10 March 1976

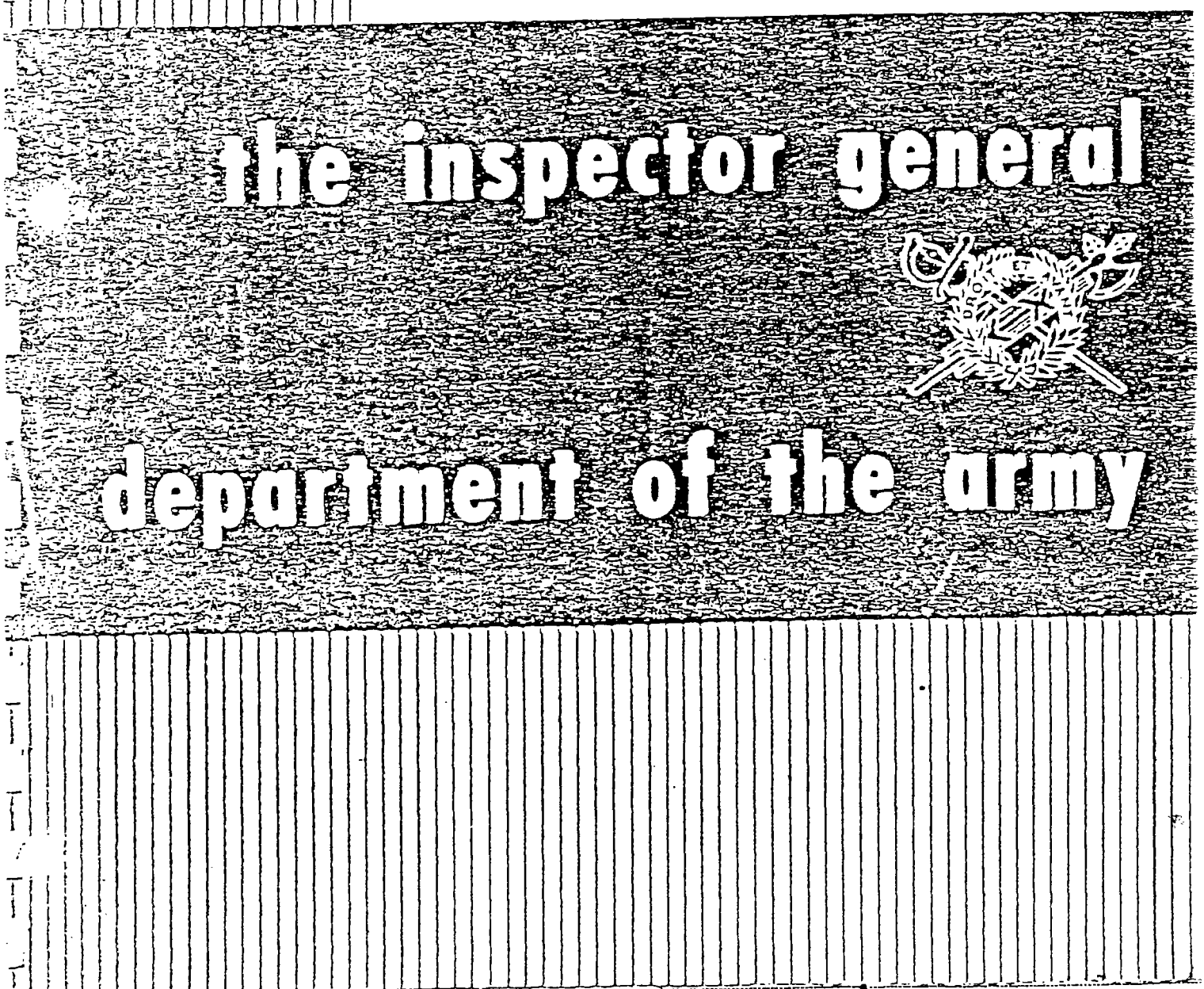
DAIG IN 21-75

report on

Use of Volunteers in

Chemical Agent Research

by



DEPARTMENT OF THE ARMY
OFFICE OF THE INSPECTOR GENERAL AND AUDITOR GENERAL
WASHINGTON, D.C. 20310

DAIG-IN 21-75

Use of Volunteers in

Chemical Agent Research

FOR MAR 19/C

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DEPARTMENT OF THE ARMY
OFFICE OF THE INSPECTOR GENERAL AND AUDITOR GENERAL
WASHINGTON, D.C. 20310

REPLY TO ATTENTION OF: 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, Headquarters, Department of the Army, pursuant to the Vice Chief of Staff Letter of Instruction, dated 21 July 1975.

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USE OF VOLUNTEERS

IN

CHEMICAL AGENT RESEARCH

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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 Command, will provide assistance 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, many 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, MO; 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 IV

THE DERIVATION OF AUTHORITY

General

The purpose of this chapter is to present the authority for the conduct of chemical warfare research with human subjects; to describe the procedures that governed the conduct of research with humans; and to discuss the interpretations of authority for the conduct of incapacitating agent research which existed at the time.

This chapter will cover the origins of medical research restrictions for the Army. It also covers the extremely high level at which decisions were made and the lengthy and thorough staffing that preceded the granting of authority to use human volunteers in research. Finally, it will include discussion of the several occasions when research was conducted without proper authority or when authority was incorrectly granted.

Chemical Corps Medical Research and the Use of Human Subjects

Just as in the history of medicine, human experimentation appears to have been an integral part of the history of the U.S. Army chemical warfare research efforts. On 28 June 1918 the President of the United States directed the organization of the Chemical Warfare Service (CWS), National Army, under the Secretary of War.[1] The CWS was created by merging the Chemical Service Section, National Army, the Chemical Element of the Ordnance Department, and the Sanitary Corps of the Medical Department. Four years later, in October 1922, the CWS created a Medical Research Division to conduct research directed at providing a defense against chemical agents.[2] Part of the defense was the provision of therapeutic and prophylactic measures. The scientists apparently shared a common belief that no matter how exhaustively an agent was tested in animals, if it was intended to protect or heal man, its efficacy had to be proved in man.

The scant evidence available for this period indicated that for the next 19 years the subjects used in various tests of mustard, phosgene, and many other chemical agents were volunteer employees of Edgewood Arsenal.[3] This expedient arrangement reportedly sufficed because the experimental staff was too small to generate experiments requiring large numbers of human subjects. However, available documents reflected that in early 1941 the threat of war caused greater urgency for the development of protective items. Consequently, the need for a larger source of volunteers also developed. The first recorded recruiting arrangement was a

request made to all technical and officer personnel at Edgewood Arsenal to signify their willingness to participate in various tests; a method which was soon reported as unsatisfactory.[3] Generally, it was considered that repeated exposure to agents was hazardous because the cumulative effects of the compounds were not known; sensitizing employees to compounds they had to work with in the course of their normal duties basically was unproductive; many of the volunteers because of their technical qualifications had preconceived opinions as to the reactions they should have to certain agents and thus were not completely objective or unbiased in their reporting; test results were subject to invalidation due to the lack of testing on a valid random population basis; and a concern that the fear of censure by co-workers motivated many of the volunteers.

This period was characterized by an absence of any evidence which would indicate who authorized the use of human volunteers, or if it was a point of concern. It was apparent that if a source of authority did exist, it probably was informal and rested with the local commander. The first indication of formal authority to recruit and use volunteer subjects in chemical warfare experiments was in 1942. Specifically, in June 1942 records reflected that the Secretary of War was requested to rule on the permissibility of using enlisted men for detail testing of mustard type agents. Reportedly, the Acting Secretary approved the test in principle and authorization was granted by The Adjutant General of the Army in the name of the Secretary.[5] This authority was followed by large-scale human experimentation at Edgewood Arsenal, as well as at field laboratories located at Camp Siebert, AL, Bushnell, FL, Dugway Proving Ground, UT, and San Jose Island. The testing programs continued throughout the war years. It also was reported that this authority was not rescinded. Subsequently, during the early 1950s this original authorization was again used for the conduct of tests at Dugway Proving Ground which involved exposing human volunteers to mustard type agents.[4] It must be noted that the evidence concerning tests involving mustard agents following World War II was a single documentary reference, uncorroborated by any other evidence.

In July 1943 the Chemical Warfare Service (CWS) was assigned responsibility for all medical research involved in the field of chemical warfare. This adjunct to the CWS mission included toxicological research and the investigation and study of hazards to the health of Chemical Warfare Service personnel.[5] With the end of World War II the immediate requirement for volunteers temporarily was diminished. There were indications that the laboratories at Edgewood Arsenal reverted to the old practice of using local assigned personnel to meet their volunteer needs. This does not imply that the end of World War II curtailed the research activity of the Chemical Corps. On the contrary, the frightening revelation that Germany had stockpiled certain organic phosphate compounds (nerve

gases) that were far more deadly than the chemical agents in the Allied arsenal, developed a new series of challenges for the Corps. Discovering methods to counteract the lethal effects of these compounds became a primary goal of medical research. However, American researchers were unable to locate any usable research evidence that the Germans had conducted meaningful human experimentations with the nerve agents. Thus it was necessary to spend the next several years confirming German research data by animal experimentation and by compiling sufficient information to determine the safe experimental dose for man.[3] When the necessary animal experiments had been concluded and the Chemical Corps investigators were confident of their ability to safely conduct experiments in man, the question again surfaced as to where the volunteers would come from.

Authority to Use Volunteers

During this period, the rules governing the use of humans had undergone major changes. The first of these changes was the Nuremberg Military Tribunals, following World War II, which produced a set of firm rules for the conduct of medical research. They were known as the "Nuremberg Code of 1947," and it established 10 specific rules intended to govern the use of humans in the conduct of medical experimentation.[6] Since this Code became the foundation for future guidance to researchers, its essential elements are repeated in this report:

> 1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved so as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the subject there should be made known to him the nature, duration and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests with each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problems under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even the remote possibilities of injury, disability or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the subject.

The second major change occurred in 1950, with the introduction of legislation governing the organization of the U.S. Army. The initial statutory authority for the Army to conduct research and development was housed in the Organization of the Army Act of 10 July 1950. Section 104 of the Act

(74 Statute 322; 5 USC 235a) held that: "The Secretary of the Army is authorized to conduct, engage, and participate in research and development programs related to activities of the Army of the United States and to procure; or contract for the use of, such facilities, equipment, services, and supplies as may be required to effectuate such programs."[7] It appears that this was the first time the Congress placed into law control over research and development activities and further vested the responsibility and authority for such programs with the service secretary. It further appears from this Act that the Congress recognized research and development functions as an integral part of the Army's role.

At this point in history there are two separate, yet related, actions impacting on research: the Nuremberg Code of 1947 and the Organization of the Army Act of 1950. Although there is little in the way of documentary evidence to indicate general knowledge or recognition of the impact of these actions, it does appear that authority for future use of humans in research would require observance of the Nuremberg Code and also would require authorization by the service secretary. However, no documentary evidence was discovered which indicated that the secretary either delegated his authority or established directives or guidelines to preclude research involving human subjects without his authorization. In fact, there was a notable lack of policy one way or the other between 1950 and 1952.

Early Policy Guidance

The matter of the use of human volunteers was under deliberate consideration by the Armed Forces Medical Policy Council during the first two years of the 1950s. In the fall of 1952, following extensive study, the Council reported to the Secretary of Defense that researchers had reached the point beyond which essential data could not be obtained unless human volunteers were utilized. Thus, they recommended that the Secretary of Defense establish a policy that would authorize the use of humans in medical research.[8] They further recommended that the Nuremberg Code of 1947 be cited as the principal guidance to the services. However, they urged that three articles of the Code be modified. The first of these recommended modifications was that Article 1 require the volunteer's consent to be in writing and his signature witnessed. Secondly, they recommended that Article 5 be modified to delete the final phrase "except, perhaps, in those experiments where the experimental physicians also serve as subjects," thereby leaving the entire article to read: "No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur." Finally, they suggested that an additional rule be added which would prohibit the use of prisoners of war as volunteer subjects.

