parathion spray," a poisonous compound commercially used as an agricultural insecticide. Reports indicated that ten volunteer subjects were employed in those experiments. Each volunteer was reportedly handled in full accord with U.S. Army policy (CS:385). The third objective of the contracts was the investigation of nerve and mustard gas accidental exposures at Edgewood Arsenal; no volunteers or drugs were involved in that portion of the contractual effort. The last of the ten contracts, in the category of nerve agent studies, was awarded to the University of Maryland to investigate minor nerve gas poisoning at the Diamond Alkali Company (location was not stated) in the early 1950s. Available reports of that contract reflected the investigation of 38 accidental exposures to chlorine gas during the course of the contract.

Incapacitating Agents Contracts

Twelve contractors were awarded a total of 25 contracts for studies or experiments involving incapacitating agents. The agent/drugs used were physical incapacitants such as morphine, demerol, seconal, scopolamine,

chlorpromazine, and secobarbital. Mental incapacitants studies included: LSD, mescaline, atropine, psilocybin, BZ (benzilate) and glycolate compounds. The number of incapacitating agent contracts listed here (25) was at variance with the number of contracts reported by the Army General Counsel in his testimony of 8 September 1975 and with an earlier report made to the Assistant Secretary of the Army. The difference was a result of obtaining more detailed contract data and an expansion of the number of chemical agents included in the research effort. As mentioned in the foreword, the initial research project was not interpreted to include many of the physical incapacitants or the glycolates, but was restricted to "hallucinogenic compounds" such as LSD and mescaline.

Three of the contracts were with the New York State Psychiatric Institute for studies of LSD and mescaline and were discussed earlier as well as in a separate report. In late 1953, the investigators of that Institute formed a private corporation called "The Research Foundation for Mental Hygiene, Inc." and were awarded two additional contracts to conduct studies with LSD and mescaline type drugs on psychiatric patients. Details regarding the performance of those contracts were not found. Thus, it can not be stated with certitude that the patients used were volunteers or that the policies established by the Army to govern the use of humans in research were adhered to in all cases.

Two of the contracts were awarded to the University of Washington for this study of Neurological action of CW agents. Review of 21 reports rezarding those contracts indicated the investigators established a volunteer pool of 35 medical students of which at least 19 were used in psychochemical drug experiments. The reports stated that all Army policies were observed by the investigators, to include complete mental and physical examinations. The studies conducted under the University of Washington contracts included the use of both male and female humans in testing LSM (lysergic acid morpholide), an LSD-like compound, LSD, and psilocybin.

Two of the contracts were awarded to the University of Maryland to perform clinical and laboratory studies of effects of a series of atropine substitutes, other candidate therapeutic agents and chemical warfare agents. Five available contract reports and contractors conference notes? reflected that experiments were conducted using military volunteers from Edgewood Arsenal as well as patients from the University of Maryland Psychiatric Institute and area hospitals and perhaps other volunteers. The studies included testing of 20 male college graduates' ability to operate an Air Force dual-pursuit apparatus while under the influence of LSD; 16 subjects were tested with LSD on the "Wechsler Memory Scale"; and 24 subjects were given LSD to test their sense of time. Others reportedly were given tests to determine the ability of dibenzyline (a blocking agent) to

attenuate the effects of LSD. Available evidence indicated that all policies regarding the use of volunteer subjects were observed.

One of the contracts was awarded in 1961 to North American Aviation's Medical Department to test "Aircraft Performance Decrement Resulting from Ingestion of 32." Two reports regarding that contract stated that 19 company employees volunteered as subjects in the experiment. The reports also stated that each volunteer was given a complete medical examination and was required to sign an individual volunteer agreement before taking part in the tests.

One contract was awarded to the Indiana University in 1951 for the purpose of studying "The Physiological Effects of Atropine and Potential Atropine Substitutes." The seven reports regarding that contract did not reveal any information regarding screening or selection of volunteers. The absence of such details was not unusual as the contract predates publication of DOD and Army policies governing use of volunteers in medical research. The studies apparently dealt primarily with chemical research. However, there was evidence of seven volunteers used in atropine studies.

Six separate contracts were awarded to the University of Pennsylvania. The initial contract (1951) was for "Study of Chemical Warfare Casualties in Man." Reports of that contract indicated that volunteers were not used and the principal effort was chemical research with one exception. On one occasion, six firemen were accidently exposed to an unknown substance, and that exposure was reportedly investigated under the terms of that contract. The second contract was a study of "Influence of Morphine and Demerol on the Respiratory Response of Man". Review of eight progress reports available regarding that contract revealed that approximately 40 volunteers were used in conjunction with morphine and demerol drug tests. The reports did not reveal the source of those volunteers or any evidence regarding the screening, selection, or execution of volunteer agreements.

The third and fourth contracts involved the "Evaluation in Animals and Man, Drug and Drug Mixtures Intended for use in Preventing or Treating CW Casualties." The four reports available regarding these contracts indicated that 10 volunteers received scopolamine, atropine, and porphine. Again, no evidence was found to reflect the source of volunteers or other matters concerning selection and medical preparations that preceded the use of volunteers.

