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August 26, 2009

Office of the Chief Counsel

Mr. John Greenewald, Jr.

Dear Mr. Greenewald:

This is the final response to your FOIA request dated June 18, 2009 and assigned RDECOM FOIA #FA-09-0036 where you sought copies of the following records:


The redacted records were subject to FOIA exemptions (b)(3) and (b)(6).

a. FOIA exemption (b)(3) covers matters that a statute specifically exempts from disclosure. Specifically, “The Search for Toxic Chemical Agents” contains data on hundreds of compounds that could be used as potential chemical agents. Therefore, “The Search for Toxic Chemical Agents” is exempt from release, in accordance with 10 U.S.C. § 130, which protects the release of technical data that could be used in a military setting and is subject to the Arms Export Control Act.

b. FOIA Exemption (b)(6) along with a Department of Defense policy allows for the withholding of government employee names, email addresses, and other personal information.

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Additionally, if you choose to appeal, the appeal must be received by the appellant authority (Army General Counsel), no later than 60 days following receipt of this letter. Please send correspondence to the following address:

Brian A. May  
RDECOM, ATTN AMSRD-CCF  
5183 Blackhawk Road, E4435  
Aberdeen Proving Ground, MD 21010-5424

Should you have any questions or concerns regarding your request I can be reached at (410) 436-2289 or brian.may3@us.army.mil

Sincerely,

//SIGNED - BAM//  
Brian A. May  
FOIA Officer, HQ RDECOM

Enclosure
Long Term Followup of Medical Volunteers

EDGEOWOOD ARSENAL ABERDEEN PROVING GROUND MD

MAR 1972


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**FROM:**


**AUTHORITY**

USAARADCOM ltr, 26 Jan 1981; USAARADCOM ltr, 26 Jan 1981

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LONG TERM FOLLOWUP OF MEDICAL VOLUNTEERS (U)

by

(b)(6)

March 1972

DEPARTMENT OF THE ARMY
EDGEWOOD ARSENAL
Biomedical Laboratory
Edgewood Arsenal, Maryland 21010

GROUP 4
DOWNGRADED AT 3 YEAR INTERVALS.
DECLASSIFIED AFTER 12 YEARS

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LONG TERM FOLLOWUP OF MEDICAL VOLUNTEERS (U)

by

Medical Research Division

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DEPARTMENT OF THE ARMY
EDGWOOD ARSENAL
Biomedical Laboratory
Edgewood Arsenal, Maryland 21010

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FOREWORD

The work described in this report was authorized under Task 1W662710AD2503, Medical Defense Against Chemical Agents, Prophylaxis and Therapy for Incapacitating Agents. The experimental work was started in June 1970 and completed in April 1971.

The volunteers in these tests are enlisted US Army personnel. These tests are governed by the principles, policies, and rules for medical volunteers as established in AR 70-25.

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Forty subjects who participated in the volunteer program at Edgewood Arsenal were studied with regard to possible harmful long term effects of the compounds they received while in the program. No subject felt that he had experienced physical or psychological changes as a result of the drug he had received. Subjects who received drugs did not show a greater incidence of chemical abnormalities than the control subjects.
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5
I. (U) INTRODUCTION.

The standard followup for medical volunteers used in drug studies at Edgewood Arsenal has been the performance of routine clinical laboratory measurements from 1 to 2 weeks after completion of the drug studies. No systematic study of these subjects has been undertaken beyond this 2-week period. The present report describes the results of a study undertaken to determine if there might be harmful long term effects as a result of exposure to compounds tested in the program.

II. (U) METHOD.

As a preliminary step, it was decided to limit this study to volunteers who were still serving in the US Army. Because of the rapid turnover of enlisted personnel, only a small percentage of the subjects who had received drugs in the program could be studied. Approximately 3% of all such subjects from the past 5 years were contacted.

A total of 40 subjects were examined over a 10-month period from June 1970 to April 1971. Six of these subjects had received two or more compounds. Twelve (30%) of these men were examined at Edgewood Arsenal, and 28 (70%) were examined at their duty stations. The average length of time between participation in the program and follow-up examination was 20 months, with the range being 8 months to 60 months.