Based upon a recommendation of the Armed Forces Medical Policy Council that human subjects be employed as the only feasible means for realistic

evaluations and/or development of effective preventive measures of defense against atomic, biological, or chemical agents, the Secretary of Defense, by a memorandum to the service secretaries, established a policy governing the use of human volunteers. The memorandum, dated 26 February 1953, was classified "TOP SECRET" and provided the following: each service secretary was authorized to use human volunteers in experimental research connected with the development of defenses of all types against atomic, biological and/or chemical warfare agents; provided specific guidance and safeguards concerning the use of human volunteers, which included the rules as set forth in the Nuremberg Code, as modified by the Armed Forces Medical Policy Council; required that in each instance in which an experiment was proposed pursuant to the memorandum that the nature and purpose of the proposed experiment (protocol) and the name of the person to be in charge of the experiment shall be submitted for approval of the service secretary; required that the service secretary approve, in writing, the proposed experiment and the person to be in charge of the experiment; and required the service secretary to inform the Secretary of Defense of each approved research proposal.[8]

Although there was no evidence that the Chemical Corps Research Laboratories were provided advance information concerning the forthcoming guidance on the use of human volunteers in research, there was evidence that the underlying principles of the "Wilson Memorandum" were known and were the subject of detailed discussions long before Department of the Army published an implementing directive. In this regard, the Medical and Related Problems Committee of the Chemical Corps Advisory Council met at the Army Chemical Center (now Edgewood Arsenal), on 20-21 March 1953, to discuss the impact and implementation of the rules established at the Nuremberg Trials and accepted in modified form by the Secretary of Defense in February 1953. In attendance at this meeting were the prominent civilian doctors who constituted the committee, legal and medical advisors to the Chief, Chemical Corps, representatives from the medical and biological laboratories, and representatives of intermediate chemical research commands.[4] The report of this meeting was significant because it indicated the existence and use of an alternate to normal command channels for the dissemination of Army policy within the Chemical Corps. Although the "Wilson Memorandum" was dated 26 February 1953, the Army's implementing instructions to that memorandum had not been published or announced at the time of the conference. Nevertheless, the Council, in anticipation of an Army policy, advanced local interpretations that later would be germane in the execution of the policy. The depth of knowledge held by the participants regarding problems associated with the use of humans in research is probably best explained by recognizing the key positions they occupied in the Chemical Corps organization and, in some instances, overlapping membership in other advisory councils within the armed forces. Some of their interpretative conclusions are worthy of mention at this point, even though most will be discussed later in

this and subsequent chapters. They concluded that it was important to differentiate between hazardous and nonhazardous experiments. In their opinion this differentiation was essential since they agreed that only protocols for hazardous experiments need be submitted for approval. In this light, they reported that gas mask training during which men passed through a chamber with a high concentration of mustard gas would be considered nonhazardous and "in the line of duty." Another consideration was an effort to seek blanket type approval for experiments already being conducted, thus simplifying an anticipated problem of obtaining approval for specific hazardous experiments. The participants agreed that the most controversial legal aspect was to determine what constituted voluntary consent. The conferees noted that the important considerations in this regard were: the age of the volunteer; mental capacity; and the amount of information which must be provided in advance of obtaining the signed volunteer statement. Additionally, it was opined that any form of coercion, mental, physical, or material, must be avoided. Further, they considered military volunteers as presenting a particularly sensitive problem since soldiers were imbued with a sense of obedience and readily could be placed in a position where the experiment was made to appear as a military duty and thus something the volunteer could not refuse.

Two months later, in May 1953, the Army Staff presented the Secretary of the Army with a proposed directive to implement the "Wilson Memorandum." Although the Secretary agreed in principle with the proposed instructions to the field, he rejected the initial proposal because it was restricted to biological agent research rather than chemical, biological, and radiological agents and because he believed that the "TOP SECRET" classification should be downgraded in order to make the instructions more readily available to subordinate elements that would be conducting the research. Evidence indicates that the first guidance to the Army Staff was published on 30 June 1953.[11] This memorandum, which was addressed through the Assistant Chief of Staff, G-4, to the Army Chief Chemical Officer and The Surgeon General, was titled: "Use of Volunteers in Research," and was to be referred to as "Chief of Staff Memorandum 385 (CS:385)." Its purpose was to provide policy and procedures for the use of volunteers in atomic, biological, and chemical research. In addition to transmitting the 11 rules contained in the "Wilson Memorandum" and legal considerations for researchers, it also directed that no research of atomic, biological, or chemical agents using volunteers would be conducted without the specific written approval of the Secretary of the Army. Moreover, it directed that proposals for such research would be forwarded to The Surgeon General of the Army for his review and mandatory comment prior to presentation to the Secretary for approval. The memorandum, as published, did not differentiate between hazardous and nonhazardous experiments as a consideration of whether to obtain Secretary of the Army approval, rather, it specified that all atomic, biological, and chemical agent experiments which used human subjects would be submitted. The document search failed to disclose

any documents which provided additional guidance qualifying or limiting the type of experiments requiring approval. Such guidance normally would have been transmitted through the Office of the Chief Chemical Officer to the Commander of the Chemical Corps Research and Engineering Command located at what is now Edgewood Arsenal. Records do indicate that on 24 July 1953, after receiving guidance from the Chief Chemical Officer, the Commander of the Chemical Research and Engineering Command notified the Commander of the Chemical Corps Medical Laboratories that the policies and procedures set forth in Chief of Staff Memorandum 385 were effective immediately and would govern the use of volunteers in all present and future experimental research.[1] The Commander also directed that research plans and requests for approval to conduct experiments using human volunteers be submitted by 7 August 1953, and that until such time as new approval was granted all experimentation using volunteers would be stopped. This action directed immediate compliance without exception to the new policy.

Initial Request to Use Volunteers

On 7 August 1953 the Medical Laboratory Commander submitted a request for approval to conduct seven research projects. Although not specifically stated, it was implied that these experiments had been in progress at the time the 24 July 1953 letter was received. The seven research projects for which approval was requested were:

a. Retention of nerve gas vapor in human respiratory tract.

b. Behavior of nerve gas liquid on the human skin.

c. Effects of nerve gas on the nervous and mental functions in man.

d. Effects of nerve gases and of therapeutic agents on visual efficiency.

e. Evaluation of candidate therapeutic agents in man.

f. Sensory threshold effects of phosgene oxime in man.

g. Comparative effects on skin of vesicant liquids, vapors, and aerosols.[13]

The Medical Laboratory Commander in his request for approval of the research plans included his interpretation that the "use of volunteers in research" applied to the exposure of individuals to the hazards of toxic chemicals, whether they were standard or candidate chemical warfare agents, or standard or chemical therapeutic agents. The Laboratory Commander expressed an assumption that the Chief of Staff directive requiring Secretary approval did not include studies of the physiological aspects of

protective material, including the protective mask, since such studies did not have to involve exposure to toxic chemicals.

The Commander, Chemical Corps Research and Engineering Command, the Chief Chemical Officer, and The Surgeon General reviewed the proposed plan and recommended to the Secretary that it be approved. The Surgeon General in his comments provided an opinion that the provisions of the Chief of Staff Memorandum 385 would apply in the event toxic chemicals were used in gas mask tests. A memorandum to Chief of Staff, dated 5 November 1953, signed by the Secretary of the Army, Robert T. Stevens, granted approval to conduct the requested research programs using human volunteers.[14] A synopsis of the Chemical Corps plan, which listed the seven investigative studies, was attached as an inclosure to the approval memorandum and contained a statement to the effect that the basic directive did not include studies of the physiological aspects of protective materials, including the protective function of the gas mask, unless such studies included exposure to toxic chemicals. Although the copy of the Chemical Corps plan referred to in the Secretary of the Army's memorandum could not be located, other documents indicated that the approved plan contained basically the same data submitted by the Medical Laboratory on 7 August 1953. Further support of that contention was contained in a 24 December 1953 letter from the Office of the Chief Chemical Officer to the Commander, Chemical Corps Research and Engineering Command, in which approval of the request of 7 August 1953 was granted. This particular letter approved all seven investigative study requests without modification or qualification; it confirmed the assumption that studies involving physiological aspects of protective material were not within the intent of the Chief of Staff Memorandum 385, unless exposure to toxic chemicals was involved; it directed that Army contractors must abide by the same basic principles and safeguards governing military researchers; and it specified that the fact that the Chemical Corps was using human volunteers in research was, of itself, unclassified.[15] This downgrading of classification apparently was attributable to the Secretary's earlier concern about the level of classification, which culminated in a Secretary of the General Staff Memorandum, dated 16 October 1953, downgrading Chief of Staff Memorandum 385 from "TOP SECRET" to "CONFIDENTIAL."[16] It appeared that the initial high classification afforded the subject may have been partially responsible for the lack of complete documentation and for early misinterpretations of the policy.

Policy interpretations are mentioned at this time because there was evidence that at least one research project was not terminated pending submission and approval of the research plan in accordance with Chief of Staff Memorandum 385. Specifically, an operation code named "TOP HAT" was conducted at the Chemical Corps School, Fort McClellan, AL, between 15 and 19 September 1953.[17]

This research project, which was termed a "local field exercise," involved the use of Chemical Corps troops in testing methods of decontaminating biological warfare agents, mustard gas, and nerve gas. A review of the scant literature available on the exercise indicated that it was conducted in contravention of the intent of the Department of Defense and Department of the Army policies. While it is possible that a separate request for approval may have been submitted and subsequently retired and/or destroyed, it is more logical to assume that the project was considered to fall within a "line of duty" exercise for Chemical Corps troops and interpreted as not subject to the provisions of policies governing the "use of volunteers in research." This conclusion is not offered as an excuse for an exercise in which soldiers were exposed to toxic chemical agents without proper authorization and without their consent, but rather to emphasize the extreme difficulty of attempting to implement a complex policy by means of a relatively simple, but highly classified directive.

Another observation of import concerns the seven investigative studies which were forwarded for approval and which appeared to be a request for approval of experiment with a "class" of drugs rather than a request for research involving a specific chemical agent. For example, the first of the seven investigative studies, "Retention of Nerve Gas Vapor in the Human Respiratory Tract," failed to specify which of the several available nerve gas agents would be used and under what circumstances. Since the nerve gas agents varied significantly in toxicity, it would appear extremely difficult for The Surgeon General to conduct a thorough evaluation of the proposal without knowing the specific chemical nerve agent to be used in the experiment. Again, there may have been additional correspondence and conferences answering these various questions about the agent to be used and the emergency treatment measures to be available on site prior to The Surgeon General recommending approval, however, no records of such were found. Thus, the available records gave the impression that the submission of the initial request amounted to nothing more than a perfunctory action for the purpose of obtaining blanket approval for ongoing research projects.

Medical Volunteer Program

By 1954 the Chemical Corps had established a framework within which to conduct human experimentation, however, they lacked an adequate pool of volunteers. There were indications some experimentation was being conducted using enlisted personnel assigned to Edgewood and technicians assigned to the laboratories. However, this source was extremely limited and could not support the type research program envisioned.

In 1955 it was decided that the most practical source of volunteers would be enlisted men stationed at Army installations in the vicinity of Edgewood Arsenal. The Medical Laboratories formed an orientation team to

visit Second Army Headquarters at Fort George G. Meade and solicit the support of the commander. The mission was successful. In April 1955 HQ, Second Army, published a directive to its major installation commanders encouraging them to publicize the program in an attempt to provide Edgewood Arsenal 20 volunteers each month for a period of 30 days temporary duty (TDY).[18]

The first contingent of 16 soldiers from Second Army Headquarters arrived at the Army Chemical Center (Edgewood Arsenal) on 2 May 1955.[19] For a brief period it appeared that the Medical Laboratories had established a complete, viable program, i.e., authority to use humans in research; a proper medical staff to conduct the research; and a steady supply of volunteers. However, within a few months more urgent priorities for Second Army's personnel resources inhibited the flow of volunteers.[3] In an effort to overcome this shortfall, the Chief Chemical Officer requested the support of the Quartermaster General, the Chief, Corps of Engineers, the Chief of Ordnance, and the Chief Signal Officer. This action resulted in volunteers coming from Fort Knox, KY, Fort Lee, VA, Fort Eustis, VA, Fort Belvoir, VA, Fort Monmouth, NJ, and Aberdeen Proving Ground, MD, in addition to those already committed by Fort Meade.

Psychochemical Drugs

On 7 September 1955 the Commander of the Medical Laboratories formally requested permission to use volunteers in research involving nonlethal psychochemicals.[20] His request, titled, "Additional Use of Volunteers in Research," was submitted to the Commanding General, Research and Engineering Command, who concurred in the request, as written, and forwarded it to the Chief Chemical Officer, Department of the Army.[21] Prior to the request being prepared and forwarded, there was a considerable body of research data concerning the effects of psychochemicals on humans available to the Chemical Corps Medical Laboratory, to include data obtained as a result of actual experimentation conducted by civilian hospitals and universities working under Army contracts.

Some of the events which preceded this request had a direct bearing on it and on subsequent actions involving psychochemicals. Several months prior to the Medical Laboratories' request to use volunteers in psychochemical research, the Chairman of the Technical Advisory Panel on Biological and Chemical Warfare, Office of the Assistant Secretary of Defense (R&D), appointed an "Ad Hoc Study Group on Psychochemical Agents" to evaluate the military potential of this type of chemical warfare. Their report, known as the "Wolff Report," after the name of the committee chairman, was published in November 1955 and presented specific recommendations for the conduct of future research involving psychochemical agents.[22] The committee concluded that experiments with psychochemical agents, of which LSD appeared to be the most promising, should be

carried out with volunteer units as soon as practicable. In this regard, the Study Group also prepared and recommended the implementation of a detailed plan for the conduct of small unit experiments. Reference to the "Wolff Report" was necessary at this point because a review of the actions surrounding the submission of the September 1955 request for "Additional Use of Volunteers" gave the impression that staffing of the request was held in abeyance pending release of the report. It apparently was known beforehand that the Study Group would not only favor testing of psychochemicals on humans, but also would recommend that tests be conducted to determine the drug's effect on small military unit operations. Records also indicated that several months prior to the September 1955 request being approved, advance planning was underway to implement the testing of small units, as recommended by the "Wolff Report."

