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INFORMATION PAPER

SUBJECT: U.S. Army Drug Testing Programs Involving Human Subjects During the 1950's, 1960's, and 1970's

1. ISSUE: Congressman John Conyers, Jr, Chairman, Legislation and National Security Subcommittee has requested of the Department of Defense information for testimony on 28 Sep 94. The Office of The Surgeon General of the Army has been requested to provide information on the subject line noted above.

2. FACTS:

a. BACKGROUND: Biomedical research programs are the oldest research programs in the Armed Forces with their beginnings in the early 1800's. From the 1800's leading up to the 1950's the military was involved in many programs testing drugs and vaccines in human subjects, a short list follows: Small pox vaccinations, gastrointestinal studies, yellow fever studies, the development of an effective antityphoid vaccine, the development of chlorine to purify drinking water, the use of emetine to treat dysentery, the development of a rabies vaccine, the use of Atabrine (quinacrine or mepacrine) was tested as a substitute for quinine in combating malaria, large scale production of Western and Eastern equine encephalitis began and the first cure of typhoid fever with chloramphenicol was reported.

In the 1950's and 1960's the military in particular studied and participated in the development of a safe Venezuelan Equine Encephalitis vaccine and an oral adenovirus vaccine. Sulfamylon, an antibacterial cream was developed for the treatment of pseudomonas infections in burn patients. The extensive involvement in Viet Nam required many studies with antibacterial and antimalarial drugs involving service members in or returning from endemic areas. In the late 60's and earlier 70's studies where conducted using gamma globulin for prevention of hepatitis. In 1976, the use of acetazolamide for Acute Mountain Sickness was validated. During the 1970's in particular, multiple other clinical investigations with the rise of antibiotics (carbenicillin, tetracyclines, etc) and other drugs (antacids and cimetidine for Curling's ulcer) would also take place parallel to that in the civilian community.

Certain studies during the cold war era have captured much attention. Studies with malaria drugs and prisoners took place from 1945 through 1975, Project White Coat began testing products for biological defense from 1954 through 1973, the first U.S. Army Chemical Corps studies with d-lysergic acid diethylamide (LSD) and other hallucinogenic drugs, BZ and scopolamine, and commercially available approved drugs began in the early 1950's and continued through 1967 for LSD, 1957 through 1969 for BZ, and 1960 through 1975 for scopolamine. The following paragraphs will

describe these three major cold war drug testing programs.

b. MALARIA RESEARCH: The U.S. Government sponsored malaria research involving prisoners from 1945 through 1975. The urgent need was created by the Japanese attack on Pearl Harbor. Practically all the world supply of quinine was denied the allies by that event and its consequences. The actual magnitude of the malaria problem in World War II greatly exceeded even the most pessimistic prediction of the time.

In response to this need, the Committee on Medical Research of the Office of Scientific Research and Development, National Research Council, organized and sponsored the initial malaria drug development program. The U.S. Army was one of several cooperating federal agencies. The great success of this effort was realized in the discovery of chloroquine, a drug with rapid and unsurpassed antimalarial activity until the development of resistance in the mid 1960's.

During the world war II and the later 1940's several sites were involved in the testing new compounds. The U.S. Army was primarily involved with Stateville Penitentiary, Illinois. From the onset, the use of prison volunteers was open to public scrutiny as evidenced by an editorial in the New England Journal of medicine in March 1945 and other public observation of the program. The volunteers were white male inmates, 21 to 45 years of age and in good physical health and mental health. They were cognizant of the nature of the experiments and were able to remain under observation for 18 months. Volunteerism was popular and there was an associated air of patriotism. More prisoners volunteered than could be accepted into the program and they were promised no special privileges or reward.

At the end of WWII Illinois Governor Green appointed a civilian committee of health professionals, clergy and businessmen to advise the Department of Public Safety relative to the ethical principles governing conditions under which prisoners might be permitted to serve as subjects for medical experiments. Their report was published in 1948 and reiterated the principles of the Nuremberg Code. The Committee concluded, "An example of human experiments which were ideal because of their conformity with the foregoing ethical rules are the experiments at Stateville."

