EXHIBIT L

BIOMEDICAL AND BEHAVIORAL RESEARCH, 1975

JOINT HEARINGS

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON LABOR AND PUBLIC WELFARE

AND THE

SUBCOMMITTEE ON ADMINISTRATIVE PRACTICE AND PROCEDURE

OF THE

COMMITTEE ON THE JUDICIARY

UNITED STATES SENATE

NINETY-FOURTH CONGRESS

FIRST SESSION

ON

HUMAN-USE EXPERIMENTATION PROGRAMS OF THE DEPARTMENT OF DEFENSE AND CENTRAL INTELLIGENCE AGENCY

AND

S. 2515

TO AMEND THE PUBLIC HEALTH SERVICE ACT TO ESTABLISH THE PRESIDENT'S COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS INVOLVED IN BIOMEDICAL AND BEHAVIORAL RESEARCH, AND FOR OTHER PURPOSES

SEPTEMBER 10, 12; AND NOVEMBER 7, 1975

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BIOMEDICAL AND BEHAVIORAL RESEARCH, 1975

Human-Use Experimentation Programs of the Department of Defense and Central Intelligence Agency

FRIDAY, SEPTEMBER 12, 1975

U.S. SENATE,
SUBCOMMITTEE ON HEALTH OF THE
COMMITTEE ON LABOR AND PUBLIC WELFARE,
SUBCOMMITTEE ON ADMINISTRATIVE PRACTICE AND
PROCEDURE OF THE COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittees met, pursuant to notice, at 10:25 a.m., in room 4232, Dirksen Senate Office Building, Hon. Edward M. Kennedy (chairman of the subcommittees) presiding.

Present: Senators Kennedy, Schweiker, and Stafford.

Senator KENNEDY. The subcommittees will come to order.

Over the period of these past few days, we have heard enormously disturbing testimony about the role of human experimentation sponsored by the Defense Department as well as the Central Intelligence Agency, and we have heard extremely moving testimony from many of the victims and the families of the victims who participated in those studies.

Of course, we could not help but be enormously impressed by the real lack of consent of many of those who participated in these tests and the lack of medical supervision, and a lack of medical followup.

To the greatest extent that took place in the mid 1950's, in the early part of the 1960's.

Our interest now is really learning about what is happening currently. There are different standards, there are probably different understandings of the importance of this whole question of human experimentation and, as tragic as those circumstances were, we really want to try to understand better what has been happening in recent times, what is happening today, and what the possibilities are for insuring that both those who have participated in these experimentations are going to have adequate followup and, of course, be given the best in terms of medical attention, but we want to make sure that those who will continue to be used in human experimentation situations are going to have adequate knowledge and understanding about the nature of these experiments and be fully aware of what the dramatic effects will be.

During the last few days of hearings, we have heard from spokesmen for the Department of the Army and the DOD who indicated to

us that they could not tell us really about what the current situation is at Edgewood Arsenal, and really could not tell us very much, or were unwilling to tell us, about what has been happening at the Edgewood Arsenal for the period of the last 5 years.

This is in spite of the fact that since July of this year, there has been a termination of any experimentation with LSD.

However, we had witnesses from DOD who indicated to us that they were in the process of bringing this material together, and that it was a lengthy and exhaustive and very comprehensive problem.

Some have asked Dr. Van Sim, who is the chief of the medical research division of the biomedical laboratories at Edgewood Arsenal, to come here this morning so that we might obtain answers from him on these various matters.

Subcommittee staff, who have had an opportunity to talk with Dr. Sim, say that he appeared clearly responsive and open and candid and willing to answer various questions. I suppose one of the problems that we have is wondering why the DOD and the Army have had problems obtaining answers which Dr. Sim has been all too willing to give to our staff.

So we look forward to your testimony, Dr. Sim.

As I understand from the preliminary exchanges, Doctor, some of the material that you gave in terms of exchange with the staff is in conflict with the testimony that we received from the Department of Defense and the Department of the Army. Therefore, I am going to ask that you be sworn in, because of the importance of this matter.

So I will ask you to rise and swear that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth, so help you, God.

Dr. SIM. I do.

Senator KENNEDY. Senator Schweiker.

Senator SCHWEIKER. Mr. Chairman, I feel this committee's work in this area is very critical and very important.

I join the chairman in emphasizing its urgency and the priority.

I think the tragedy of the situation—not only as expressed by today's hearing—is that it has taken so long for this material to come out. It implies that our system is not working, that we in the Congress are not adequately exercising our oversight authority, and that other areas of the Government are using the term "national security" in a way in which I am sure it was never meant to be used.

I think one of the jobs of this committee, particularly in this area, is to make sure whatever safeguards we set up in the future to protect our people so the Government cannot hide behind "national security" as a reason for the people not knowing what is happening.

The focal point of our actions after the hearing should be to provide new mechanisms and techniques which will not permit improper practices and experimentation to be carried on under the guise of national security.

That is all, Mr. Chairman.

Senator KENNEDY. Thank you very much, Senator Schweiker.

Doctor, could you tell us what your position is?

STATEMENT OF DR. VAN M. SIM, CHIEF, MEDICAL RESEARCH DIVISION, BIOMEDICAL LABORATORIES, EDGEWOOD ARSENAL, MD.

Dr. SIM. My position is that of chief of medical research division of the biomedical laboratories at Edgewood Arsenal.

As such, I have been responsible since 1956 for the conductance of the drug testing program on Army and Air Force volunteers.

Senator KENNEDY. What kinds of human-use drug testing programs have been underway at Edgewood since 1967?

We want to know what has been happening since 1967.

Dr. SIM. Since 1967, we have four general classes of drug testing programs that have been carried on.

The first would be the improvement of riot control type compounds as typified by our present standard compound, which is C.S.

The second would be to complete the work, the necessary work, on antidotes and treatment for the incapacitating agents, so-called, anticholinergics, as typified by B.Z. (a benzilate).

The third is to improve the posture of the soldier and sailor and marine and airman in providing for him a better and more comprehensive self-carrying package that he will be able to administer to himself in the field or others in case of an attack by a compound, such as GB (Savin), a nerve gas or nerve agent, so-called.

These are the three primary areas:

In addition to that, we have done work on improving our present field therapy by adding Oxime preparations for use in the reversal of anticholinesterase poisoning.

We have made studies using alcohol, drugs, and combinations of the two. The barbiturates, Valium, amphetamines and tetrahydrocannibinols are commonly used. We had to understand what part they would play if, in fact, a person were further tested with another type of compound or, in fact, what impact it would have on both the civilian and military population from chronic use of these materials.