The fifth and sixth contracts were awarded in the mid and late 1960s to conduct experiments of "Threshold Doses in Humans and Evaluation of Drugs in Man." Review of 55 progress reports revealed that approximately 320

inmates at Holmesburg Prison were tested with 16 different chemical agents including ditan, atropine, scopolemine and various experimental glycolate agents.

Since glycolates have not been previously described in this report, a brief description is provided at this point. "The glycolates cause incapacitation by interfering with muscarinic functions (i.e., activation of smooth muscle and secretory glands) and the central nervous system functions of acetylcoline; they depress or inhibit nervous activity. In addition to delirium, there is physical incoordination, blurred vision, inhibition of sweating and salivation, rapid heart rate, elevated blood pressure, increased body temperature, and, at high doses, vomiting, prostration, and stupor or coma. The onset time may be minutes or hours, depending on the structure of the compound, and the duration, hours or days. The effects may be reversed almost completely by treatment with physostigmine or other centrally active cholinesterase inhibitors such as VX."13

The largest dollar value contract (DA 18-035-AMC-126(A)) of the six awarded to the University of Pennsylvania was different than any of the previous contracts with the other universities. In fact, the records and reports indicated that there were three major differences. First, it was the first known contract that the Medical Research Laboratories entered into involving prison inmates. Secondly, it was the first indication found that the contract investigators may not have been fully prepared to conduct experiments with humans at the outset of the program. Finally, the records of the execution of that contract indicated that one of the purposes of the contract was to allow military medical investigators to conduct experiments using prison immates as their subjects. Indications of the unpreparedness of the contractors medical investigators was reflected in a 5 November 1964 report of a visit by the Chemical Corps Medical Contract Project Officer, Edgewood Arsenal, to the contractors' facilities. That report held that: "Throughout the entire three-day period, testing was hampered by equipment, such as needles, syringes, and alcohol sponges, not being readily available. On the second day of testing no medical personnel, other than ourselves, were present, not did any appear, or make contact with us prior to our leaving Friday afternoon." The report also stated: "It is our opinion . that in order for this program to be successful, there needs to be guidance and supervision of the testing by the contractors. This is especially important in this early stage of the program for training of the nursing personnel and establishing standard operating procedures."10 Another report of a visit by the Edgewood Arsenal Project Officer to Holmesburg Prison in March 1966, held that the competence of the contractor staff and facilities were adequate, thus, indicating that improvements had been made in the one and a half years between the reported visits. However, that report cited proof of the third point mentioned above, i.e., medical investigators from Edgewood were conducting experiments on prison immates. This report stated that the purpose of the visit was twofold: first; the introduction of new military medical investigators; and secondly, "to conduct a supervised experiment involving high doses of an incapacitating agent to determine the capability of the contractor to assume responsibility for experiments of this type."

The concern that the contract was used as a means to provide subjects for use by Edgewood Arsenal medical personnel was presented to the Edgewood Arsenal legal advisor by the contracting officer in October 1966. The legal counsel ruled that "the contract cannot be treated as one merely to provide subjects for the use of Edgewood medical personnel." Later in October 1966, the contracting officer met with the Chief of Medical Research Laboratory and the contract project officer and reached an understanding that the contractor had been and would, in the future, be allowed and required to assume full responsibility for the work conducted under the terms of the contract. Although this agreement appeared to indicate that Army medical investigators had not taken part in either actual experiments or in direct supervision of experiments on immates, available evidence indicated that as late as 1964, experiments on prison immates at Holmesburg Prison were personally conducted or supervised by military medical investigators.

The same civilian medical investigators who conducted research at Holmesburg Prison under University of Pennsylvania contracts formed the Ivy Research Laboratories, Inc. That organization received two contracts (one in 1968 and the other in 1970) from the Chemical Corps to continue work at Holmesburg Prison with immate volunteers. The purpose of these contracts was to determine the threshold response dose of adult human subjects to various chemical agents furnished by the Medical Research Laboratories at Edgewood. The chemical agents investigated were: choking agents, nerve agents, blood agents, blister agents, vomiting agents, incapacitating agents, and toxins. The 21 progress reports regarding these contracts indicated that at least 94 inmates were used in experiments. In addition to the reports, one actual contract was found. Review of that contract indicated the contractor was required to comply with Department of the Army policies established by AR 70-25 (Use of Volunteers in Research). There was no evidence that the investigators at Holmesburg failed to comply with any of the policies set forth in the Army regulation.