In the 1950's ~~revived~~ interest in malaria research was renewed ~~generated~~ by the Korean War. U.S. Army support for research involving prisoners at Stateville was augmented and led to the discovery of Primaquine which to this day is still a vital component in the anti-malaria drug armamentarium.

In the 1960's the discovery of chloroquine-resistant malaria in Southeast Asia initiated the need for new effective anti-malarial drugs. In addition to Stateville Penitentiary, additional facilities for clinical trials of new drugs were required. In 1963 to 1964 studies were initiated under government contract at Kansas City Jail, University of Missouri, and Maryland House of Correction, University of Maryland. As an

integral part of their contract the essential elements of Army Regulation 70-25 were included. Two additional facilities were used briefly in the early 1970's, Oklahoma State Prison at McAlester, Oklahoma, and the Florida Correctional Institution, (University of Florida College of Medicine). The U.S. Army Investigational Drug Review Board approved each study and insured that the potential volunteers were informed as to the nature and hazards of their participation in the studies, and that they were allowed the right to withdraw from participation without prejudice. All of the U.S. Army prison programs were stopped in 1975. Alternative procedures for continuing antimalarial drug testing in free living volunteers were subsequently developed by the Walter Reed Army Institute of Research and are active today.

The U.S. Army worked with approximately 7000 prisoners over the period ~~from~~ 1945 to 1975.

We have (been told) that there were three deaths during the early years: one unknown cause, one a prison assassination, and one case of acute leukemia temporally related to participation in the program. Since the U.S. Army has been directly involved there was one additional case that may have been related to malaria infection or his treatment. Briefly, this man was infected with malaria, treated with quinine, responded normally with eradication of parasites from his blood but who ~~suddenly~~ subsequently developed renal failure. He died about 2 months later from septicemia ~~secondary to~~ peritoneal dialysis. The pathologic diagnosis was TTP, an obscure disease of unknown etiology.

c. LSD, BENZILATE (BZ) AND SCOPOLAMINE STUDIES: The remarkable hallucinogenic properties of lysergic acid diethylamide (LSD) were discovered in Switzerland in 1943. In the 1950's LSD at first glance seemed to possess many properties desirable in the "ideal" chemical warfare agent ~~and~~ a humane weapon temporarily disabling enemy troops so they could be captured unharmed. It was known to be effective in incredibly small amounts and conveniently colorless, odorless, and tasteless. Because of these properties, in addition to the rumored use of LSD or some similar agent by the Soviet bloc nations for the purpose of interrogation and behavioral control (brainwashing), the U.S. Army Chemical Corps and the U.S. Army Intelligence Corps decided to conduct a series of experiments with LSD. These tests began in 1955 and continued through 1967. Volunteer research subjects were solicited from the Army in general and from the Chemical Corps. Mistakes were made involving the process of informed consent in some cases where the subjects were volunteering for research but were not told they were in drug research or if they did know they were in drug research they may not have been told what drugs they were taking. All available evidence indicates that with one exception with the initial intelligence testing, LSD-exposed subjects voluntarily participated in the chemical warfare testing and were informed ahead of time that they would be receiving a psychoactive agent. The question is not whether the subjects volunteered, but whether

they were provided sufficient information to permit an enlightened decision. Strict medical supervision was provided during the testing and prior to the actual receipt of the drugs. Almost all subjects received some degree of psychological screening and 30 to 50 percent of the Army volunteers were turned down during the screening process. The bulk of the testing was carried out at Edgewood Arsenal, Maryland, although other sites such as Ft. Benning, Ft. Bragg, Ft. McClellan and Dugway Proving Ground were used occasionally. Projects were designed to obtain information not only about the possible usefulness of LSD in operations against an enemy force, but also about means that might be taken to defend against the use of LSD to disrupt U.S. forces. By, 1967, the necessary data had been obtained and further LSD research was discontinued. The civilian community over these same years was testing LSD on a much larger scale. somewhat elucidate On 28 July 1975 Acting Secretary of the Army Norman R. Augustine suspended testing of chemical compounds on human volunteers at Edgewood Arsenal.