Senator SCHWEIKER. Doctor, you mentioned the work you were doing was for the Army and Air Force, is that correct?

Dr. SIM. Yes.

Senator SCHWEIKER. Is there any other intelligence agency or any other branch of Government, any other program whatsoever being carried out there in which you are cooperating, any other contractor or subcontractor or any agent in any way?

Dr. SIM. No.

We have the responsibility to the Department of Defense—that means for the Department of the Navy, for the Army, the Air Force, the Marine Corps—to investigate drugs and chemicals and their effects on men, and come up with a diagnosis, treatment, prevention, preventative medicines, prophylactic medicines and treatment procedures for the Department of Defense. That is it.

Senator SCHWEIKER. All right.

Senator KENNEDY. Then, some of the results that you found were supposed to be sent to the Central Intelligence Agency, is that right?

Dr. SIM. As far as I know, Senator, if they were sent to the CIA, that was above my echelon.

We provided the information provided all of the documents

that were required, and where they were sent forth, I do not know.

Senator KENNEDY. You sent them to whom?

Dr. SIM. We sent them forward. We distributed all of our copies of our publications Army-wide throughout the Department of Defense, to the Navy, Air Force, and Marine Corps and to any requesting agency within the Government.

That could be Food and Drug; it could be Central Intelligence; it could be DIA; it could be anybody. But everybody gets the distribution of our report.

Senator KENNEDY. What does the report say?

Does it tell what you are doing at Edgewood Arsenal?

Dr. SIM. It tells exactly about particular experimental programs. It is a completed report.

Senator KENNEDY. Why do you think that the Surgeon General of the Army was unable to tell us what was going on at Edgewood and that it was going to take them a long period of time to find out what was going on?

Dr. SIM. There are two parts to that, Senator.

The first part is that every document—we have several types of reports. We have technical memoranda which are generated in-house. They are incomplete works.

Second, we have finished research reports.

Third, we have special publications and, fourth, we have open publications.

Now, all copies of these have to go through the Army screening program before they are published. When they are published, they are sent through normal distribution channels to all agencies of the Government.

To further amplify that, I would say that in checking this over, 11 copies went to the Department of the Army, including the Surgeon General's office throughout; 11 copies went to the Department of the Navy, including several Bureaus and the Bureau of Medicine and Surgery; 6 went to the Marine Corps; and the Air Force received 10 copies.

Now, this is standard procedure. They all received this information.

Senator SCHWEIKER. You said there were four categories, did you not?

Dr. SIM. Four categories of?

Senator SCHWEIKER. Which of those four categories are you describing now?

Dr. SIM. I am describing the finished technical report of any study category.

Senator SCHWEIKER. Categories 3 and 4, as you described?

Dr. SIM. Now, are you talking about category 4 as far as individuals?

Senator SCHWEIKER. You just said there were four categories of data.

Which category of data is distributed as follows: 11 to the Army, 11 to the Navy, 6 to the Marine Corps?

Dr. SIM. The second one, the Edgewood Arsenal technical report, or the third one, the Edgewood Arsenal special publication, would be distributed fully to all those.

The technical memoranda were not necessarily always sent to all

groups, but they certainly would reach the Department of the Army, the Surgeon General's office, the R. & D. Command, because they are finished reports.

Now, the open publication ones have to go through those channels anyway in order to be cleared.

Senator KENNEDY. How long have you been doing that?

Have you been doing that just recently?

Dr. SIM. No, sir.

We have been doing that since I have had the program, since I have been responsible for the program, since 1956.

Every finished report went through the regular channels and is in repository within governmental libraries of the Army, Navy, and Air Force.

Senator KENNEDY. Does that include the number of experiments and the subjects?

Dr. SIM. It does not include the subject's name. It does include the number of people.

Senator KENNEDY. And the number of the experiments and the nature of the experiments, is that right?

Dr. SIM. Yes, sir.

Senator KENNEDY. Why do you think Mr. Charles O. Ablard, General Counsel for the Army, testified that of the total number of experiments and human subjects, there is reason to believe that these records may not be complete, and that the total number of participants may be somewhat higher?

He continued to say:

Available records do not indicate whether these procedures were, in fact, followed in each case or exactly what information was imparted to the prospective subject.

Why do you think Mr. Ablard says there is reason to believe that these records may not be complete?

Were they complete?

Dr. SIM. Yes; they were complete.

Senator KENNEDY. These words had all the information on this that you were required to provide under the regulations?

Dr. SIM. Every one of the experiments from day 1 and the first volunteer has a complete file on every test that he has been on and every record; including a physical examination, psychiatric examination, psychological examination, complete test protocol, what drug he received, what other tests he was on, a final written workup of that individual, plus a complete evaluation by the doctor.

That is part of the medical records, and we have every one of those from the beginning.

They have not had time to look to see how complete they are, Senator.

Senator SCHWEIKER. Would this include informed consent procedures and structuring of your experiments?

Dr. SIM. Yes, sir; it includes everything.

The average volunteer file is approximately 53 pages on each individual for every time that he became a volunteer.

Senator SCHWEIKER. Are you saying, in essence, that these various branches have been inundated with reports on what you have been doing in detail?

Dr. SIM. Perhaps it is not so much that, Senator, as not being specifically interested in a program. I think this has more to do with it.

After all, in the research area there are multiple reports that go in, and there are those who are sitting in the chain of command that have to review them; if they do not have a specific interest in that area, it may be that they did not.

Senator SCHWEIKER. Who makes that decision, Doctor?

Dr. SIM. They do.

Senator SCHWEIKER. That is my point. That is not your decision.

Dr. SIM. That is not our decision.

Senator SCHWEIKER. As I understand it, your decision is to send 11 to the Army, 11 to the Navy, and then through the chain of command they make that determination.

Senator KENNEDY. Let me ask you this, Doctor, if we can get back to this.

I think you have been very responsive concerning the information that you have made available to the Departments of Defense, the Army, the Air Force, and other branches.

In completing your particular responsibilities in the three areas that you initially identified, did you have to administer hallucinogenic drugs to various human subjects?

Dr. SIM. Yes, sir.

Senator KENNEDY. Other than LSD?

Dr. SIM. Yes, sir.

Senator KENNEDY. Can you describe to us from 1967 to the present the kind of drugs that were being used, the number of different kinds of experiments that were taking place, and then I want to come to questions of consent and medical supervision.