The follow-up consisted of a structured interview and a repetition of a battery of laboratory tests* usually performed 1 week after a drug study.

The structured interview consisted of a standard series of questions designed to obtain information regarding possible long term effects of drugs received during the volunteer's participation in the program (see the appendix). An attempt was made to disguise the direct purpose of the questionnaire by including questions asking for the subject's evaluation of the total program: food, barracks, physical facilities, etc. Specific inquiry was directed to the possibility that intercurrent physical disease or psychological stress might have affected the subject's current level of functioning.

Controls for the 31 subjects who received drugs during their volunteer period were 9 subjects who had been on tests not involving drugs (exercise, environmental stress, equipment, etc.).

III. (U) RESULTS.

Table I shows the distribution of drugs and controls. Table II shows the abnormalities found in both drug and control groups. No subject felt that he had experienced physical or psychological changes as a result of participation in the program. All blood counts were within normal limits for this laboratory.

* (U) Complete white blood cell (WBC) count, differential white blood cell count, hemoglobin, hematocrit, urinalysis, blood urea nitrogen (BUN), blood glucose, serum glutamic oxaloacetic transaminase (SGOT), bilirubin, alkaline phosphatase, and total protein.
Table I (C). Compounds Given to Study Group (U)

<table>
<thead>
<tr>
<th>Compound</th>
<th>Number of volunteers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control (no drug)</td>
<td>9</td>
</tr>
<tr>
<td>CS: irritant</td>
<td>8</td>
</tr>
<tr>
<td>Toxogonin</td>
<td>4</td>
</tr>
<tr>
<td>2-PAMCI</td>
<td>3</td>
</tr>
<tr>
<td>Scopolamine</td>
<td>4</td>
</tr>
<tr>
<td>Atropine</td>
<td>3</td>
</tr>
<tr>
<td>Benztettide</td>
<td>1</td>
</tr>
<tr>
<td>EA 3528 (lysergic acid diethylamide maleate)</td>
<td>2</td>
</tr>
<tr>
<td>BZ (3-quinuclidinyl benzilate)</td>
<td>2</td>
</tr>
<tr>
<td>EA 3834 (1-methyl-4-piperidyl-a-isopropylmandelate)</td>
<td>1</td>
</tr>
<tr>
<td>302.608 [1-methyl-1,2,3,6-tetrahydro-4-piperidyl)methyl-a-isopropylmandelate]</td>
<td>1</td>
</tr>
<tr>
<td>CS 27349 (1,2a-tropanyl benzilate hydrochloride)</td>
<td>1</td>
</tr>
<tr>
<td>Physostigmine</td>
<td>1</td>
</tr>
<tr>
<td>DHP (disopropylfluoros hospate)</td>
<td>1</td>
</tr>
<tr>
<td>Prolixin</td>
<td>1</td>
</tr>
<tr>
<td>Compazine</td>
<td>1</td>
</tr>
<tr>
<td>Thorazine</td>
<td>1</td>
</tr>
<tr>
<td>Pentobarbital (barbiturate)</td>
<td>1</td>
</tr>
<tr>
<td>Bacteria</td>
<td>1</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>47</strong></td>
</tr>
</tbody>
</table>

A. Urinalysis.

Two subjects, both of whom had received BZ, showed less than 10 red blood cells per high power field in their urine on repeated testing. However, intermittent hematuria had been recorded prior to drug administration in these two subjects. Three control subjects, one who had received toxogonin, one who had received EA 3528, and one who received both EA 3528 and scopolamine had up to 10 white cells per high power field in their urine. One subject who received atropine showed a 1+ sugar reaction in his urine.

B. Blood Chemistry.

One subject who received EA 3528 had an elevated SGOT, as did one control subject. One subject who had received toxogonin had an elevated bilirubin level, and one control subject had a slight elevation of BUN level.