In January 1956 the Office of the Assistant Chief Chemical Officer for Planning and Doctrine reviewed the "Wolff Report" and commented on the recommendation which proposed that, prior to a military group being administered LSD, they should be given a carefully prepared training lecture on the effects of LSD. The reviewer stated that: "in view of the fact that a great many of the effects observed in the group may be the result of suggestion (placebo effect) it would appear desirable to have one control group which has neither been given a training lecture on LSD-25, nor any information as to the symptoms of the drug being administered. Symptoms due to suggestion would thus be reduced to a minimum and at the same time a more realistic combat situation would be utilized since it is assumed that enemy personnel, under combat conditions, would not have recently been briefed on the effects of LSD-25."[23] It is not known whether the reviewer in this instance would have caused the drug to be administered to all of the volunteers or to selected members of each group. Implicit in the comment, however, is the theme that, from the military standpoint, a lack of knowledge on the part of the volunteer was necessary for a realistic experiment. Neither the correctness of the comment nor the value of the added realism is at issue. What is involved is that in spite of clear guidelines concerning the necessity for "informed consent," there was a willingness to dilute and in some cases negate the intent of the policy. It will be demonstrated again during the discussion of the specific experiments that this attitude of selective compliance was more of the norm than the exception. Other evidence indicated that in 1956, prior to the approval to use human volunteers in testing of psychochemical drugs, research investigators at Edgewood Arsenal attempted to secure permission to employ a NIKE site crew as the small unit to be used in the type experiments recommended by the "Wolff Report."[24]

Another example of selective compliance with existing policy occurred in February 1956. A memorandum from the Deputy Chief Chemical Officer for Scientific Activities to the Commander of the Research and Development

Command recommended that the Chemical Corps scientific studies of LSD, a U.S. patented compound, be continued; that for military security reasons the owner of the patent not be advised of the present and possible future interest in the compound; and that a careful record of the quantities synthesized be maintained. This recommendation was made after a legal opinion was received from the Chemical Corps Patent Agency which, in effect, stated that use of the patent compound in the manner intended would be an infringement of the patent owner's rights and actionable by the patent owner; that based on this "the Chemical Corps may use the invention set forth in the reference patent and its only liability for so doing will be a requirement to pay a reasonable sum for so doing." It further opined that "governmental use of the invention need not be disclosed to assignee where such action would compromise security." [25] It is not known if the patent owner of LSD ever received notification of the use of his patent or reimbursement for such use. The point of this example is not simply to show possible violation of patent rights, but to again demonstrate the existence of a frame of mind and purpose which fostered a willingness to bend or break rules and policies so as to insure mission accomplishment; a continuing reliance on the "end justifies the means."

In March 1956 the staffing action on the September 1955 request for "Additional Use of Volunteers," which had apparently stopped pending receipt and review of the "Wolff Report," resumed when the Chief Chemical Officer forwarded the proposal to The Surgeon General, requesting his comments and concurrence. The forwarding indorsement pointed out that the Chemical Corps was conducting research investigations, using volunteers, in defense against chemical warfare, and that a small portion of such research, conducted entirely by highly qualified contractors, involved experimentation with psychochemical drugs. This research was reportedly authorized by the Secretary of the Army in his 5 November 1953 memorandum.[26] However, a review of the referenced memorandum does not indicate any reference to psychochemicals. To the contrary, the approved plan contained seven specific experiments involving nerve agents, oximes, and vesicants. Further, the Secretary of the Army directed that the same principles and safeguards which applied to the Department of the Army would apply equally to contracts awarded to outside contractors. The Chief Chemical Officer further stated that the increasing importance of the "minimum destruction" concept and the need for a defense against agents causing temporary incapacitation had led to the need for a concentrated study of psychochemical agents. Studies which, for the first time, would involve the use of psychochemicals on volunteers in the Chemical Corps laboratories. The proposed plan for testing psychochemicals provided the protocol, the name of the medical doctor in charge, and a proposal for the conduct of operational exercises to determine the vulnerability of military personnel to psychochemical agents in various military exercises. These exercises included: command post operations;

logistical exercises; squad drills; bridging operations; and fire direction center operations. Moreover, the request estimated that 200 volunteers would be required in the first year of experiments. This request was for a "class" of chemicals (psychochemicals) and for types of experiments rather than specific drugs for a specific experiment. This procedure, although not specifically prohibited by existing policy, appeared to be a departure from the intent of the policy, and as such did not provide those in the approval chain with a clear or complete picture of what actually was being proposed as it related to the volunteer. There was no evidence found indicating that objections or questions were raised concerning this lack of specificity. Although, on 11 April 1956 The Surgeon General, in his reply, did refer to earlier discussions and correspondence on the subject matter and that the proposal, as submitted, was a satisfactory development of ideas discussed, provided for adequate safeguards, and recommended approval by the Secretary of the Army.[27] However, no record of the earlier discussions or correspondence was located, nor was there other evidence discovered which would indicate that those higher in the chain of approval, to include the Secretary of the Army, received information other than that contained in the proposal and The Surgeon General's review. It was recognized that informal coordination or briefings could have provided more of the details as to the specific drug to be used. However, subsequent events do not reinforce this supposition. On 17 May 1956 the Director of Research and Development, in a memorandum to the Chief of Staff, U.S. Army, approved the plan as submitted, although there was a specific requirement that the Secretary of the Army must approve, in writing, each proposed use of human volunteers.[28] There was evidence that this deviation from policy was questioned immediately by responsible Chemical Corps personnel. However, a memorandum for record indicated that as a result of a discussion between a Chemical Corps legal advisor and an officer in the Director of Research and Development office, it was determined that the approval action was proper. There was no evidence found which would indicate that the Secretary of the Army approved the proposal, either in writing or orally; or that he delegated approval authority to the Director, Research and Development; or that he even had knowledge of the approval made in his stead. Several witnesses stated that since the Director of Research and Development was a member of the Secretary's staff, as the forerunner of the current Assistant Secretary of the Army for Research and Development, he would have been in the proper execution of his responsibilities when he approved the request in the name of the Secretary.[30]

Nevertheless, on 24 May 1956 the Medical Laboratory at Edgewood Arsenal was notified that the psychochemical testing plan had been approved. Since approval came through normal command channels, there would have been no reason for the Medical Laboratory Commander to question the authority to proceed with the planned experiments.[29] This request and subsequent approval appeared to have established two precedents:

(1) requests for the use of volunteers in drug testing could be approved on a "class" basis without specific mention of the wide variety of drugs involved, or their individual potential effects; and (2) regardless of earlier guidance, all protocols did not require the written approval of the Secretary of the Army. Undoubtedly, these two precedents laid the groundwork for future dilution of what had originally appeared to be clear and unequivocal centralized control of the authority to use volunteers.

Army-Wide Recruitment

Available records indicate that by early 1957 inadequate numbers of volunteers were being made available to the Chemical Corps for conduct of human experiments. Thus, in April 1957 The Adjutant General of the Army directed the Army area commanders in the United States to establish a program to obtain volunteers for use at the Chemical Warfare Laboratories at Edgewood Arsenal.[31] This document cited the need for 50 volunteers per month and established a schedule for the six Army areas to furnish volunteers for 30-day TDY periods. The directive gave Chief of Staff Memorandum 385, dated 30 June 1953, as authority to conduct this program. It emphasized that voluntary consent of the human subject was absolutely essential; and stated that in all experiments involving volunteer subjects, the individual would be thoroughly informed of all procedures and what to expect during each test. Furthermore, the volunteer would be free to determine whether or not he desired to participate.

On 11 July 1957 the Chief Chemical Officer wrote a letter addressed to all Chemical Officers in the Zone of Interior (ZI), in which he encouraged them to energetically support the volunteer program, emphasizing the importance of the volunteer's contribution to the national defense effort.[32]

Air Force-Navy Participation

During the same timeframe, the United States Air Force and the Department of the Navy were invited to participate in the volunteer program by sending 10 men each month. Records reflected that the Air Force contributed volunteers starting in November 1957; the Navy apparently elected not to join the program at this time.[3] Available records reflected that between May 1955 and December 1957 approximately 540 volunteers were employed in the program at Edgewood Arsenal; 14 of these were reported to have been from the Air Force.[3] However, indications were that this figure did not include the assigned technical assistants and researchers who "informally" volunteered. However, records indicated an additional project involving Air Force and Army participation in August 1961 when the Chemical Research and Development Command submitted a protocol for "experimental exposures of men to propellant vapors." This experiment was reported as an Air Force research project conducted with the use of Air Force volunteers.[47] Although

there was evidence that the protocol was submitted through U.S. Army Chemical Corps channels for the purpose of receiving Secretary of the Army's approval, there were no records discovered which indicated that such approval was granted. It is possible that approval was granted and records not retained in historical files. However, the important point is not the absence of records, but that responsible investigators and commanders recognized that this type of research test was not included within the broad authority previously received.

V-Agent Studies

Further interpretation of which experiments actually required personal approval by the Secretary of the Army was found in the documentation concerning approval to conduct volunteer tests with V-agents (lethal nerve agents). In May 1958 the Commander, Chemical Warfare Laboratories, submitted a request, subject: "Use of Volunteers in Research on V-Agents," through Chemical Corps Command channels, requesting authority to test V-agents in man. Specified in the proposal was the statement that one of the proposals, submitted and subsequently approved by the Secretary of the Army in November 1953, included the use of G-agents (nerve agents), which are highly toxic organo-phosphorus compounds. The request continued that even more effective organo-phosphorus compounds, known as V-agents, had been synthesized.[33] The Chief Chemical Officer, in forwarding the request to The Surgeon General for his comments and/or concurrence, stated that research investigations being conducted under the 5 November 1953 approval involved G-agents and implied that the request to use V-agents was simply a logical extension of the initial plan. In June 1958 the Chief, Research and Development Division, Office of The Surgeon General, responded to the May 1958 request by pointing out that a critical review could not be made on the basis of information provided in the proposal, however, it did state that the proposal, as written, satisfied the minimum requirements under Chief of Staff Memorandum 385. The Surgeon General commented that since human studies on V-agents were a logical extension of the nerve gas studies previously approved by the Secretary of the Army, that the same responsible medical doctor was in charge, and the investigation would adhere to the provisions of Chief of Staff Memorandum 385, then it was believed that no new authorization was required.[34] The requested comments were returned to the Chief Chemical Officer, and ultimately the research project involving the use of V-agents in human volunteers began.

In reviewing The Surgeon General's comments in this instance, it was noted that there was reference to more stringent safeguards used in the volunteer program with BW agents. These included: submission of a protocol for each new series or phase of study; a critical review by The Surgeon General to insure compliance with Chief of Staff Memorandum 385 before proceeding; and continual review of experimental results. This indication of the use of a double standard in implementing policy on use of volunteers was not further explained.

The Surgeon General's comments point out this difference very succinctly and ultimately agreed with the original contention that it was a logical extension of G-agent research, requiring no further authorization. Documentation was not found which would explain how after a proposal to employ a more highly toxic agent on humans was received, and the reviewing official in The Surgeon General's office concluded initially that a review or constructive comments could not be made on the basis of the information provided, and still be adequate to satisfy the minimum requirements of the Chief of Staff Memorandum 385 policy. In spite of these unanswered critical questions, the reviewer, in effect, agreed with the proposal and added weight to the interpretation of policy made by the Chemical Corps.

Policy Interpretations

Meanwhile, in the fall of 1957 the U.S. Army Chemical Research and Development Command had directed the term K-agent be used instead of psychochemical agent. Although these terms continued to be used interchangeably, it was noted that at this point in time the Medical Laboratory at Edgewood Arsenal had approval to use volunteers in experiments involving three classes of compounds: G-agents; V-agents; and K-agents. However, the Secretary of the Army actually had signed only the authorization for seven investigative studies using nerve agents (G-agents). At this point it appeared that the deviance from the established policy could be attributed to a failure of staff officers at Department of the Army level to comply with the letter and the intent of policy established by the Secretary of Defense and expanded on by the Secretary of the Army.

In early November 1958 the Medical Laboratory at Edgewood submitted, through Chemical Corps channels, a request to use female volunteers in conjunction with the psychochemical research program. The request was then forwarded to The Surgeon General for comment, who recommended that the request be disapproved on the basis that the early stage of research in the area of psychochemical research and the serious legal and public relations implications involved in the use of female volunteers made it inadvisable to use females at this time.[35] Apparently, the Chief Chemical Officer agreed since that was the basis cited in his disapproval of the request. Subsequently, the Deputy Commander of the Chemical Warfare Laboratory, in an internal memorandum to the laboratory director stated that females could not be used on the basis that their use was strictly prohibited by the provisions of Chief of Staff Memorandum 385.[36] At this time we find one request, use of female volunteers, but two different reasons why they could not be used; one of which involved an interpretation of Chief of Staff Memorandum 385.