Dr. SIM. There were several categories of drugs studied since 1967. All of them were representative of classes of compounds for which we had previous authority to study. Riot control compounds such as CS and CR; incapacitating compounds represented by the glycolates B.Z., EA3580, EA3834; therapeutic and prophylactic compounds thought to be effective against anticholinesterase compounds such as Sarin (GB) or Soman (GD). We did not study the effect of nerve agents themselves during this time period because they had been studied previously. Therapeutic and prophylactic compounds thought to be effective in prevention or treatment of incapacitating agents such as the glycolates (agent B.Z., an anticholinergic compound) were also studied.

Senator KENNEDY. Would you hold just a minute, Doctor?

(Discussion off the record.)

Senator KENNEDY. We apologize to the witness.

Could we have the last question and answer read?

[The last question and answer, as recorded, were read by the reporter.]

Senator KENNEDY. You were talking about B.Z.

Would you continue?

Are these all hallucinogenic drugs?

Dr. SIM. B.Z. is an anticholinergic like Atropen.

Senator KENNEDY. What does it do?

Dr. SIM. B.Z. causes both physical and mental incapacitation. The physical incapacitation comes on first. It is represented by feelings of a dry mouth, difficulty with vision, some difficulty with gait, and then a

person does not remember, and for a period of time he is in a state in which might best be described as semiquiet delirium.

Senator KENNEDY. For how long?

Dr. SIM. That depends.

With B.Z., it may be as long as 12 or 20 hours at which time he becomes ambulatory and gets up and moves around, but is unable to answer or retain memory for things that happened during the course of the experiment.

In about 72 hours, they are completely recovered, and we have had no reports of any difficulty as far as after effects.

Senator KENNEDY. Will you continue.

Dr. SIM. Yes.

We have not studied any anticholinesterase compounds except when Physostigmine (a weak anticholinesterase) is used for the treatment of B.Z. The work on nerve agents was terminated in about 1965, and there has been no further work done with these compounds.

We have continued work on some of the tranquilizers which are commonly used by the public, namely things like Valium, Trilafon, Thorazine, and so forth.

A point about Thorazine, we found out in our early experience with LSD, that it was effective in attenuating the LSD reaction. We studied Thorazine alone also.

As far as the other incapacitating agents, they are all in the same class as B.Z., except that they are glycolates, which is only a structural modification, but the effect is exactly the same.

I would like to clarify something because of erroneous newspaper reporting. LSD–25 and its analogous compounds are entirely different in their effects on humans. The dose required for effect from LSD is between 50 to 200 micrograms per individual. The dose required for effect from the anticholinergics such as B.Z. is from 5 to 10 times that amount. The duration of LSD–25 effects is usually from 6 to 12 hours for full recovery, but the effects of the anticholinergics may last from 2 hours to several days. The LSD–25 individual has few physiological changes, but a heightened activity of their central nervous system. During the period of acute effects, although hallucinating, they do have moments where they are entirely aware of what is going on around them. The person suffering from anticholinergic intoxication has physical incapacitation first, represented by dry mouth, visual disturbance, and ataxia (difficulty in balance). This is followed by a somnolent state during which period the individual is completely out of touch with his environment. Within a short time his physical disability improves, but he continues to be disoriented for a period of time depending on the particular compound.

Senator KENNEDY. This included V.X., is that right?

Dr. SIM. Yes, sir, but not since 1967.

This all terminated before that time.

Senator KENNEDY. V.X. was terminated?

Dr. SIM. Yes.

Senator KENNEDY. Is that a lethal drug?

Dr. SIM. That is a lethal compound, yes, sir.

Senator KENNEDY. Can that be tested on human beings?

Dr. SIM. It can be and was.

Senator KENNEDY. What happened?

Dr. SIM. I was the first subject on that so I have some memory of it.

The test consisted of an intravenous infusion lasting seven hours. My acetylcholinesterase level dropped to near zero, and I had all the signs and symptoms of an anticholinesterase poisoning.

Senator KENNEDY. Did it almost kill you?

Dr. SIM. No, sir, it did not, but I would never give a drug to an individual without first knowing what the facts and hazards were as well as the necessary treatment required.

This is a personal thing as far as I am concerned. I have never given a drug to an individual when I have not had experience with that class of drug personally. The experiment is done first on me. That has been my credo since I have been in charge of the program.

People do not agree with me entirely on this. They say it is not entirely objective, but I have to live with myself, and I have to conduct this program.

Senator KENNEDY. That is a very, very commendable attitude.

Senator STAFFORD. Will the doctor tell us what his symptoms were in this case?

Dr. SIM. The symptoms were those that are typical that would happen in a case of pesticide poisoning like Parathion.

There was some difficulty with breathing. First, I had the sensation of my nose running, and I was having difficulty with vision, seeing, a distortion of vision; sweating; tremors; nausea and vomiting.

Finally, the exposure was terminated. I might say we never do any of this testing unless we have an antidote for the particular compound that we are going to study. This is inherent in medical investigation practice.

We do not give drugs to people when you cannot reverse the situation with an antidote, and we have never tried treating or giving anybody a drug without first having all the methods and all the materials available that would terminate that exposure.

Senator KENNEDY. That may have been the practice at your center, but we have heard some rather disturbing and distressing stories of when that was not the case in tests sponsored by the Department of Defense, experimentation which ended up in tragic situations. Just briefly now, how many different drugs, hallucinogenic drugs, were you testing from 1967 to the present that were designed to incapacitate an individual?

Dr. SIM. I do not have the figures exactly.

Senator KENNEDY. Approximately.

Dr. SIM. Approximately, I would say that we probably have done seven of the incapacitating drugs since 1967, and they are all in the same series as B.Z. like the ones that we have done before.

Senator KENNEDY. Of those, how many individuals were involved?

Dr. SIM. The total number of people to come on the program of this type?

Senator KENNEDY. Since 1967.

Dr. SIM. Since 1967.

We had one hiatus, and no volunteers in 1973 and 1974, due to a change in assignment from Continental Army Command to Military Personnel Center. That delayed us about 1 year, so we had no volunteers.

The number of volunteers has averaged about 300 to 400 per year that have gone into this program between 40 to 60 percent were found eligible for drug studies.

Senator KENNEDY. Were they military?

Dr. SIM. They are all military, sir.

Senator SCHWEIKER. I understand Edgewood has done some contract work with prisoners and students.

How many prisoners and students would be involved in that?