The other drugs in this program were primarily BZ and Scopolamine. Benzilate (BZ) is a glycolate ester, ~~and~~ has a different site of action than the LSD/Mescaline/amphetamine group and is an atropine like acetylcholine antagonist. Scopolamine (hyoscine) is a belladonna alkaloid related to atropine and inhibits the action of acetylcholine. It can be called an antimuscarinic agent.

Other drugs are also shown on a Psychoactive Agents Roster as abbreviations that were sometimes tested in combination with LSD, BZ or Scopolamine, they include: VX, pam, 5HTP, G-VAGT, Progly, CS, mechol, GD, heparin, THA, NITDIO, DIBENZ, DM, ACTH, SERNYL, DITRAN, ALD, 3443, 2233RM, ALCOHOL, BOL, 301060, 1476, MAISIL, ESERIN, THORAZ, SECO, PHYSOS, GF, DFP, VALIUM, THIAMI, BTA, NEMBUT, PAMCHL, ANTIPY, PROGLY, LANOXI, AMYLNI, COMPAZ, PROLIX, AMYTAL, RITALI, CAFFEI, PAMINE, BENACT, 2PAMCL, PAH, SODNIT, LIDOCA, ISUPREL.

There are 54 contracts or reports of contracts, with Universities and chemical companies form 1950-1971. ~~Of these 25~~ Twenty five were awarded for incapacitating agent research. The agent/drugs used were physical incapacitants such as morphine, demerol, seconal, scopolamine, chlorpromazine, and secobarbital. Mental incapacitants studies included LSD, mescaline, atropine, psilocybin, BZ and glycolate compounds.

Over 7000 volunteers participated in many types of research, which included drug research (686 LSD subjects), at Edgewood Arsenal without a single fatality or serious injury.

d. LSD FOLLOW-UP STUDIES: Several LSD follow-up medical evaluation studies took place in the 1970's, beginning with Project 33, in 1974-75. In the meantime, public and congressional interest in chemical warfare testing was stimulated by, among other things, the disclosure of the tragic suicide in 1953 of an Army mathematician shortly after surreptitiously being given LSD by non-military experimenters. In 1975, congressional

investigators requested that measures be taken to locate and evaluate for possible long-term adverse effects all former participants in Army chemical warfare research with LSD. Project 28 and Project 50/50 followed with the number indicating the number of participants in the follow-up study. In 1978 a follow-up office was established and it proceeded to contact all individuals from a comprehensive roster of 686 individuals believed to have received LSD. Of those, 320(47%) individuals electing to participate were provided travel at government expense to selected Army Medical Centers for evaluation. A 158 page summary report of this medical follow-up program was prepared in 1980.

As a group, the "LSD Subjects" appeared to be relatively stable socially, unusually well educated, and economically successful. The medical and psychiatric findings for those 220 subjects examined directly, as well as that obtained from the additional 100 subjects examined by questionnaire, appeared to generally parallel (both in type and frequency) ~~the~~ findings which could be expected ~~to be found~~ in a comparable segment of the general ~~male~~ population.

e. PROJECT WHITECOAT: Originated in 1954 following a series of meetings between representatives of the General Conference of the Seventh-day Adventist Church and of The Surgeon General of the Army. It continued at Fort Detrick, Maryland until the end of the draft in 1973. Infectious disease research continues today with volunteer soldiers and civilian subjects. Project Whitecoat was originally established to determine the vulnerability of man to attack with biological weapons using Q fever as a prototype. Personnel for Project Whitecoat were recruited from military personnel with a 1-A-O (conscientious objector) classification undergoing Basic and Advanced Individual Training at the Medical Training Center, Fort Sam Houston. These personnel were given a complete and comprehensive explanation of the program including discussion of the risk involved. The following day they were interviewed individually and offered an additional opportunity to ask questions and indicate their desire to participate or not. Many more individuals volunteered than could be accepted. After administrative processing these volunteers were assigned to various noncombatant ~~type~~ duties at Fort Detrick. Volunteers were briefed on individual projects and those who chose to volunteer signed consent forms. Multiple vaccine and antibiotic studies were conducted on a wide variety of infectious diseases. The entire program was initially monitored by the Commission of Epidemiological Survey of the Armed Forces Epidemiology Board.

Project Whitecoat involved 2200 soldiers between 1954 and 1973.

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