Thus, it appears that each request which involved application of the provisions of Chief of Staff Memorandum 385 resulted in an interpretation of the policy. More startling was the lack of consistency in the interpretations, ranging from the most strict to the widest possible latitude.

Another example of the highly flexible interpretations of policy occurred in November 1958, when the Chemical Warfare Laboratory Commander submitted a request to have an additional physician authorized to accept direct responsibility for the conduct of experimentations on human volunteers during the absence of the primary doctor. This doctor was to be in addition to the responsible physician required to be appointed by the Secretary of the Army in accordance with DOD policy. The Surgeon General recommended that another doctor be authorized to accept direct responsibility in the absence of the responsible physician and included an additional control to be used if the request was approved. However, the Chief, Research and Development, disapproved the req est and stated that: "as interpreted in all actions to date, the provisions of Chief of Staff Memorandum 385 do not permit the dilution of personal responsibility in the prosecution of the human volunteer program." Included with this disapproval was a copy of an opinion by The Judge Advocate General (TJAG) in which it was opined that there was no legal requirement that anyone be designated to assume direct responsibility when the designated doctor was absent.[37] To the contrary, the policy clearly contemplated one person should be so designated and would retain responsibility at all times. However, it also contemplated that other qualified persons would be placed in charge of specific experiments, subject to direction and control of the designated doctor. Again, we have an example of inconsistent interpretation.

Finally, in June 1969 a proposal titled, "Physiological Stress Aspects of Chemical Agents," was submitted by the Director of the Biomedical Laboratory at Edgewood Arsenal.[66] The proposal clearly indicated the intent to use safe amounts of chemical agents in human volunteers in connection with selected physiological stress experiments. However, it did not specify which chemical agents were to be used. The Office of The Surgeon General reviewed the protocol in the light that chemical agents would be used, although the protocol stated that a separate request for approval of actual chemical agents would be submitted.[67] The Office of the Chief of Research and Development approved the request and ruled that since chemical agents were not included in the protocol, Secretary of the Army approval was not required under AR 70-25.[68]

On 12 September 1969 the Office of The Surgeon General returned the approved request to Edgewood Arsenal.[69] Although it is known that experiments under this protocol were conducted at Edgewood, no evidence was found of the Secretary of the Army's approval of the specific chemical agents used. The submission of this particular protocol without mention of the chemical agents to be employed seemed to have negated the purpose of retaining authority at any level above the laboratory. The Army regulation in force at that time (AR 70-25) required the "detailed plan" to be submitted to The Surgeon General. The plan could hardly be considered a "detailed plan of experiment" without inclusion of the

chemical agents intended to be used on the volunteers. It is conceivable that with approval of the protocol, less the chemical agents, the investigators could employ chemical agents previously approved in connection with the new plan.

Even though there were significant advances and changes in the research and the volunteer programs between 1953 and 1958, there was no indication of corresponding changes or updating of the policy directives.

By December 1958 there appeared to be concern about which chemical compounds were approved for use in volunteer subjects. Evidence of this concern was found in correspondence between the Director of the Medical Research Laboratories (Edgewood Arsenal) to the Commander, Chemical Warfare Laboratories (Edgewood Arsenal), and the Commanding General, Chemical Research and Development Command (Washington, DC), during the month of December 1958.[38] The gist of these documents was that the Medical Laboratories had initiated or intended to initiate research programs using volunteers to test chemical agent EA 1779 (CS), a riot control agent that causes extreme irritation to mucous membranes, and agent EA 1476 (tetrahydrocannabinols, a marihuana like compound). This was in addition to approvals already received for experiments with G-, V-, and K-agents. The documents indicated that the Chemical Research and Development Command agreed that research approval had been granted for G-agents (GA and GB), V-agent (VX), and K-agent (LSD-25); however, the Medical Laboratory was directed to suspend EA 1476 volunteer studies until Secretary of the Army approval was granted.[39] Available records indicated that the protocol for EA 1476 had not been submitted as of the end of December 1958, although there was an inference that some volunteer studies had been conducted. Additionally, the Medical Laboratory was permitted to continue volunteer studies with EA 1779 (CS), provided the protocol was submitted to their next higher command (Chemical Warfare Laboratory) by 30 December 1958.[40] The records indicated that the protocol for EA 1779 was submitted to the Commander, U.S. Army Chemical Research and Development Command, on 30 December 1958.[41] This series of documents indicated that the various Chemical Commands were in substantial agreement in regard to which protocols by class and agent were authorized for use in volunteer studies. The documents also indicated other areas of concern, to include: the desire to be in full compliance with Chief of Staff Memorandum 385 (CS:385) as evidenced by the suspension of the EA 1476 (marihuana) experiments; and the desire to avoid delays in the program while pending submission of the necessary protocol as evidenced by the granting of interim permission to continue EA 1779 (CS) studies while awaiting formal approval.

In February 1959 the Commander, Chemical Warfare Laboratories, reportedly learned that a woman had been exposed to EA 1779 (CS) in a planned experiment at the Medical Research Laboratory at Edgewood.[36] As a result of

this incident, the Chemical Warfare Laboratories Commander sent his laboratory commanders a memorandum in which he stated that the use of females in human volunteer research programs was not authorized. Additionally, he emphasized that there were three definite control measures governing any particular experiment: the basic policy document on the use of human volunteers (Chief of Staff Memorandum 385); the specific protocol that was developed for use of a particular agent; and the detailed plan for the actual exposure of human volunteers which required approval by the individual designated by the Department of the Army as responsible for the use of chemical warfare agents on human volunteers.[36]

Following the 30 December 1958 submission of the protocol for EA 1779, no evidence was discovered which indicated actual Secretary of the Army approval for use of this agent. However, in July 1959 EA 1779 did appear on a list of agents approved to be used on humans which was published by the Chemical Warfare Laboratories. Also in July 1959, a directive from the Commander, Chemical Warfare Laboratories, Edgewood Arsenal, established that no individual could use on himself any agent for which an approved protocol was not available; another indication of tightening of controls.

In July 1959 the protocol for research involving chemical agent EA 1476 (marihuana) and related compounds and for phencyclidene (sernyl) benzilates and related compounds was submitted through Chemical Command channels. One of the accompanying documents included a declaration that prior to learning of the interpretation that each class of chemical agents necessitated separate approval from the Secretary of the Army for volunteer testing, chemical agent EA 1476 had been tested in about 36 volunteers.[44] There was no indication of who decided that each class of chemical agent had to be approved separately, or who decided on "class" approval as opposed to individual agent approval, which appeared to be the intent of the original directive from the Secretary of Defense ("Wilson Memorandum"). Although the initial request of 17 July 1959 was for two different classes of compounds (tetrahydrocannabinols and benzilates), the only protocol found for the period of time was the former. Moreover, the request from the Chief Chemical Officer to The Surgeon General for comments and/or concurrence addressed only EA 1476 and related compounds. On 21 July 1959 the protocol was concurred in by The Surgeon General. It is assumed that the protocol was then processed through normal command channels, although no documentation was found which indicated such staffing prior to the Secretary of the Army action in October 1959. On 8 October 1959 Secretary of the Army Wilber M. Brucker forwarded a memorandum to the Chief of Staff, U.S. Army, which stated: "approval is granted for the conduct of research investigations using volunteers for studies in defense against nonlethal incapacitating chemical warfare agents. These experiments will conform to the proposed plans submitted by the Chief Chemical Officer and reviewed by The Surgeon General, U.S. Army (Inclosure 1)." The memorandum further provided: "additional authority is granted to pursue similar

volunteer studies with other nonlethal incapacitating chemical warfare agents provided The Surgeon General, U.S. Army, concurs with the protocol and procedures proposed by the Chief Chemical Officer, U.S. Army."[45] Clearly, Secretary Brucker delegated approval authority to two special staff members of the Department of the Army (Chief Chemical Officer and The Surgeon General) as regarded future "nonlethal incapacitating chemical warfare agents." It was not evident how often and to what degree that delegation was used. The nonavailability of documents in this regard may be attributed to the dilution of a formal approval procedure. Secretary Brucker's action did not require a signature approval "by either the Chemical Officer or The Surgeon General," nor was there any evidence that he required a copy of an approved plan to be provided either to his office, the Office of the Army Chief of Staff, Director of Research and Development, or the Secretary of Defense as required by the "Wilson Memorandum." It was possible that future approvals were informally coordinated with The Surgeon General and verbally approved by the Office of the Chief Chemical Officer. This possibility was supported, as mentioned earlier in this report, in that during the late 1950s and early 1960s interest and research in nonlethal incapacitating chemical warfare agents was very intense.

Secretary Brucker's approval was transmitted from the Chief, Research and Development, to the Chief Chemical Officer and The Surgeon General on 13 October 1959 without further guidance. On 16 October 1959 the Office of the Chief Chemical Officer relayed the approval to the Commanding General, Chemical Corps Research and Development (R&D) Command, again without adding amplification or clarification. The Chemical R&D Command forwarded it to the Chemical Warfare Laboratories on 23 October 1959 with a caution that experiments must conform to the proposal already approved for EA 2148 and EA 1476 (marihuana compounds) and related compounds and benzilates and related compounds. On 17 November 1959 the approval reached the Director, Medical Research Laboratory, Edgewood Arsenal, and directed that volunteer studies would be limited to EA 2148 and homologs, EA 1476 and homologs, LSD-25, CS, and benzilates.[46] It was of interest that the 17 November 1959 document did not include the term "related compounds"; this could have been an oversight or an effort to limit the latitude permitted the laboratory investigators. Taken literally, the omission of "related compounds" after benzilates would preclude experimentation, without additional approval, of candidate agents other than benzilates in the glycolate class. The original approval of benzilates and "related compounds" apparently would have permitted experiments with any glycolate agent. However, the evidence does not clearly indicate that this was an intentional restriction, or that it was perceived as a restriction by the research investigators.

It was also not surprising that there was a lack of evidence of new chemical agent protocols being submitted during this period. As far as the medical research investigators were concerned, approval was at hand to

use volunteers in research involving the following: G-agents (nerve); V-agents (nerve); K-agents (psychochemicals); CS (irritants); tetrahydrocannabinols (marihuana); and benzilates (which could be interpreted to include other glycolates).

Benzilate Research

As was discussed earlier, the search for incapacitating agents intensified when the Kennedy administration took office. Specifically, Department of Defense "Project 112" placed a high priority on development of a chemical incapacitating agent. Records indicated that by 1962 the primary agent to meet this requirement was a benzilate called agent "BZ" or "EA 2277." Plans for this agent apparently called for development of munitions, stockpiles, and storage facilities, as well as essential research. By April 1962 the program had progressed to the point that on 23 April 1963 the Assistant Secretary of the Army (Research and Development) appointed a project officer to provide overall supervision of the project. On 20 June 1962 the Secretary of the Army signed a memorandum to the Secretary of Defense notifying him that the Army had already initiated action to have the doctrine for employment, storage, and handling of agent "BZ" completed prior to delivery of the munitions.[61] It apparently was assumed that formal Secretary of the Army approval for the agent research was included in Secretary Brucker's 8 October 1959 approval for use of volunteers in tests of "Phencyclidene ('Sernyl'), benzilates and related compounds."[45]

In March of 1972 the Director of the Biomedical Laboratory at Edgewood Arsenal submitted a proposed protocol for the "glycolate agents."[70] The request stated that Secretary of the Army approval had been obtained in earlier years, but that the Office of The Surgeon General and Office of the Chief, Research and Development, had suggested resubmission. No evidence was found which confirmed that either of the proposals were approved by the Secretary of the Army. However, it is possible that reference to earlier approval by the Secretary of the Army related to Secretary Brucker's approval of "benzilates and related compounds" in October 1959.[45]

Regulatory Controls

On 26 March 1962 the first Army regulation governing the "Use of Volunteers as Subjects of Research" was published (AR 70-25).[48] The purpose of the regulation was to "prescribe policies and procedures governing the use of volunteers as subjects in Department of the Army research, including research in nuclear, biological, and chemical warfare, wherein human beings are deliberately exposed to unusual or potentially hazardous conditions. These regulations are applicable worldwide, wherever volunteers are used as subjects in Department of the Army research." This regulation did not indicate supersedure of any previous directive(s), however, it

appeared to be intended for that purpose. It provided for certain exceptions to policy for those performing normal hazardous duties, such as flight and jump training, fire and gas drills, and the like, similar to those discussed during the early Chemical Corps Advisory Council meetings. It listed basic principles to be observed by investigators, which were nearly identical to those recommended to the Secretary of Defense by the Armed Forces Medical Policy Board in early 1953. The regulation provided that: "a physician approved by The Surgeon General will be responsible for the medical care of volunteers. The physician may or may not be the project leader, but will have authority to terminate the experiment at any time that he believes death, injury, or bodily harm is likely to result." This provision appeared to be a change in the interpretation of guidance provided by the "Wilson Memorandum," which apparently intended that the service secretary would approve, in writing, the physician in charge, as well as the protocol for the experiment.