Dr. SIM. In the present program—and there is only one program involved—they were doing the same type of thing.

Senator SCHWEIKER. How many people were involved, prisoners, and what drugs were used there?

Dr. SIM. The same drugs that were used in our program.

What the prison drug program was designed to do was to make studies on compounds to give us some feeling as to the potency of the material of this class of compound, and then relate that information to us so that we could make a decision as to whether or not it was an important compound to continue.

The numbers in that were usually around 100 to 200 per year total. Now, they never studied any compounds that we did not study, and only did *minimum effective* dose studies.

Senator SCHWEIKER. How about students in that period?

Dr. SIM. In the student program, nothing but therapeutic drugs were used. The student program was set up in clinical pharmacology, and the only thing that these students were given was Pam compounds, Oxime, which are for therapeutic use. We did not do drug studies on contract at all except for Oximes in students and minimal dose studies of incapacitating compounds in prisoners.

Senator SCHWEIKER. In your supporting contract this would have been reported through the same chain of command procedure as your in-house work, is that correct, sir?

Dr. SIM. That is correct.

Senator SCHWEIKER. Does the Navy participate?

Dr. SIM. We asked the Navy twice to participate in this program, and went through the CNO, and got a negative response at all times.

Senator KENNEDY. Why was that, do you know?

Dr. SIM. I do not know. Because the Air Force dropped out of it, too. I think because of the requirements for personnel elsewhere at the particular time we were asking, and there just was not enough interest to conduct it.

They said it is the Army's province. If they cannot find a volunteer——

Senator KENNEDY. Your testimony is that the Surgeon General of the Army was kept informed on all the tests that were taking place at Edgewood?

Dr. SIM. Senator, I want to say this. As far as I am concerned, we made the reports. Whether they were distributed by the Surgeon General's direct representative, who was the director of the lab all the time from 1946 on, was not my responsibility.

Senator SCHWEIKER. You say everything you were doing went up the chain of command, and do not know where it went from there?

Dr. SIM. Yes, sir; that is right.

Senator KENNEDY. You say your reports went to the Surgeon General.

Do you know whether there were other ways in which the Surgeon General was kept informed?

Dr. SIM. Yes.

Senator KENNEDY. Would you describe that?

Dr. SIM. We had quarterly staff meetings, going over the whole program. The Surgeon General had a liaison man come to those meetings. We have a liaison man from the Surgeon General that is assigned to us, and he attends any of the staff meetings that are of interest to him.

In addition to that, we have a written report of these quarterly so-called review and analysis of the program.

In addition to that, I have a semiannual in-department review analysis of the program, and the Surgeon General's people are always invited to that. They are always accompanied by a printed form so that they have some idea of the program.

In addition to that, we have monthly reports on volunteers that have been going on continuously, and these monthly reports merely state what the progress was during the month, what type tests the people were on; these have been current, they are all crossreferenced, so there is no problem in relation to saying how many people were on this program or how many people were on that.

We have another form of reference.

Now, those things, as far as I know, should have gone forward to all interested parties that had a need to know.

Senator KENNEDY. Let me ask you, as of the moratorium of 1975, were there any drugs, incapacitating drugs, being tested?

Dr. SIM. As of that time, not for that particular period. In the two periods preceding, there had been some studies on skin penetration of one of the glycolate compounds.

Senator KENNEDY. What period was that?

Dr. SIM. That would be the 3-month period from January—no, I am sorry—from October through December.

Senator KENNEDY. Of 1974?

Dr. SIM. Of 1974.

Senator KENNEDY. But after December 1974 there was no testing conducted?

Dr. SIM. Oh, yes.

Senator KENNEDY. Of the incapacitating drugs.

Dr. SIM. Well, Physostigmine as a treatment drug could be classified as an incapacitating drug.

Senator KENNEDY. What about hallucinogenic drugs?

Dr. SIM. Hallucinogenic, no. We were mainly concerned with our new treatment problems that had been presented to the committee before, I believe.

Senator KENNEDY. Do you plan any in the future?

Dr. SIM. I do not know what—I would plan some for the future; yes, sir.

Senator KENNEDY. Pardon?

Dr. SIM. I would plan some for the future. There are a few things that need to be done that are necessary.

Senator KENNEDY. Have there been proposals made to conduct these?

Dr. SIM. We have made four proposals to the Surgeon General since 1974, and we have had no positive action on any of them yet.

Senator KENNEDY. Why is that?

Dr. SIM. I would like to, if I might, Senator, clarify as far as time, if I have your permission, throughout the years.

This whole thing started in 1953, the first authorization was for both the G agents and Vesicants.

In 1955, the psychochemicals, including LSD–25 the hallucinogenic compounds and therapeutic compounds and antidotes were asked for and approval granted.

In 1958, we went in for V compounds, and the Surgeon General approved and commented.

In December of 1958, we had permission for the nerve agent V and for LSD–25 and for many of the other compounds including 1476 or marijuana type compound.

In 1959, we asked for authorization and received it for all the others in the specific classes. The only other ones that we asked for during the period of 1964–69 were those that involved physiological stress and thermal stress in association with chemical agents and operations in the field, wearing protective clothing.

So that is the story of asking for permission through the chains of command up to the Secretary of the Army on down.

Senator KENNEDY. Could you describe for us what precautions were taken in terms of obtaining informed consent from test individuals and what kinds of medical protection were provided, supervision during these tests, and followup?

Let us take, first of all, the consent issue.

How many protocols were submitted on those and what steps did you take to the Human Review Board?

Dr. SIM. Sir, every individual who has been on that program has signed the same consent form with witnesses.

When I supplied the Surgeon General with the 585 cases on LSD, I handed him 585 written consent proposals that were accompanying the names of those individuals.

This has been true throughout our program. We have not changed that consent. We have not changed our form, nor have we changed our method of informing the individual about what type of test is going on.

We do not tell him the exact structured formula of the drug. We never have, because we feel that it would prejudice the test.

But we always tell them the type of drug, generally what he might expect, how it will be administered, and over what duration of time he might expect some discomfort.

Senator SCHWEIKER. Doctor, I would like some clarification.

Would a person know he was taking LSD?

Dr. SIM. A person would not know he was taking LSD, sir, because we did not tell them they were taking LSD. LSD would mean nothing to a man in the 1950's.

Senator SCHWEIKER. What would you tell a man who was taking LSD?

Dr. SIM. We would tell a man he was taking a drug that would affect his behavior, and it would probably last for 6 to 12 hours, during which time we were there at all times, and we would terminate that exposure at any time that he so desired.