*(U) The chemical names of agents are listed in Table I.
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Table II (U). Abnormalities in Drug and Control Subjects

<table>
<thead>
<tr>
<th>Test</th>
<th>Control (9)</th>
<th>CS (8)</th>
<th>Toxogonin (4)</th>
<th>Scopolamine (4)</th>
<th>Atropine (3)</th>
<th>LA 3528 (2)</th>
<th>BZ (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjective physical and psychological changes</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Complete blood counts</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>RBC</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>WBC</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Glucosuria</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Serum chemistries</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>SGOT</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>3 (38.5)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>BUN</td>
<td>1 (23.3)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Flashbacks</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

*aNumbers in parentheses are the number of subjects.

*bNormal range for this laboratory, 7.2-24.6 mg%.

*cNormal range for this laboratory, 0.54-1.25 mg%.

*dNormal range for this laboratory, 8.0-20.8 mg%.

C. Flashbacks.

One subject who had received EA 3528 reported experiencing effects similar to those experienced while on the drug study in the program. This episode occurred while he was inhaling incense of an unknown type in Vietnam. Another subject reported an experience similar to his drug experience with BZ. This occurred while he was drinking alcoholic beverages about 3 weeks after he had received BZ.

IV. (U) DISCUSSION.

With the exception of the two flashbacks, the incidence of abnormalities in the drug group as a whole did not exceed that of the controls. The flashback phenomenon with LSD has been reported in the literature, but it can be explained in this particular instance by the inhalation of an unknown compound. The occurrence of flashbacks following BZ has not been reported, but it is also complicated in this instance by the concomitant ingestion of alcoholic beverages.

The finding of white blood cells in the urine of two subjects who received EA 3528 deserves some comment. This widely studied compound has not been associated with renal or urinary abnormalities. In addition, the incidence of three or more WBC's in the urine of 100 clean catch specimens of normal volunteers has run as high as 50% at Edgewood Arsenal. Thus, it is difficult to attribute the finding of WBC's in the urine to a long term effect of EA 3528.

The incidence of abnormalities in blood chemistry values is slightly higher in the control group than in the total drug group, but does not approach statistical significance. In order to exclude the possibility of long term effects from specific compounds, more cases should be studied.
V. CONCLUSIONS.

Subjects who received drugs in the human volunteer program at Edgewood Arsenal did not experience long term physical or psychological effects. When compared to a control group of volunteers who were not exposed to drugs, they did not show a greater incidence of routine laboratory abnormalities. The study was limited, however, by the small number of subjects who had received specific compounds. In addition, it was not a random sample of all volunteers used in that only subjects still in the US Army were included.
APPENDIX

QUESTIONNAIRE:

1. All addresses since participating in the program.
2. Has subject been overseas, and if so, where?
3. Change in marital status, and if so, what?
4. Deaths in family, and if so, whom?
5. Intercurrent illness with details as to hospitalization and after effects.
7. Surgery since participating and details.
8. Has subject received drugs or had toxic exposure?
10. Comments about the facilities at Edgewood Arsenal (food, barracks, etc.).
11. Did subject feel he learned anything as a participant?
12. Did subject receive a drug during the program?
13. How valuable does he feel such a drug would be to the Army?
14. Has he noticed any personality changes? Describe. To what are they attributed?
15. Has he noticed any physical changes? Describe. To what are they attributed?
16. How did participation affect his attitude toward chemical warfare?
17. Has he experienced any reactions similar to those he had while a participant in the program?
18. What is his impression of the effects of the program on him?
LONG TERM FOLLOWUP OF MEDICAL VOLUNTEERS (U)

This work was started in June 1970 and was completed in April 1971.

(U) Forty subjects who participated in the volunteer program at Edgewood Arsenal were studied with regard to possible harmful long term effects of the compounds they received while in the program. No subject felt that he had experienced physical or psychological changes as a result of the drug he had received. Subjects who received drugs did not show a greater incidence of chemical abnormalities than the control subjects.

KEYWORDS
Volunteers
Followup study
Drugs
Long term effects
Flashbacks
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