Appointment of Responsible Physician

A brief discussion of the history of the appointment of "responsible physicians" for the medical volunteer program is in order at this point.

Evidence indicated that in April 1956 the Secretary of the Army approved the appointment of Dr. Van M. Sim as physician responsible for volunteers in chemical warfare research.[49] The records further indicated that in November 1958 an effort was made to expand the "one physician in charge" requirement (as mentioned earlier in this chapter), when the Chief Chemical Officer requested the Secretary of the Army to appoint Dr. Kimura, assigned to the Medical Research Laboratory, as the alternate physician in charge, to act as such when Dr. Van M. Sim was temporarily absent from the laboratory. However, the request was not approved[50] and the requirement for a responsible physician remained unchanged.

Authority to appoint the physician in charge had remained with the Secretary of the Army. This was indicated on 18 June 1959 when the Under Secretary of the Army, acting for the Secretary, appointed Colonel Lindsey, newly assigned Director of the Medical Laboratory, to replace Dr. Van M. Sim as the responsible physician.[51] This level of authority apparently continued until 17 July 1962 (after publication of AR 70-25) when a request to have Colonel Lindsey's replacement as director (Colonel Bauer) appointed as responsible physician was forwarded to the Office of the Chief Chemical Officer, who forwarded the request through The Surgeon General to the Chief, Research and Development. On 6 August 1962 The Surgeon General recommended approval and on 17 August 1962 the Chief, Research and Development, approved the designation of Colonel Bauer.[52] Although the regulation (AR 70-25) provided for The Surgeon General to approve the responsible physician, in this instance the appointment was

made by the Chief, Research and Development. On 20 March 1963 the Commander, Chemical Research and Development Laboratory, submitted a request to have Dr. Van M. Sim appointed responsible physician to replace Colonel Bauer. The request was forwarded through the U.S. Army Munitions Command and U.S. Army Materiel Command to The Surgeon General, who, on 16 April 1963, recommended to the Chief, Research and Development, that Dr. Sim be appointed on an interim basis until a Medical Corps officer was assigned as Director of the Laboratory. On 18 April 1963 the Chief, Research and Development, approved The Surgeon General's recommendation and further requested that the Commander, U.S. Army Materiel Command, upon the assignment of a Medical Corps officer as Director of Medical Research, take necessary action to designate him as the responsible physician.[53] Several months later, on 26 September 1963, Colonel Blair was appointed to replace Dr. Sim, a position he held for eleven years.[54] Although it could not be determined at what level of authority this appointment was made, correspondence directed to the Commander, U.S. Munitions Command, was obtained and it is assumed that the Commander, U.S. Army Materiel Command, approved the designation. By 1974 the practice of service secretary approval of the "Medical Officer Responsible for Volunteers" had come full cycle. On 9 September 1974 Colonel McClure, Director, Biomedical Laboratory, was appointed by the Secretary of the Army, even though the governing regulation (AR 70-25, dated 31 July 1974) required, as did the earlier version, that The Surgeon General approve the appointment of the physician responsible for the medical care of volunteers.[73]

Although the level of approval authority for appointment of the physician responsible for volunteers in research apparently was changed, the authority to approve a specific protocol was retained by the Secretary. Paragraph 6, AR 70-25, dated 26 March 1962, Approval to Conduct Experiments, provided that: "It is the responsibility of the head of each major command and other agency to submit to The Surgeon General a written proposal for studies which come within the purview of this directive. The proposal will include for each study the name of the person to be in charge, name of the proposed attending physician, and the detailed plan of the experiment. The Surgeon General will review the proposal and forward it with his comments and recommendations on medical aspects to the Chief of Research and Development for approval. When a proposal pertains to research with nuclear, biological or chemical agents, the Chief of Research and Development will submit the proposal, together with The Surgeon General's review, to the Secretary of the Army for approval. No research with nuclear, biological or chemical agents using volunteers will be undertaken without the consent of the Secretary of the Army."[48] AR 70-25 was revised in July 1974. The revision transferred the final approval authority from the Chief of Research and Development to The Surgeon General for all research using volunteers, except research involving nuclear and chemical warfare agents. Approval for nuclear and chemical warfare agents was retained by the Secretary of the Army.

Medical Corps/Chemical Corps Agreements

The procedures for gaining approval of the use of human volunteers in chemical warfare agent experiments apparently was well defined, to include mandatory review and comment by The Surgeon General. In effect, once The Surgeon General had reviewed a protocol, his role in that phase of chemical agent research was finished, unless specific requests for assistance or advice were received. Thus, the medical expertise available from the Office of The Surgeon General apparently was absent during the actual conduct of experiments. A means to alleviate this problem may have been available through the initiation of a series of Joint Medical-Chemical Agreements.

The first known agreement was dated August 1958 and was titled: "The Joint Medical-Chemical Agreement to Conduct Research and Development." This agreement, which was signed by The Surgeon General and the Chief Chemical Officer, provided that The Surgeon General would assign a medical doctor as Director of the Medical Research Laboratory (Biomedical Laboratory) who would have his performance rated by the Commanding Officer of the Chemical Warfare Laboratories at Edgewood Arsenal. The Director's performance would be indorsed by the Commanding General, Army Medical Research and Development Command. Thus, the Director would work primarily for the Chemical Corps and have the initial part of his performance report completed by his Chemical Corps superior; and secondarily he would serve as the chemical warfare advisor to the Commanding General, Army Medical Research and Development Command (which was directly under The Surgeon General), who would be the indorsing officer for the duty performance report.[56] The agreement appeared to be an adequate method for insuring that The Surgeon General's office was kept informed of the Medical Research Laboratory's efforts. The agreement was renewed in March 1959 with the appointment of a new Chief Chemical Officer[57] and again in January 1963, when the Chemical Corps' responsibilities were transferred to the Army Materiel Command.[58] Another reference to this agreement was found in an August 1972 version, which was amended in November 1972, to allow for: annual program planning and evaluation to be made jointly between The Surgeon General and the Commanding General, U.S. Army Materiel Command; performance evaluation of the Biomedical Laboratory director to be made by Edgewood Arsenal Technical Director and indorsed by the Commander, Medical Research and Development Command; and for the submission of research protocols to U.S. Army Materiel Command for new classes of chemical agents not previously approved. These protocols were to be reviewed by The Surgeon General and forwarded to the Secretary of the Army for approval.[59]

Other Regulatory Controls

In 1964 two separate Department of Defense Instructions were published which seemed to separate chemical and biological research from investigational drugs research. The first, Department of Defense Instruction

Number 5160.5, dated 7 February 1964, subject: Responsibilities for Research, Development, Test and Evaluation on Chemical and Biological Weapons and Defense,[62] directed that each service would be responsible for preparation and conduct of its own programs and that the Army would be responsible for joint requirements. The second publication was Department of Defense Instruction Number 5030.29, dated 12 May 1964, subject: Investigational Use of Drugs by DOD. It stated that: "DOD assumes full responsibility for the protection of humans involved in research under its sponsorship, whether this involves investigational drugs or other hazards." To monitor this responsibility, DOD directed that each military department establish, within the office of its respective surgeon general, a formal board of professional personnel to consider each research proposal from within that military department or from its contractors, or grantees, which may involve the use of human subjects in clinical investigation of new drugs. (To implement this, the Army established the Army Investigational Drug Review Board.) Furthermore, the DOD instruction provided that before a clinical test with an investigational drug was performed under the sponsorship of a military department, the plan of the test and other pertinent details would be submitted to the appropriate review board. The board, in turn, would indicate its approval and forward the plan with its approval to the service surgeon general for confirmation. DOD further directed that each service would prepare a plan to implement the requirements discussed above within 60 days. Attached to the DOD instruction was a memorandum of understanding between the Department of Health, Education and Welfare and DOD concerning: "Investigational Use of Drugs by the DOD."[63]

Although both of the DOD instructions were signed by the Director of Defense Research and Engineering, they did not make reference to each other or mention a possible relationship. Nevertheless, the Army apparently perceived the requirements as separate and distinct. As an example, it appeared that between 1964 and 1974 a basic drug such as LSD could be processed through two different channels, depending on its proposed use. If the investigator was within the Medical Research and Development family, the protocol would go before the Army Investigational Drug Review Board (AIDRB) and receive final approval from The Surgeon General, if warranted (AR 40-7). On the other hand, the protocol from investigators employed at the Biomedical Laboratory at Edgewood Arsenal would be routed through the Army Materiel Command channels to The Surgeon General for concurrence on the medical aspects of the protocol (AR 70-25) and final approval was to come from the Secretary of the Army after receiving The Surgeon General's comments. AR 70-25 did not, and still does not, require the drug (LSD in this case) to be reviewed by the Drug Review Board as part of The Surgeon General's procedure. To compound the problem, those drugs which were already being investigated on human subjects as investigational drugs were not required by regulation to be submitteddfor review

after the AIDRB was established. Thus, two different systems existed to seek approval for the same drug. Neither system, chemical or medical, apparently provided for retroactive application to ongoing agent or drug research previously approved.

Finally, in November 1964 the Department of the Army published AR 40-7 (13 November 1964), subject: Clinical Use of Investigational Drugs.[64] This regulation superseded AR 40-2, dated 14 November 1960, and directed that new drugs required for investigational use would not be used without prior approval of The Surgeon General. AR 40-7 also provided for extensive review of the proposed protocol by the AIDRB. This regulation subsequently was revised and republished on 21 July 1967, 30 September 1969, and 4 April 1975, without major modification or change.[65]

On 10 September 1975 LTG Richard R. Taylor, The Surgeon General of the Army, testified before Congress that: "in October 1974, The Surgeon General established the Human Use Review Office under the direction of the Assistant Surgeon General for Research and Development. The Human Use Review Office was charged with administering and coordinating activities of the Army Investigational Drug Review Board, the U.S. Army Medical Research and Development Command Contract Review Board and The Surgeon General's Human Use Committee and Clinical Investigation Committee, to insure uniform application of ethical standards for human research studies conducted within or sponsored by the Army Medical Department and other Army Agencies. The Human Use Review Committee is the central Army processing point for all extramural and intramural human subject research which require approval under provisions of Army Regulations." While discussing Defense Against Chemical Weapons, Lieutenant General Taylor reported: "Furthermore, the review mechanisms applied to Edgewood have been tightened over the last two years so that protocols are reviewed by the Army Investigational Drug Review Board and Human Subjects Research Review Board and relevant Department of Defense and Food and Drug Administration regulations are followed."[72]

Suspension of Human Volunteer Program

On 28 July 1975 Acting Secretary of the Army Norman R. Augustine suspended testing of chemical compounds on human volunteers at Edgewood Arsenal.

FOOTNOTES

CHAPTER IV

1. General Order No. 62, dated 28 June 1918, by The War Department.

2. Chemical Warfare Service, Edgewood Arsenal, General Order No. 15, dated 12 October 1922.

3. Chemical Research and Development Laboratory Special Publication 2-51, Evaluation of Medical Research Volunteer Program, published in 1962.

4. Chemical Corps Advisory Council, Medical and Related Problems Committee Meeting Minutes of 20-21 March 1953.

5. Office, Chief Chemical Warfare Service Officer, Order No. 48, dated 3 July 1943.

6. Text of Testimony of Lieutenant General Taylor, The Surgeon General, Department of the Army, to U.S. Senate, 94th Congress, 1st Session.

7. Section 104 of the Act of 10 July 1950 (74 Statute 322; 5 USC, 235a).

8. Armed Forces Medical Policy Council Papers, Fall 1952.

9. Secretary of Defense Memorandum for Secretary of the Army, Navy, and Air Force, subject: Use of Human Volunteers in Experimental Research, dated 26 February 1953. "Wilson Memorandum."

10. Secretary of the Army Memorandum for Chief of Staff, Army, subject: Use of Human Volunteers in Experimental Research, dated 20 May 1953.

11. Chief of Staff Memorandum through Assistant Chief of Staff, G-4, for Chief Chemical Officer and The Surgeon General, subject: Use of Volunteers in Research, dated 30 June 1953 (CS:385).

12. Commanding General, Chemical Research and Engineering Command, Letter, subject: Use of Volunteers in Research, dated 24 July 1953.

13. 1st Indorsement to 12, above, dated 7 August 1953.

14. Secretary of the Army Memorandum for Chief of Staff, Army, subject: Use of Volunteers in Research, dated 5 November 1953.