This has been an unwritten thing that we have always terminated exposure if the subject desired.

Further, he can refuse any test program, any single drug, or any

multiple drug, or he has always been able to refuse that. He has always been able to stop it, and we have also been able to on the spot terminate it if the physician decides.

Senator SCHWEIKER. How could you terminate a one-shot dose of LSD?

Dr. SIM. You might come up and say, "I want out of this."

Senator SCHWEIKER. You would not give repeated doses, would you?

Dr. SIM. Not in the same day; no.

Senator SCHWEIKER. So that could not be terminated the same day; could it?

Dr. SIM. No. No; but there is—the reason for the repeated dose of LSD, if and when they were given, was to see whether or not the person would build up a tolerance to the material. And if they did build up a tolerance, how much it would require in order to go through that tolerance.

Now, from our standpoint, this was important.

Very few people received multiple doses on, say, various days, but we become interested in tolerance.

Senator STAFFORD. Doctor, to go back to terminating at the request of the volunteer an experience, somebody in the middle of being under the influence of LSD and having a very bad experience, what could you do to terminate that experience right then and there?

Dr. SIM. Right then and there, sir, we gave Thorazine which attenuates the acute reaction from LSD. It modifies the experience. It sort of "semidrugs" them, and they can tolerate this. And in the normal period of time, which is about 6 to 8 to 10 hours, he comes out of it, but he does not go through the most stressful part of the experience.

Whenever they asked to be terminated, they were terminated.

Senator KENNEDY. On this question of informed consent, perhaps you could submit for us copies of the forms that were provided to the subjects.

The consent form which was signed by one of our witnesses earlier this week says, "I recognize that in pursuance of certain experiments transitory discomfiture may occur."

That is the extent of the warning, at least in this case, that the victim who was taking LSD was given. And it does not seem to me that if that is the same kind of form that was used at the Army Biomedical Laboratories at Edgewood Arsenal that test subjects were given sufficient information.

Dr. SIM. Is that not the normal type of form?

Senator KENNEDY. If you would be kind enough to supply us with copies. That is the type form that was signed by Colonel Jordan when he participated in an experiment.

Dr. SIM. That, sir, is a different type of procedure for obtaining consent.

Colonel Jordan was a member of a group team that volunteered. He was at Fort Benning. There was some at Fort Bragg. There was some at Fort McClellan.

Now, that was handled by the unit. That was handled entirely by that unit at Fort Benning.

Senator KENNEDY. Maybe you could submit those so that we may examine them.

But do you not think it is worthwhile to have one standard form?

Do you not think that would be worthwhile?

Dr. SIM. Correct, sir, and they should have had——

Senator KENNEDY. Let me ask you.

This committee authorized legislation for the Commission on the Protection of Human Rights, and they had been developing the consent forms in terms of experimentation for the Department of HEW.

Do you not think it would be useful and helpful if your particular division, and the rest of the Department of the Army and DOD, worked with them to develop the form which would provide the greatest amount of protection for those that would be participating in experiments?

Dr. SIM. Absolutely.

Senator KENNEDY. Will you welcome the opportunity to work with the Commission in the development of such form?

Dr. SIM. Senator Kennedy, I would more than welcome the opportunity.

Senator KENNEDY. I have not had a chance to talk with my colleague, but I would hope that we might be able to join in a letter to the Commission to request they review this and work with Dr. Sim and the Department of the Army.

We have some legislative aspects which we are working on, and I think Dr. Sim, your forthcoming attitude on this can be enormously helpful, and we will pursue it.

Let me ask you this.

I understand that since 1964, you have submitted from Edgewood directly to the Human Use Review Office only three different protocols, is that correct?

Dr. SIM. Yes.

Senator, I recited the agent agreements that were signed by the Secretary of the Army preparatory to that. These are a new thing.

Now, we had a Medical Advisory Council up until the AMC takeover, and they met twice a year, to decide on these programs.

Since that time, we have attempted, not ourselves, but we have suggested there be forums, outside groups, that would review this program from time to time and make recommendations.

We have forwarded the names of the individuals to be contacted. That is not as yet in effect except in the form of the NLRB.

Senator KENNEDY. At least, we were under the impression on the basis of that Memorandum of Understanding, that all the protocols were going to be submitted.

Dr. SIM. Yes, sir, they are.

[The following material was supplied by Dr. Sim to further qualify the colloquy:]

There seems to be some confusion about the questions asked and the answers. What I am now led to believe is that FDA and Surgeon General agreed that every experiment would be subject to protocol review, irrespective if it has been granted previously. As a matter of fact, FDA really never entered into the picture at all until the problem of efficacy of a drug for therapeutic value was being considered, with the endpoint being the drug would finally arrive on the civilian market for use (i.e., oximes for organophosphorus insecticide poisoning).

Since we were not involved in any new classes of compounds which we had not studied previously, and since we did not receive specific information that all future protocols must be submitted, we therefore did not become aware of this until either late 1973 or early 1974. It must be remembered that we have had a very strict protocol board in existence locally since the inception of the volunteer program, and we have 7000 healthy volunteers to support us.

Senator KENNEDY. Only three were submitted.
Dr. SIM. That is right.
Senator KENNEDY. Out of how many?
Dr. SIM. Well, as I said, these are all new compounds, new types——
Senator KENNEDY. There were only three new ones?
Dr. SIM. There were only three new ones that we submitted so far, one for the treatment of cyanide, one for a new therapeutic compound that we thought was extremely important.
Senator KENNEDY. Your interpretation was that you were to submit a protocol only if the experiment involved a new compound?
Dr. SIM. Not now it is not. Everything we have to submit.
Senator KENNEDY. When did you adopt that practice?
Dr. SIM. About 1974.
Senator KENNEDY. Not until then?
Dr. SIMS. That is correct.
Senator KENNEDY. Why is that?
Did not the Memorandum of Understanding provide that the protocol of each experiment was going to be submitted and reviewed?
Dr. Sim. The protocol of understanding came about as a result of your investigation, I think, in 1973, and when we resubmitted for the program in 1974, that is when it came out.
Now, not that it was not in being before, but it was not one in which we were specifically instructed.
Senator KENNEDY. At least your instruction, I gather, that you received was that your only requirement was to provide the submission to the Human Review Office if there was going to be a new class?
Dr. SIM. New compounds, new classes of compounds or new items.
Senator KENNEDY. Even though the Memorandum of Understanding between the FDA and the DOD explicitly shows that each protocol was to be submitted.
I do not know whether you are aware of that, but your orders were to submit protocols for each of the new experiments, is that correct?
Dr. SIM. Right.
Senator KENNEDY. Could you give my staff a copy of the consent form?
Dr. SIM. Yes.
Senator KENNEDY. The point, I suppose, here is that although the Food and Drug Adminstration felt that, under their memorandum of understanding, there was going to be a submission of each protocol, and even though the Army felt that way as well, by the time the word got to you, your understanding was that it was supposed to be each new experiment and in a new compound area?
Dr. SIM. Yes.
Senator KENNEDY. Until 1974?
Dr. SIM. Right.
Senator KENNEDY. And then every experiment?
Dr. SIM. Every experiment.
I might add to that, when we did all the work on oximes, we presented that as a complete technical data package to the Food and Drug Administration. And from that time on, it said any company, if they followed Food and Drug protocol in relation to this, could manufacture this compound and sell it. And there was no further animal work and no further human work that was required to be done.