The completion of the Ivy Research contracts was delayed in February 1971 when the immates filed a civil suit concerning the conditions at the prison. Although the records indicated that the medical research was not an element of the complaint, the work was stopped until the suit was settled. Nine months later preparations were made to continue the

volunteer experiments. However, in March 1972, a fire within the prison damaged facilities and equipment located on the prison grounds which belonged to the prison, Ivy Research Laboratories and the Army. Because of the fire and of criticism of Ivy Research by the Prison Board, the contract was terminated in February 1973. No work on volunteers had been done since February 1971. 17

One of the contracts was awarded to American Institute for Research,
Silver Spring, MD in 1964. The objective of the contract was to develop
a comprehensive test battery to measure the effects of incapacitating
agents on the abilities basic to performance of militarily relevant
tasks. Review of seven reports available regarding the contract indicated that the American Institute investigators conducted psychoactive
chemical compound experiments on military volunteers. It was not clear
from the reports if the volunteers came from Edgewood Arsenal or elsewhere or if the experiments were conducted at Edgewood Arsenal. Moreover,
the only agent mentioned in the reports was EA 3580, a glycolate. Other
studies conducted under the terms of the contract appeared to focus on
academic type testing to determine the validity of the screening and
selection process used to determine which military volunteers were
eligible to receive psychochemical drugs.

In 1955 an Army grant (DA18-108-CML-5596) was provided to Tulane University, Department of Psychiatry and Neurology, for research in abnormal brain functioning as related to mental illness. The few Army records available regarding the experiments conducted under the terms of the Army grant revealed that mental patients, normal volunteers and neurological patients were used by the Tulane medical investigators. The actual terms of the grant were not found and therefore no determination was made concerning the grantees' compliance with Department of the Army policies nor could any judgment be made as to the quality of consent rendered by the patients. One particular experiment involved giving LSD and mescaline to mental patients who previously had wire electrodes implanted in their brains. Reports indicated that the research group believed that a basic biochemical abnormality was responsible for the bizarre behavior demonstrated by many psychotic patients; and that the wire electrodes served a twofold purpose: to record electrical abnormalities in patients' brains, and to stimulate patients brains in hope of curing or ameliorating the patients' problem. The reports suggested that the implantation of electrodes was financed under a grant from the Commonwealth Foundation and not the Army grant. Finally, it was not clear what the Chemical Corps interests in the experiments were at the time, although, it was surmised that their interest did not go beyond gathering evidence of the effects of LSD and mescaline in humans. Some credence was lent to that belief by the reports provided the Chemical Corps, which did not discuss the implantation procedures, purpose or effect; rather they stressed the effects of the drugs. 18

Three contracts were awarded Baylor University for experiments with physical incapacitating agents in human subjects. The five reports concerning the contracts established that the volunteers were screened, selected and medically examined in accordance with Army policy directives. The experiments involved the use of adult volunteers of both sexes with therapeutic drugs such as demerol, morphine and scopolamine.

One of the contracts involving physical incapacitating agents was awarded to the Institute for Behavioral Research to study "Drug effects and complex behavioral repertories under conditions of full environmental control." Experiments under that contract primarily involved monkeys and baboons. However, there was evidence of some volunteer experiments with sedatives or tranquilizers such as seconal, dimethyl tryptamine and chlorpromazine.

The remainder of the contracts were not involved in psychochemical drug studies. Mount Sinai Hospital was awarded four contracts to conduct studies of patients with hypothalamic diseases; neither drugs nor volunteers were involved. Louisiana State University was awarded two contracts to conduct studies of poisoning and effects of organic phosphare insecticides in man and animals. Those studies involved the investigation of accidental exposures and did not include the use of drugs or volunteers. The Maryland Medical-Legal Foundation was awarded a contract to study cases of botulism intoxication throughout the country. They collected data and apparently paid victims (called volunteers in their reports) for blood samples. Hahnemann Medical College and Hospital was awarded four different contracts for evaluaction of blocking agents (chemical compound used to attenuate the effects of drugs or chemical agents). They used volunteer subjects extensively; progress reports reflected that they used no coercion or enticement to gain volunteers and followed stringent medical safeguards in every human test. New York University was awarded two contracts which involved collection of data on patients with endocrinalogic disorders (disorder of the glands). No drugs or volunteers were involved in those studies.

The data upon which this chapter was based was found in various Army files; no effort was made to search the contractors files or to request the contractors assistance in contributing data that may have been available in their files. Moreover, research for this chapter did not include contracts with chemical companies or laboratories for the development, synthesis or procurement of chemical compounds or equipment.

Finally, with the exception of the Holmesburg Prison inmates and an occasional mention in contract reports, the names of volunteer subjects

Case4:09-cv-00037-CW Document126-14 Filed08/25/10 Page21c0621 or patients were not disclosed in the records and reports during inqui .

Recapitulation of Contract Data

In summary, 54 contracts or progress reports of contracts, were reviewed as a basis for this portion of the report. Those contracts are categorized below.

categorized Selow.	Nr.	of Cont	ractors	Nr. of Contracts
Category			5 Y	
Unrelated to Incapacitating		6		6
Agent Research		4		10
Nerve Agent Studies (N) ²	(1)2	12		2.5
· Incapacitating Agent Contracts	(1)	5		13
Miscellaneous Research Studies	(M) -	27		. 54

^{2 = ()} Category of research, listed at Column 8 of Contract Chart