15. Chief Chemical Officer Letter, subject: Use of Volunteers in Research, to Commanding General, Chemical Corps Research and Engineering Command, dated 24 December 1953.

16. Secretary of the General Staff Memorandum, subject: Use of Volunteers in Research, dated 16 October 1953.

17. Summary of Major Events and Problems for FY 54.

18. Headquarters, 2d Army, Letter, subject: Recruitment of Human Volunteers, to Class I and II Installation Commanders, dated 11 April 1955.

19. Medical Research Laboratories Disposition Form prepared by the Clinical Research Division, dated 8 March 1956.

20. Medical Research Laboratories Letter, subject: Additional Use of Volunteers in Research, to Commanding General, Chemical Research and Engineering Command, dated 7 September 1955.

21. Chemical Corps Research and Development Command Letter to Chief Chemical Officer, Department of the Army, subject: Additional Use of Volunteers in CW Research, dated 22 March 1956.

22. Report of The Ad Hoc Study Group on Psychochemical Agents, published 19 November 1955.

23. Medical Research Laboratories Disposition Form, subject: PBC 206/1 (Reference Wolff Report), dated 16 January 1956.

24. Chemical Corps Research and Development Command Letter to Dr. Wolff, dated January 1957.

25. Deputy Chief Chemical Officer for Scientific Activities Memorandum, subject: LSD Patent Rights, to Commander, Chemical Research and Development Command, dated 3 February 1956.

26. Chief Chemical Officer Letter to The Surgeon General, subject: Additional Use of Volunteers in CW Research, dated April 1956.

27. The Surgeon General Letter to Chief Chemical Officer, subject as 26, above, dated 11 April 1956.

28. Director of Research and Development Memorandum for Chief of Staff of the Army, subject as 26, above, dated 17 May 1956.

29. Chemical Research and Development Command Letter to Chemical Warfare Laboratories, subject as 26, above, dated 24 May 1956, with Memorandum for Record by Dr. Sporn.

30. Informal conversations with Colonel Vogal (Retired), Dr. Sporn, Dr. K. C. Emerson, Colonel Steed (Retired).

31. The Adjutant General of the Army Letter, subject: Use of Volunteers in Research, to Commanding Generals of Zone of Interior (ZI) Armies, dated 18 April 1957.

32. Chief Chemical Officer Letter to All Chemical Officers, subject: Medical Research Volunteer Program, dated 11 July 1957.

33. Chemical Research and Development Command Letter, subject: Additional Use of Volunteers in Research, to Chief Chemical Officer, dated 20 May 1958.

34. The Surgeon General Letter, subject: Additional Use of Volunteers in Chemical Warfare Research, to Chief Chemical Officer, dated 12 June 1958.

35. Chief Chemical Officer Letter, subject: Use of Female Volunteers, to The Surgeon General, dated 14 November 1958 (forwarding request from Chemical R&D Command, dated 4 November 1958).

36. Chemical Warfare Laboratories Internal Letter, subject: Use of Volunteers for Agent EA 1779 Tests, dated 10 February 1959.

37. Medical Research Laboratories Letter, subject: Appointment of Additional Responsible Physician, to Chief Chemical Officer, dated 4 November 1958.

38. Chemical Corps R&D Command Letter to Commander, Chemical Warfare Laboratories, subject: Use of Volunteers, dated 8 December 1958.

39. Chemical Corps R&D Command Letter to Commander, Chemical Warfare Laboratories, subject: Use of Volunteers, dated 15 December 1958.

40. Chemical Warfare Laboratories Letter to Director of Medical Research, subject: Use of CW Agents on Volunteers, dated 23 December 1958.

41. Chemical Warfare Laboratories Letter to Army Chemical R&D Command, subject: Use of Volunteers in Testing EA 1779 (CS), dated 30 December 1958.

42. Chemical Warfare Laboratories Letter, 27 July 1959, regarding approved agents to be used on humans.

43. Summary Sheet, Chief Chemical Officer to Chemical Corps R&D Command, proposed volunteer studies of EA 1476 and related compounds, dated 30 July 1959.

44. Chemical Corps R&D Command Letter to Chief Chemical Officer, subject: Proposed Volunteer Studies of EA 1476, dated 17 July 1959.

45. Secretary of the Army Memorandum for Chief of Staff, subject: Use of Volunteers in Research, dated 8 October 1959.

46. Chemical Corps R&D Command Letter to Commander, Chemical Warfare Laboratories, dated 23 October 1959; Letter from Chemical Warfare Laboratories to Director, Medical Research Laboratory, dated 17 November 1959, subject: Use of Volunteers in Research.

47. Chemical Corps R&D Laboratories Letter to Commanding General, Chemical Command, subject: Experimental Exposures of Men to Propellant Vapors, dated 2 August 1961.

48. Army Regulation 70-25, dated 26 March 1962, R&D Use of Volunteers as Subjects of Research.

49. Chief of Research and Development Memorandum to Chief Chemical Officer, subject: Appointment of Physician in Charge of Volunteers, dated 20 April 1956.

50. The Judge Advocate General Memorandum regarding physical presence of physician in charge, dated 17 November 1958.

51. Chief Chemical Officer request of 17 April 1959, Medical Officer Responsible for Volunteers. 18 June 1959 approval by Under Secretary, Army.

52. Chemical R&D Letter to Commanding General, Chemical R&D Command, subject: Medical Officer Responsible for Volunteers, dated 17 July 1962.

53. Chemical R&D Letter to Commanding General, R&D Command, subject as 52, above, dated 20 March 1963.

54. Army Materiel Command Letter of Appointment, Medical Officer Responsible for Volunteers, dated 26 September 1963.

55. Army Regulation 70-25, Research and Development Use of Volunteers as Subjects of Research, dated 31 July 1974.

56. Joint Medical-Chemical agreement to conduct Research and Development, signed by Major Generals Hays and Creasy in August 1958.

57. Joint Medical-Chemical agreement to conduct Research and Development, signed by Major Generals Hays and Stubbs in March 1959.

58. Joint Army Medical Service-Army Materiel Command agreement on Responsibilities for the Conduct of R&D Defense Against CG Agents, signed by General Besson and Lieutenant General Heaton on 23 January 1963.

59. Memorandum of Agreement, Army Materiel Command-The Surgeon General, of August 1972.

60. Summary Sheet, subject: Project Manager for Agent EA 2277, dated 18 April 1962.

61. Secretary of the Army Memorandum to Secretary of Defense, subject: Use of Chemical Agent BZ, dated 20 June 1962.

62. Department of Defense Instruction Number 5160.5, subject: Responsibilities for Research and Development, Test and Evaluation on Chemical and Biological Weapons and Defense, dated 7 February 1964.

63. Department of Defense Instruction Number 5030.29, subject: Investigational Use of Drugs by DOD, dated 12 May 1964.

64. Army Regulation 40-7, Clinical Use of Investigational Drugs, dated 13 November 1964.

65. Army Regulation 40-7, Clinical Use of Investigational Drugs, dated 21 July 1967; superseded on 30 September 1969 and 4 April 1975.

66. Edgewood Arsenal Letter to The Surgeon General, subject: Physiological Stress Aspects of Chemical Agents, dated 19 June 1969.

67. 26 August 1969 The Surgeon General Indorsement to Chief, Research and Development, Department of the Army.

68. 3 September 1969 Chief, Research and Development, Indorsement to The Surgeon General.

69. 12 September 1969 The Surgeon General Indorsement to Edgewood Arsenal.

70. Biomedical Laboratory Letter to The Surgeon General, subject: Plan for Glycolate Agents, dated 6 March 1972.

71. News Release from Office, Chief of Information, Department of the Army, dated 28 July 1975.

72. Prepared statement by Lieutenant General Taylor, The Surgeon General, Department of the Army, before the Subcommittee on Administrative Practice and Procedure of the Judiciary Committee, 10 September 1975.

73. Secretary of the Army Memorandum for Commander, U.S. Army Materiel Command, subject: Medical Officer Responsible for Volunteers, dated 9 September 1974.

CHAPTER V

HUMAN VOLUNTEER SELECTION AND SCREENING

General

The purpose of this chapter is to address the implementation of the Human Volunteer Program, to include recruiting and the thoroughness of the medical screening of volunteers.

As mentioned previously, volunteers have served the medical element of the U.S. Army Chemical Research and Development Laboratories since the establishment of the Medical Division in 1922.[1] Records indicated that prior to World War II the volunteers were employees of Edgewood Arsenal who usually were part of the various research test projects. During World War II there was large-scale use of volunteers at various test sites throughout the United States. Following World War II human volunteer resources were apparently met as they were prior to the war, i.e., by local assigned personnel. This was the case until May 1955 when the first contingent of the formal volunteer program arrived at Edgewood.[2] Very little is known about the recruiting methods, medical screening procedures, and utilization of the volunteers prior to 1955; nor was it determined if this void was the result of routine destruction of records or if there were simply fewer and less complete records maintained. It is probable that the Nuremberg Trials had a significant impact on the thoroughness with which research records were maintained. As discussed in Chapter IV, the Armed Forces Medical Policy Council established the rules of the Nuremberg Code as an essential part of future medical research involving the use of human subjects when in 1952 they recommended that the Secretary of Defense permit the use of humans in medical research.

Secretary of Defense Wilson's memorandum to the service secretaries in February 1953 established the procedures to obtain authority to conduct research with chemical agents involving human volunteers. However, program initiative still rested with the laboratory. It was the responsibility of the research investigator to justify the need to use humans in experimentations. There was evidence that this responsibility was not new to the Chemical Corps medical investigators, nor was it taken lightly. In fact, months before the Secretary of the Army had approved implementing instructions, the Chemical Corps Advisory Council was considering the impact of the new requirements the Nuremberg Code placed on them. On 20 and 21 March 1953 the Chemical Corps Advisory Council met at Edgewood Arsenal to consider these medical and related problems.[3] The Council members noted that human experimentation within

the practice of medicine had been conducted for a long period of time, although usually on severely ill patients who went to a doctor for help. The Council stressed that the problems confronting the Chemical Corps were entirely different in that experiments would be performed on normal, healthy individuals and subjecting them to a certain degree of danger. Thus, they allowed that careful consideration had to be given and safeguards established in terms of the moral, ethical, and technical aspects of the problem of using humans. They reported that basic decisions would have to be made regarding the type of experimental work which was feasible and correct; the rules of conduct which would be followed to create the maximum safeguards; and the procedures which would be established to determine whether the information to be obtained would justify the risk involved. Following these considerations they reported that the practical problem of how to obtain a steady flow of human volunteers would have to be addressed.

The Council (which consisted of both military and nonmilitary members) discussed numerous problem areas, many of which are prevalent today. The Chairman of the Council (a civilian medical doctor) opined that "certain problems must be considered more adequately if normal subjects are to be used in experiments, the purpose of which is not to benefit the subject or people with disease, but to aid in military matters. The experimenter in each instance must be a physician, and, in view of the moral and ethical practices embodied in the Hippocratic Oath, it will be extremely difficult for the physician to judge, in an unbiased manner, the type of experiment to be performed and what the possible hazards are to the patient. From that point of view, consideration must be given to methods of choosing experimental subjects, what regulations govern the divulging of information to volunteer subjects as to the hazard involved, and whether or not that should, in any way, be the responsibility of the physician directly involved in the experiment." They also discussed the need to define "nonhazardous" experiments and those which may be hazardous to a degree and which would be considered line-of-duty (such as troop gas chamber exercises). The Council also recognized the need for a clear and overall set of fundamental principles, so that a proposed plan for experimentation could be evaluated in terms of those criteria, thereby avoiding individual decisions which would eventually result in a wide range of standards. Although there was no direct evidence to indicate the impact that this Council had on formulating future policy, it is apparent from the subject matter discussed that they had considerable expertise in the field of chemical and medical research, especially as it would involve human volunteers. The implementing authority, Chief of Staff Memorandum 385, for use of volunteers in research was published by the Army Chief of Staff on 30 June 1953.[4] This document set forth eleven basic principles for the use of human volunteers in research:

a. The voluntary consent of the human subject is absolutely essential and must be obtained in writing with a proper witness.

b. The experiment must be such as to yield results essential to the Army or for the good of society, unprocurable by other methods.

c. The experiment must be based on animal experimentation and knowledge of the problem so that the anticipated results will justify performance of the experiment.

d. The number of medical volunteers used shall be the minimum required to obtain the essential data.

e. The experiment will be conducted so as to avoid all unnecessary physical and mental suffering and injury.

f. No experiment will be conducted if there is any reason to believe that death or disabling injury may occur.

g. Proper precautions will be made and adequate facilities provided to protect the medical volunteer against all foreseeable possibilities of injury, disability, or death.

h. The experiment will be conducted only by scientifically qualified persons and the medical care of the volunteers supervised by a qualified physician.

i. The physician in charge must be prepared to terminate the experiment at any stage if he has any cause to believe continuation may result in injury, disability, or death.

k. The medical volunteer must be informed that at any time during the course of the experiment he has the right to revoke his consent and withdraw from the experiment, without prejudice.

l. Use of prisoners of war in human experimentation is prohibited under any circumstances.