We handed that to Food and Drug and said here is the total package on the oximes. You can use it for the common good of the public, and let any manufacturer make it.

This is an example of the sort of cooperation we have had, but we developed this early under a classified program, and then declassified it and gave it to Food and Drug for the civilian population's use.

Senator KENNEDY. Could you tell us a little bit about what you did over in your department for the protection of human subjects?

Did you have any other kind of arrangement, or did you try to develop any other kind of procedure for protection of human subjects, or did you just follow the consent form and followed the procedures that have been outlined by the Army?

Dr. SIM. Over and above that, we did many things.

Each class, each compound, in fact, posed a new problem, Senator, that we had to be completely aware of when we were conducting studies. So, no matter what the regimen and protocol was that was standard, we always had to have special precautions.

If it happened to be a compound that would cause respiratory difficulties, we not only had to have respiratory drugs there, but we had to have the people trained in a particular speciality where, if necessary, immediate attention could be given to that problem, where there would be prevention of anything rather than just doing a standard protocol and saying we covered it.

We always did the standard protocol, but we did much more.

Senator KENNEDY. Doctor, we just mentioned the consent form that Colonel Jordan signed, which said, "I recognize in pursuance of certain experiments transitory discomfort may occur."

I just asked you for the one you used, and it is identical to that form.

Dr. SIM. Yes, but I do not know whether his has—does his have the first?

Senator KENNEDY. It is absolutely identical. The two forms are absolutely identical.

Dr. SIM. Well, I did not see Jordan's form.

Senator KENNEDY. I will send it down to you. We will insert it into the record.

[The material referred to follows:]

70-026 O - 76 - 15

INFORMATION FORM

For use of this form, see AR 340-15; the proponent agency is The Adjutant General's Office.

FROM: (Name, Office Symbol, Room No., Building, Phone No.)	SUBJECT
SGRD-OC	Transmittal of Forms

TO	FROM	DATE	CMT #
SGRD-	SGRD-OC		

Attached forms are forwarded for following action:

a. Revise DD Form 1498, if necessary, from info on OTSG Form 1079.

b. Forward original Form 1498 and certified copy to SGRD-ID.

2 Incl
1. Form 1079
2. Form 1498 w/copy

COMPTROLLER

TO: SGRD-ID FROM: SGRD- DATE: CMT 2

DD Form 1498 with certified copy attached for submission to OCRD.

1 Incl
as

PROJECT MONITOR

APPENDIX E

DA FORM 2028 1 FEB 63 REPLACES DD FORM 444, EXISTING SUPPLIES OF THIS FORM WILL BE ISSUED AND USED UNTIL 1 FEB 63 UNLESS SOONER EXHAUSTED. GPO: 1970-407-235

VOLUNTEER'S PARTICIPATION AGREEMENT
U. S. ARMY CHEMICAL WARFARE LABORATORIES
U. S. ARMY CHEMICAL CENTER, MARYLAND

NAME Jordan, William R.

Age 31 Race Caucasian Grade 1st LT Serial No. 085337

Organization 4th Co TSB

Name of Nearest Relative Ruth G. Jordan (wife)

Address of Nearest Relative 330 Battle Park

Telephone Number of Nearest Relative [illegible]

I, William R. Jordan, certify that I have received, read and understand a document entitled, "Medical Research Volunteer Program," copy of which is annexed hereto, and that the general nature of the experiments I have volunteered to participate in have been explained from the standpoint of possible hazards to my health. It is my understanding that the experiments are so designed, based on the results of animal and previous human experimentation, that the anticipated results will justify the performance of the experiment. I understand further that experiments will be so conducted as to avoid all unnecessary physical and mental suffering and injury, and that I will be at liberty to request that the experiments be terminated at any time if in my opinion I have reached the physical or mental state where continuation of the experiments becomes undesirable.

I recognize that in the pursuit of certain experiments transitory discomfiture may occur and when such reactions seem especially likely to occur I will be so advised. I recognize, also, that under these circumstances, I must rely upon the skill and wisdom of the physician supervising the experiment to institute whatever medical or surgical measures are indicated to protect me.

I certify that there has been no coercion, element of fraud or deceit, undue moral suasion or other adverse pressure brought to bear in my volunteering for this duty. I have done so of my own free will, completely aware of all hazards, rewards and recognition involved.

DATE: 8 Dec 59 WITNESS: [illegible]

SIGNED: [illegible signature] WITNESS: [illegible signature]

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22 May 57

Dr. SIM. Those are the recommended ones that were supposed to go to the unit, and I have not seen Jordan's.

Senator KENNEDY. The point is whether they went to the unit or not; the question is as to adequacy of the warnings.

We are talking about experiments. You say that they have given consent, yet it says certain transitory discomforts may occur, and you are feeding them LSD.

Dr. SIM. Let me answer in this way.

Number one, that was in 1958 or 1959, and what we know about LSD today compared to what we knew then, would not have changed the intent or care of our study.

Senator KENNEDY. Is this the form that is being used?

Dr. SIM. That is the form that is being used today and that was processed through the Judge Advocate's office, and this is the recommended form that came down from the Department of the Army.

Senator KENNEDY. That is the one that was being used on all those drugs even from 1967 through 1974?

Dr. Sim. Yes, sir.

Senator KENNEDY. So regardless of what drug was used, the same form was used for all test subjects?

Dr. SIM. Yes, sir.

When the volunteer comes in, he signs that agreement.

Now, any time these come up, he has the option of whether he wants to go on that drug or not. So he does not sign one for every drug. He signs one for every period.

Senator KENNEDY. That is even worse, is it not?

Dr. SIM. No.

Senator KENNEDY. How is he going to find out about it if he just comes in and signs for a whole period?

You say in pursuance of certain experiments, transitory discomfort may occur, and the drug may vary dramatically in terms of its impact.

Dr. SIM. You are correct.

For every drug, he is talked to individually in relation to that drug and told what the effect is. He then has the option of saying, "Well, I do not want to go on this test."

Senator KENNEDY. How is that presented to him?

Let me finish.

Do you have some other form which is used, whether it is for LSD or B.Z., or any of these other drugs, or is the informal consent just dependent upon oral communication?

Dr. SIM. No.

It depends on the oral communication. This is a very close type group that is working together with these people every day. And they do talk to them prior to all these tests.

Now, the same physicians and the same nurses and the same people practically live with these people during this period of time, so it is a very, very close working relationship.

Senator KENNEDY. Doctor, I do not doubt that the same doctors and nurses are going to be staying there or supervising.

What I am asking is whether, on the basis of the form that is submitted, and on the basis of the conversations with test subjects that they can have a complete awareness of what they are getting into with all the implications of how a particular drug may affect the test subjects.

We have heard witnesses who sat at that very witness table just a few days ago who testified to enormous kinds of change in their lives and, in some instances, absolutely tragic circumstances, and it does not appear to me that this form which refers to transitory discomfort, is an adequate warning. The form does not even name the drug.

Nor does it appear that oral communications from doctors to test subjects is adequate because there is nothing in writing that would help determine the extent to which this kind of warning is given.

So that later in their lives even if they read about the after effects of LSD, and have experienced the kinds of chronic depression and flashbacks and all the other kinds of aftereffects associated with the drug they will never know why.

They will never be able to relate this because they do not even know. They have not received any indication, any notice. You have not told them and, evidently, your doctors working with them have not told them.

So, these 300 to 400 military men who have taken these hallucinogenic and incapacitating drugs since 1967—300 or 400 a year, which is close to 3,000 servicemen—may have suffered these depressions or flashbacks, or other mental problems, but they have no way of tracing it back to your testing.

How are they going to know when they get these aftereffects, that they are not suffering from epilepsy, but are sufferening drug aftereffects, as we saw with Colonel Jordan?

They are just loose somewhere out in this country, and the Army evidently does not have the necessary followup procedure.

How are their interests going to be protected?

Dr. SIM. I understand what you are saying, and I have been concerned with it. And I think if you provide copies of letters about my concern to the individual who comes in with a letter, wondering about something that happened to him as a result of the drug——

Senator KENNEDY. But does the responsibility end there when an individual comes in with a letter?

Do you not have at least a responsibility to make sure that they have the most complete informed awareness of what this drug may do to them and to their minds and their bodies?

Do you not have a responsibility, and does not the Army have a responsibility to follow up on these young people to make sure that they are going to have adequate kinds of medical followup and not just in the immediate future?

Do you not have that responsibility today for those who have been involved in these experiments?

Dr. SIM. Yes, very definitely.

Senator KENNEDY. Are they doing anything now?

Dr. SIM. Yes, sir.

Senator KENNEDY. Are you following up on everyone of those young persons?

Dr. SIM. We are following up; the Army is following up on every one of the 585 cases we have.

We started the program in 1971, which went back to 1967.

Senator KENNEDY. Let me understand your answer.

Are you prepared to say now that for everyone that has been participating in the Army drug testing program, every young person who

has participated in that program, that the Department of Defense is following up with every individual, to notify him of the nature of the drug he took, the potential side effects, and that the military is prepared to insure that they are going to be given full and adequate medical treatment today and for any time that can be reasonably related to involvement in that drug testing program?

Dr. SIM. The answer is yes and no, both.

Senator KENNEDY. How can it be no?

Dr. SIM. The yes is on the LSD which has been launched.

In 1971, we started on the other program, which included all drugs, and started a program in which we had both the controls and people who had been on experimental drugs.

Results of that small one were dissatisfying to us. We did not find changes. We did not have either the money or the medical people to continue the size of investigation that we felt was necessary.

Senator KENNEDY. Is it your testimony that you did not have the money to follow up on these cases?

Dr. SIM. No.

My testimony is we did not have the money to follow up on and the people to follow up on the type of investigation that we thought was necessary, and we stated it. That was in 1971.

Senator KENNEDY. That is an intolerable situation, is it not, Doctor?

Dr. SIM. Well, it is intolerable.

Senator KENNEDY. Are you prepared to say it is Army policy to conduct a drug testing program using young Americans who may suffer the most serious kinds of damaging effects—both mental and physical—and then say that the Army does not have the manpower or the money to follow up and insure that those young people who have volunteered are not going to receive the very, very best that this country can afford?

Dr. SIM. You are right, and I agree with you fully. Absolutely I agree with you.

Senator KENNEDY. Wait a minute.

You agree with me what?

Dr. SIM. That it should be done.

Senator KENNEDY. That it should be done?

Dr. SIM. That it should be done.

We went before the National Science Foundation in 1973.

Senator KENNEDY. Is it being done?

Dr. SIM. It is being done, as the Surgeon General testified, I believe.

Senator KENNEDY. What is your "no"?

You gave us a "no."

Dr. SIM. My "no" is that we have not launched one for every class of compounds that we have.

Senator KENNEDY. So the answer is no?

Let us understand it.

It is yes with regard to LSD for 485, but no with regard to?

Dr. SIM. With regard to some of the others, yes.

Senator KENNEDY. That is the point. It is not being done with regard to every young American who participated in these experimental programs involving testing of hallucinogenic drugs.

Can you tell us that it is covering every single American?

Dr. SIM. No; it is not covering everyone.