The greatest emphasis in terms of detailed guidance was placed on the first of these principles, i.e., volunteer consent, which will be discussed in depth in Chapter VI.

A request to conduct experiments with nerve gases on volunteers was submitted in August 1953. Permission was granted in November 1953, however, it did not provide for a source of volunteer subjects. On 12 March 1954 The Surgeon General prepared a set of principles, policies, and rules for

for the use of human volunteers in medical research. With four exceptions, these principles generally were the same as those published in Chief of Staff Memorandum 385. The first rule was in the form of expanded guidance regarding volunteer consent. Next, rules 7 and 8 of the Chief of Staff Memorandum 385 guidance were expanded as follows: "Adequate preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death. This includes hospitalization and medical treatment as may be required. The experiment should be conducted only by scientifically qualified persons (including an adequately trained physician) who shall be required to exercise the highest degree of skill and care throughout the experiment. Competent consultants should be available on short notice in this connection." Finally, there was included an additional rule: "Agents used in research must have the following limiting characteristics: controllable lethality; no serious chronocity anticipated; effective therapy available; and adequate background or animal experimentations." These were not intended to replace the rules set forth in the basic policy (Chief of Staff Memorandum 385), but rather to clarify their intent.[5]

Prior to this, in April 1953, the Chemical Corps Advisory Council recommended a system be developed to provide a pool of volunteers for chemical warfare research at the Army Chemical Center (Edgewood Arsenal).[6] This problem was again discussed by the Medical Committee of the Chemical Corps Advisory Council on 30 September 1954. The report of that meeting indicated a request for a continuing supply of volunteer subjects had been submitted to the Office of the Secretary of the Army and the official in charge of manpower in the Office of the Secretary of the Army had expressed approval of the request. Thus, favorable action was reportedly anticipated in time to have volunteers available by January 1955. It was further recorded that if such military volunteers were not supplied, the Medical Laboratories would have to continue obtaining a sporadic source of volunteers, both military and civilian, from the personnel of the Army Chemical Center. This comment was attributed to the Chief of the Clinical Research Division, Medical Laboratories, and is interpreted to mean that between the time formal approval for the use of volunteers was granted in November 1953 and the time of the Committee meeting (September 1954), volunteers were recruited from personnel assigned to Edgewood Arsenal. There were no volunteer medical records found which would corroborate this assumption. However, witnesses contacted during the inquiry stated such records normally were not kept for volunteers from the laboratory.

The Committee report also contained a statement that: "The Laboratories drew up a formal program and submitted it to the Secretary of the Army for approval (referring to the 7 August 1953 request for approval to test nerve agents in humans); approval for the plan had been received (referring to the 5 November 1953 approval by Secretary Stevens)." This program

reportedly visualized four types of studies for human volunteers. "The first category consists of planned, hazardous experiments where there is a clear-cut risk, but with intelligent, adequate supervision, safeguards, and adequate therapy available, it is felt that no irrevocable damage will be done. Experiments will not be attempted where such damage can be foreseen. These form the type of experiments for which the Army Secretary's approval has been received and the only kind where such approval is required. Another category includes risk of accidental exposure to hazardous degree. The fullest possible studies should be made of any such unplanned exposures. The third category consists of experiments that are only potentially but not definitely hazardous. The experiments would be hazardous if the individual, despite previous examination and check-up, should prove unusually sensitive, or if there occurs an accidental error or break in technique. The fourth category of procedures will be those designated non-hazardous, experiments involving no hazard greater than that of crossing a highway."[7]

Preparation for Volunteer Recruitment

On 13 October 1954 the Commander of the Chemical Corps Medical Research Laboratories submitted a request to the Commanding General, Chemical Corps Research and Engineering Command to establish a procedure for the recruitment of military volunteers for use in medical research associated with chemical warfare.[8] This request recommended establishment of an Army-wide volunteer recruitment program that would provide the Medical Research Laboratory a continuous flow of 20 volunteers per month. The request was forwarded to the Chief Chemical Officer, Department of the Army, on 13 October 1954. Based on a recommendation from the Office of The Surgeon General, the Medical Research Laboratory's proposal was disapproved in favor of a less expensive plan.[9] The alternate plan suggested that specific installations, such as Fort Meade, be contacted and the groundwork laid, through The Surgeon General's representative at each station, to obtain approval of the local commander to recruit volunteers from his installation. On 25 January 1955 the Army Chemical Center (Edgewood Arsenal) published the first known Standard Operating Procedure (SOP) dealing with military volunteers for chemical warfare.[10] The stated purpose of this memorandum was to outline the procedures for processing of military volunteers for medical research conducted at the Army Chemical Center by the Chemical Corps Medical Laboratories. The directive provided for the recruitment of volunteers from Second Army Headquarters at Fort Meade, MD, for temporary duty (TDY) at Edgewood Arsenal. The volunteers were to be provided administrative support, rations, quarters, and supplies upon arrival. Following these arrangements, volunteers were scheduled for physical examination and orientation relative to the test program. The directive also allowed the Medical Laboratory

staff to retain the volunteer for observation and treatment beyond the normal attachment, if necessary. No mention was made of the details of the physical/mental examinations to be given prior to the volunteer's acceptance into the program or of a follow-up examination at the completion of his temporary duty.

Records found at Edgewood Arsenal indicated that during the period 9-23 January 1955 the Chemical Corps Medical Research Laboratories and the Aero Medical Laboratory, Wright-Patterson Air Force Base, conducted a joint research project at Wright-Patterson Air Force Base to investigate "Carbon Monoxide Gassing of Human Volunteers."[11] No authority for the conduct of this experiment was found during the inquiry. If approval was not sought because the test was considered "only potentially, but not definitely hazardous," and thus according to the earlier interpretation not requiring Secretary of the Army approval, it would have indicated, as a minimum, a propensity towards a liberal interpretation of policy. Also, it is possible that approval was obtained through U.S. Air Force channels, although no records of this were retained or found in the laboratory files. However, records were found which indicated that the Army Medical Laboratories supplied 10 volunteer subjects for the project; individual medical records for these volunteers were not located.

In late February 1955 the Medical Research Laboratories began their preparation for recruiting volunteers from Fort Meade by furnishing an information letter to the installation indicating the type of test planned for use of volunteers.[12] The volunteers were advised that three types of investigations would be conducted:

a. The minimum systemic and local effects of certain toxic agents, which would involve inhalation of small amounts of nerve gas. The document allowed that volunteers would be thoroughly informed about all procedures and what was to be expected during each test; every precaution would be taken to protect the volunteer against danger or serious discomfort; and physicians and other scientists who had previously been volunteer subjects would be in attendance at all times.

b. The evaluation of chemical warfare equipment, such as the testing of chemical items designed to protect the individual soldier. Testing of this equipment required wearing trials before the items were standardized.

c. Investigations involving the problems of adapting defensive items to natural human capacities, such as a manual dexterity test using protective gloves. Moreover, each volunteer was to be free to determine whether or not he desired to participate after he received a full explanation of the test procedure and he was to be free to terminate his 30-day temporary duty tour at any time.

Included with the information letter referenced above was a document titled: "Medical Research Volunteer Program," which was intended to be mandatory reading for all volunteers, and an acknowledgement that it had been read and understood was included in the "Human Volunteer Agreement" form. At the same time, the Medical Laboratory established an "Indoctrination and Screening Team" of two Chemical Corps officers and one medical officer to be responsible for selecting the qualified individuals from among the volunteers. The appointment of this team and other arrangements were made as a result of a commitment by 2nd Army Headquarters to provide 20 volunteers per 30-day period to the extent possible.[13] The letter also announced that the orientation and identification of individuals under consideration for selection would be accomplished only by personnel assigned to the Chemical Corps Research and Engineering Command. Further, 2nd Army would transmit and provide for exploitation of the preliminary recruiting material provided by the Chemical Corps. Additionally, 2nd Army would assemble prospective volunteers, as requested, for detailed orientation and final screening. However, 2nd Army would not engage directly in any aspect of the orientation and screening process. Available records indicated that during March and April 1955 Chemical Corps Medical Research Laboratories personnel developed a program in conjunction with Headquarters, 2nd Army, representatives and the chiefs of the various technical services (Quartermaster General, Chief of Engineers, etc.) to recruit, screen, and select volunteers from the 2nd Army area. On 21 April 1955 Headquarters, 2nd U.S. Army, published a directive to the installation commanders in its Army area establishing procedures for selecting volunteers.[14] The directive provided that when finally selected, the volunteer would be placed on TDY to Edgewood Arsenal for 30 days. The requirement for volunteers was established as 20 per month. The directive provided that when sufficient nominations were received, an orientation team from the Chemical Corps Research and Development Command would conduct a briefing for the volunteers. Those who still remained after the briefing would be requested to sign a volunteer participation agreement.

No direct evidence of the type medical and psychological examination given to these early participants was available, however, some newspaper articles published during the recruiting effort were located; they indicated that preliminary examinations were planned for volunteers. In March 1955 the Baltimore Evening Sun and the News-Post published articles about the upcoming experiments.[15] In these articles it was reported that the volunteers would be carefully screened for physical and psychological suitability prior to testing. In April 1955 a similar article appeared in the Army Times[16] which reported that "All volunteers would be screened carefully by three different groups to determine their physical and psychological suitability." The three groups, although not further identified, probably were: (1) the military unit, where potential volunteers were screened to insure they met the initial selection prerequisites: Intelligence (Aptitude Area I Score of 80 or above), completion of basic military training,

physical profile (a general health rating established from medical examination and recorded in the individual medical records), age group of 17 to 35, remaining service of at least six months, and have an organization and Army official record which contained no adverse information; (2) the orientation team mentioned earlier that met with the volunteers after initial screening and prior selection for travel to the Medical Research Laboratories; and (3) the doctors who examined the volunteers at the Laboratories prior to participation in experiments.

First Formal Volunteers from Second Army

The first contingent of 16 soldiers from Second Army Headquarters was reported to have arrived at the Army Chemical Center under this program on 2 May 1955.[1] A computer printout, based on data available from individual volunteer medical records, indicated that the first experimental use of these volunteers occurred on 20 May 1955.[17] A sampling of the available volunteers' records revealed that the medical examination of these early volunteers included: a standard report of medical examination; report of medical history; chest X-ray; urinalysis test; and an EKG recording. Many of the records, however, were incomplete in that they did not reflect the type of chemical agent administered to the volunteer, the method of administration of the drug, or the dosage given. It also was apparent that the original plan for medical evaluation of the volunteers did not include a final or exit type physical examination for the volunteers. However, arrangements to correct this oversight were made prior to the departure of the group that arrived in May 1955.[18] The exit examination provided during the 1955 time period appeared to consist of a chest X-ray and an exit interview. There was an indication that the purpose of the interview may have been for an evaluation of the volunteer's attitude in order to reinforce future recruiting efforts, rather than evaluation of his total medical well-being.

Volunteers from this source continued to arrive at Edgewood, during the remainder of 1955, from Fort Knox, KY, Fort Meade, MD, and Fort Monmouth, NJ.[19] Approximately 140 volunteers were received during 1955. The available records of these volunteers, which were, in most cases, incomplete, indicated that they received a medical examination, signed a volunteer statement (although not available in all cases), and were used in experimentations involving nerve and mustard gases and perhaps other agents. However, by June 1956 the number of volunteer subjects from Second Army and the various technical service installations dwindled to five or six per month. The Medical Research Laboratory stated that despite their vigorous efforts in recruitment of volunteers, troop commanders did not place sufficient priority on the program. They argued that Department of the Army should compel troop commanders to release volunteers despite shortages in other critical areas.[19] With the inclusion of psychochemical compound experimentation in 1956, the medical screening was expanded to

include a social history interview and the Minnesota Multiphasic Personality Inventory (MMPI) to exclude those volunteers who might react adversely under situations of psychological stress. Although available records were not sufficiently complete to determine exactly when these tests were included, it appears they were being employed in early 1957 and perhaps late 1956, when the first volunteer records clearly indicated the use of LSD on volunteers.

Continental Army-Wide Recruitment

In April 1957 the recruiting base was expanded to include all Army installations within the United States.[20] The Department of the Army directed Army commanders to assist in the recruitment of volunteers and to release a minimum of 30 per month on a rotating basis the six Army commanders were each given two months per year in which they would furnish volunteers). The term "Recruitment" was defined in other publications[1] as: "restricted to publicizing the program, accepting applications, and selecting a quota from among those who applied." No coercion or enticement of volunteers was permitted. The April 1957 directive held that: "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion." It further provided that: "In all experiments involving volunteer test subjects, the individuals are thoroughly informed about all procedures, and what can be expected during each test." The Army commanders were asked to emphasize the program within their commands and to stress such matters as: the need for volunteers; thorough physical examinations; awareness of the application process; necessity of a volunteer agreement statement; quality of accommodations at the Edgewood Arsenal test site; a liberal pass policy for volunteers; availability of letters of commendation for volunteer service; and the availability of temporary duty (TDY) pay ($1.50 per day) to volunteers.[20]

The renewed emphasis placed on the recruiting of volunteers from all Army areas within the United States was apparently productive as the total volunteers received in 1957 was reported as 298 as compared to 100 for 1956.[21] Total volunteers for 1958 was reported as 383.[1] During this period (1955-1958) only two volunteers were reported as "physically unqualified."[1,21] It must be noted that official and unofficial documents discovered during the inquiry differ (in some instances considerably) in reporting the number of volunteers, and all figures are reported as the best evidence available rather than as absolute figures.

In late 1957 the Air Force agreed to furnish volunteers to the Chemical Corps. Records indicated that this practice continued until July 1961 and included approximately 350 airmen.[1]

During 1958, in addition to the normal clinical experiments conducted at Edgewood Arsenal, "field tests" were conducted with volunteers from Fort Bragg and Fort Holabird.[22] These tests will be discussed in separate chapters of this report.

Recapitulation of Volunteer Utilization - 1962

By the end of June 1962 reports indicated 2,588 volunteers had been used at Edgewood since 1955; approximately 350 of these were Air Force personnel.[1] During the same period, 49 volunteers were reported as physically unqualified; 61 had requested release from the program; 35 were reportedly returned to their units for disciplinary reasons; and 6 had refused to participate in the program after arrival at Edgewood.[1] Figures available for the "use of volunteers" showed that 11% were used in lethal agent tests; 27% in incapacitating agent tests; 13% in miscellaneous physiological tests; and 49% in material tests.

Medical Evaluation of Volunteer Subjects

Reports reflected that by 1962 volunteers spent their first three days at Edgewood receiving what was termed the most thorough physical examination they ever had. The examination, which was conducted by a physician, included chest X-ray, electrocardiogram, tests of liver and kidney function, as well as hematological tests (blood studies). The MMPI (Minnesota Multiphasic Personality Inventory) was reportedly given to all volunteers and scored by a psychologist or psychiatrist to determine behavior patterns of the volunteers. Successful completion of these tests qualified the subject for use in experiments with anticholinesterase compounds (nerve agents), riot control agents, some therapeutic drugs, and tests of protective material (which often did not involve drugs). If the volunteer passed these tests, he was given an electroencephalograph test, a personal interview with a psychiatrist, and a blood chemistry analysis. To be eligible for psychotropic drug experiments the volunteer had to successfully complete all screening tests.[1]

Post-1962 Recruiting Procedures

In March 1962 the basic guidance for "Use of Volunteers as Subjects of Research" was published in AR 70-25. In July 1962 The Adjutant General, Headquarters, Department of the Army, published a letter to the Commanding General, U.S. Continental Army Command (CONARC), subject: Use of Volunteers in Research, authorizing procurement of volunteers by recruiting from the Zone of Interior (ZI) Army areas for temporary duty periods of 60 days.[24] The screening process was changed somewhat at this time. Army area commanders would select the major installation in their area where volunteers would be recruited. The post commander would survey his troops

for potential volunteers, following which a Chemical Corps recruiting team would arrive at the post and present a briefing to an assembly of as many as 500 enlisted personnel. A follow-up Chemical Corps team would arrive later to review the medical histories of the potential volunteers and select 60 from those considered most eligible. The 60 men were placed on TDY orders to Edgewood Arsenal, where each volunteer again was given a standard physical examination without regard to the date of his last examination. Obvious medical rejects were dropped from the agent program immediately after a disqualifying finding was determined. In addition to the general physical examination, volunteers received a complete hemogram, urinalysis, serology, chest X-ray, EKG, EEG, liver and renal function batteries, psychological tests, and a psychiatric interview. The final selection of volunteers for the agent program was made by a board of medical officers who were permitted to reject volunteers who otherwise met all qualifications if, in their judgment, the subject should not be used. One report held that as of 15 December 1963, 2,863 volunteers had been available and were used in 2,279 exposures of 90 chemical agents.[24] These figures, although from official reports, cannot be considered absolute since they are in conflict with other official publications, and in some cases vary as much as 27% (Footnote 24 indicated that there were 218 volunteers available in 1957, while the publication in Footnote 1 showed 298 volunteers for the same period).

Records indicated that this volunteer selection system was still in use in July 1966 when the Commander of Edgewood Arsenal reported that, as of 1 July 1966, a total of 4,360 volunteer test subjects had been utilized in the medical research program at Edgewood Arsenal with no deaths, no injuries, and no observable residual effects.[25] On 17 January 1967 The Adjutant General, Department of the Army, again directed the Commanding General of the Continental Army Command to provide volunteers to Edgewood Research Laboratories.[26] This letter provided for the volunteers (average of 40 per month for 60 days TDY) to be medically screened by their station surgeon if a team from Edgewood could not be made available for that purpose. Otherwise, the directive was similar to those published previously.

Evaluation of Volunteers for Use in Psychochemicals

Available historical records located during the research effort indicated that a comprehensive set of Standard Operating Procedures (SOPs) was available within the Clinical Research Department of the Medical Research Laboratories. One of these SOPs, published in 1968, dealt with "volunteer screening and selection" and provided detailed guidance for the psychological/psychiatric selection of volunteers.[27] It provided guidance for screening the medical history of the volunteer, evaluation of his general aptitude (GT Score), the MMPI test, family history, and other data. The final result of the screening process was to place each volunteer in a

category c efuln s. A rating of "A" meant the lunteer cleared for psychochemical testing; "B" meant he could receive a low-dose of psychochemicals only; "C" meant no psychochemicals could be used on the volunteer; and "D" meant the volunteer could be used for equipment tests only.

Re-Evaluation of Volunteer Requirement - 1973

In general, the process of Army area commanders providing up to 500 personnel for orientations/briefings conducted by a team from Edgewood Arsenal continued through 1973, when Army organizational changes caused a re-evaluation of the method of recruitment. However, the screening and selection process for determining which volunteers qualified for use in which experiments remained about the same.

A review of the volunteer medical record files revealed that no records were retained for the period prior to May 1955, if, in fact, records were prepared at all then; and that from 1955 through 1958 most of the records were inadequate and incomplete. Gradual improvement was noted in both record completeness and the medical screening process starting in 1959. There were some notable exceptions to this general improvement trend; one such exception was evident in the comparison of official reports for the year 1960, which indicated that in excess of 500 volunteers were used at the Medical Research Laboratories. However, only approximately 40 volunteer records actually indicated that a chemical agent was administered. Other exceptions to good record keeping and medical screening processing were apparent in the lack of records concerning the military intelligence drug testing program conducted at Edgewood during 1958-1960, and to a lesser extent, the "field tests" conducted at Forts Bragg, Benning, and McClellan. These will be discussed individually in later chapters.

The reorganization of the Army, to include formation of the Training and Doctrine Command (TRADOC) and the Military Personnel Center Command (MILPERCEN) in 1973, required the Medical Research Laboratories to renew their efforts to obtain volunteers.[28] At the request of the Office of the Chief of Research and Development, Department of the Army,[30] the Biomedical Laboratory (formerly Medical Research Laboratories) submitted a justification to continue the selection process in a manner similar to methods used prior to the reorganization, i.e., have the area or post commanders assemble troops for orientation and briefing (installations to be selected by the newly formed TRADOC); and continue to have the initial screening process to preselect approximately 80 (formerly 60) volunteers for temporary duty at Edgewood Arsenal, where the second screening process would continue to take place. Additionally, the period of TDY was requested to be raised from 60 to 90 days to allow for better utilization of the volunteers.[29]

As of 30 June 1973 records reflected that 6,408 different volunteers had been used in medical research by the Biomedical Laboratory for a total of 6,709 volunteer tours (this includes repeat tours).[31]

It appeared that the change in Army organization did have an effect on the Biomedical Laboratory's recruiting efforts, although not immediately. By January 1974 there were no volunteers available and it appeared it would take six months to reinitiate the Laboratory's systematic selection process.[32] Volunteer records indicated that the program was again in operation by May 1974;[32] it continued until 28 July 1975 when the Acting Secretary of the Army directed a temporary suspension of all testing of chemical compounds at Edgewood Arsenal using human volunteers.[33]

FOOTNOTES

CHAPTER V

1. CRDL Special Publication 2-51. Evolution of the U.S. Army Chemical Research and Development Laboratories Medical Research Volunteer Program, published in November 1962.

2. Briefing text, Human Investigation Facility, Directorate of Medical Research, U.S. Army Chemical Research and Development Laboratories, Edgewood Arsenal, MD, 1963.

3. AC-723 Chemical Corps Advisory Council, Medical and Related Problems Committee Meeting, 20-21 March 1953.

4. Chief of Staff Memorandum for Chief Chemical Officer and The Surgeon General (CS:385), subject: Use of Volunteers in Research, dated 30 June 1953.

5. Principles, Policies and Rules of the Office of The Surgeon General, dated 12 March 1954.

6. AC 727 Chemical Corps Advisory Council Meeting, 23-25 April 1953.

7. AC(55)S-303 Medical Committee, Chemical Corps Advisory Council, 30 September and 1 October 1954, published in September 1955.

8. Letter, subject: Recruitment of Volunteers for Research Experimentation, from the Chemical Research and Engineering Command to the Chief Chemical Officer, Department of the Army, dated 13 October 1954.

9. Same as Footnote 19.

10. Memorandum Number 11, Military Volunteers, dated 25 January 1955.

11. Letter, subject: Appreciation for Cooperation in CO Studies, from Chemical Corps Medical Laboratories to Commanding General, WADC, Wright-Patterson Air Force Base, dated 1 February 1955.

12. Letter, subject: Recruitment of Military Volunteers, dated 24 February 1955.

13. Letter, subject: Recruitment of Military Volunteers, from Second Army to Commanding General, Chemical Corps Research and Engineering Command, Army Chemical Center, MD, dated 4 February 1955.

14. Letter, subject: Enlisted Volunteers for Chemical Corps Medical Laboratories, from HQ, Second Army, to Commander, Class I and II Installations, dated 21 April 1955.

15. News Article, The Evening Sun, Baltimore, March 28, 1955, "Chemical Device Tests Stated."

16. News Article, Army Times, April 2, 1955, "Army to Test New Poisons, Equipment on 20 Volunteers."

17. Computer printout of 9 January 1976 from Biomedical Laboratory, Edgewood Arsenal, of years, agent, dose, and date of administration.

18. Disposition Form, dated 19 May 1955, subject: Human Volunteers, from Chief, P&E Office, Medical Research Laboratories, to Asst/TCW Medical Research Laboratories.

19. Memorandum for Commanding General, CMC C RDCOM, subject: Recruitment of Volunteers for CW Research, dated 6 September 1956.

20. Letter Directive, subject: Use of Volunteers in Research, from Department of the Army, Adjutant General, to Commanding Generals, ZI Armies, dated 18 April 1957.

21. CWL Special Publication 2-13, U.S. Army Chemical Warfare Laboratories Report on The Medical Research Volunteer Program, printed June 1958.

22. Meeting of the Medical Committee, U.S. Army Chemical Corps Advisory Council, 3-4 November 1958.

23. Briefing notes of 1962, titled, "Volunteer Program at CRDL." Briefing by Major General Stubbs to Deputy Secretary of Defense.

24. Briefing text 1963, Human Investigation Facility, Directorate of Medical Research, U.S. Army Chemical Research and Development Laboratories, Edgewood Arsenal, MD. Title, "Volunteer Program."

25. Letter regarding "Use of Volunteers as Subjects of Research," dated 29 July 1966, from Commander, Edgewood Arsenal, to Commanding General, U.S. Army Medical Research and Development Command.

26. Letter, subject: Use of Volunteers as Subjects of Research, dated 17 January 1967, from The Adjutant General, Department of the Army, to Commanding General, U.S. Continental Army Command.

27. Clinical Research Department SOP No. 5, dated 12 August 1968, "Volunteer Screening and Selection."

28. Chief of Staff Regulation No. 601-1 (CSR601-1), Department of the Army, Office of the Chief of Staff, dated 27 March 1973.

29. Letter, subject: Requirement for Volunteer Program, Biomedical Laboratory, Edgewood Arsenal, dated 20 September 1973.

30. Letter, subject: TDY Personnel of Use as Volunteers to Research, dated 9 October 1973, from Chief of Research and Development, Department of the Army, to Commander, U.S. Army Materiel Command and The Surgeon General.

31. Booklet titled, "Recruitement and Selection of Medical Research Volunteers," prepared in 1973.

32. Letter, subject: Recruitment of Medical Research Volunteers, from Biomedical laboratory Director, to AMC, dated 8 January 1974.

33. News release, from Office of Chief of Information, Department of Army, dated 28 July 1975.