Senator KENNEDY. Do you not think it should?
Dr. SIM. I think it should, yes.
Senator KENNEDY. Why is it not?
Dr. SIM. I do not have the money or manpower to do this. I just do not.
Senator KENNEDY. Did you ask for money or manpower?
Dr. SIM. No; I have not asked for the money and manpower.
Senator KENNEDY. Will you?
Dr. SIM. I would. I will.
Senator KENNEDY. Let us know if you do not get the money or manpower.
Dr. SIM. I would be happy to.
Senator KENNEDY. I think that is very important. I just want to assure you that I will do everything that I possibly can to make sure that you do get the money and manpower, and I am sure that the members of this committee will work just as industriously as I to insure it.
You stated yourself that this is something that must and should be done.
Dr. SIM. Right, sir.
Senator KENNEDY. It is really, I think, just an incredibly important responsibility. I have been impressed by your obvious concern for these young people, but you could not have listened to the witnesses that we have heard in terms of the impact on their lives and not recognize the continuing and ongoing responsibility for it.
Dr. SIM. Right.
Senator KENNEDY. We want to make sure at this point that we understand completely that there may very well be, and I am sure there are, some extremely important reasons for human experimentation in terms of drugs from the military point of view, although I think, obviously, this ought to be reviewed, but in terms of the protection, and I think I have outlined that earlier.
Dr. SIM. Yes.
Senator KENNEDY. Before there is an implementation of any testing, there necessarily has to be a justification for experimentation. We are not competent—at least I am not—to make that judgment, but I think the need ought to be reviewed constantly.
What I think is really inexcusable is not having the complete and full adequate notification, both in terms of the full implications of the drug, and the kinds of supervision and the followup.
Let me ask you this.
I think you responded to the kind of medical supervision that takes place during the experimentation. Maybe you can talk about the medical attention during the experiment.
Did you have doctors around?
Dr. SIM. Right.
The entry physical examination and psychological examination takes approximately a week. Those people are categorized one, two, three, four, on the basis of their medical history, medical workup, the psychological and psychiatric interviews, and their total profile as far as a multifaceted personality.
Then they are placed in four categories—one, drugs unqualified; no drugs; limited drugs; and then only equipment or anything else.

So those are the categories, and there is a medical staff decision after review of the individual's record before he is assigned to it.

Then, from the day the man is placed on a drug program, he is briefed about the program. He is worked up with any specialties that are required with a physician in attendance, and the day he is in a setting with the nurses and the physicians at all times, he remains there during the course of that test.

The material is given by a physician, he is followed on a 24-hour basis by a physician, and when he leaves that program he has follow-up studies done during the course of his stay there.

Before he leaves Edgewood completely, he goes through another whole battery of tests again to assure there is nothing hanging on. Sometimes they are asked to stay over if there is a question about one lab test or something, for a week or 2 weeks, or even return at another period of time, to recheck things. This is the normal procedure.

Now, if there is anything that causes a problem in relation to disease or something that this person has had while he is there, that is referred back to his Army station, to the dispensary there, and we are asked to check.

For many of these men, this is a very unusual thing because we have picked up so many things in physical examinations and taken them off the program, sent them to specialists and consultants for both physical and psychiatric reasons, where they could get adequate treatment without ever going on a program.

So it is the most complete comprehensive medical review a person has an opportunity to get. From that standpoint, it has been extremely valuable for the serviceman.

Senator KENNEDY. Did you have any deaths involved in this program?

Dr. SIM. No, sir.

Senator KENNEDY. Never a death?

Dr. SIM. No, sir.

Senator KENNEDY. Do you know if any of the materials that were developed at Edgewood were ever taken off the premises?

Dr. SIM. Yes.

I do not know whether the materials were actually made at Edgewood, but they could have been made by a pharmaceutical house or chemical company and could have been taken to institutions or could have been taken to a university, or could have been taken to a research place for study.

Not necessarily at all. It could be just a chemical analysis, chemical test or animal test that the investigator might have wanted to do.

Senator KENNEDY. Do you know if any of the materials were ever used in the Army?

Dr. SIM. Any of these materials that have been used in the Army?

Senator KENNEDY. Any product that was developed there or used at Edgewood, ever used in the military?

Dr. SIM. No, sir.

Senator KENNEDY. Did you not know that?

Dr. SIM. I do not know.

Senator KENNEDY. Whether it was or was not?

Dr. SIM. I do not know whether it was or was not.

Senator KENNEDY. Would you know?

Dr. SIM. I think I would know if it were something like B.Z., I guess. I think I would.

Senator KENNEDY. Would you not know if it was any of the other hallucinogenic drugs?

Dr. SIM. No, not necessarily.

My reason for that is simple.

B.Z. was one that originated with us. Some of the others did not originate with us. For instance, LSD, and it could have been used, because they got them from other sources.

Senator KENNEDY. Can you tell me how many other subjects were used at Fort Bragg, Fort McClellan and in the Fort Benning programs?

Dr. SIM. How many were used on it?

Senator KENNEDY. Say for 1967.

Dr. SIM. There was not any then, Senator. All the work at Fort Bragg, Fort Benning was done prior to that period of time.

Senator KENNEDY. During what period?

Dr. SIM. 1958 to 1961.

Senator KENNEDY. And that includes Fort Bragg, Fort McClellan and Fort Benning?

Do you know the number of people involved?

Dr. SIM. I submitted the list. That can be made available to you. I submitted the total list with the names.

Senator KENNEDY. How do you know there were no deaths involved if you did not have a medical followup?

Dr. SIM. That is good a question because there have been people who have been killed in Vietnam.

Senator KENNEDY. That is not what we are talking about.

Dr. SIM. No. But I mean not as a result of that, but people happen to still be in the Army, and I do not know any which has been attributed personally, who was on our program.

Senator KENNEDY. Is it not possible that you would not know about it if someone committed suicide or someone had an enormous depression?

Dr. SIM. It is possible I would not.

Senator KENNEDY. There is probably very little chance that you would, is that not so?

Dr. SIM. In the case of some of these officers, I think I probably would have heard.

Senator KENNEDY. Are the officers the larger percent?

Dr. SIM. No. It is a small percent.

In the case of the officers, I would have. In the case of the others, I would not have.

Senator KENNEDY. Are the tests put in the medical records of the servicemen?

Dr. SIM. The tests are not put in the medical records. They are cross-referenced, but on the medical record of the servicemen is a cross-reference in which it states the type of test, and there is another location file for the test. This is done for security reasons.

Senator KENNEDY. So, in every enlisted man's case, at least in his medical record, it is indicated he was involved?

Dr. SIM. Yes, sir, or was not involved, because many of these people are controls and received no drugs.

[The following material was subsequently supplied for the record:]

FACT SHEET ON LSD STUDIES AT EDGEWOOD ARSENAL

(Author: Dr. Van M. Sim)

GENERAL

In April 1943, the hallucinogenic properties of d-lysergic acid diethylamide (LSD) were discovered by Dr. A. Hofmann of the Sandoz Research Laboratories. He filed a patent request 28 April 1944 that was approved by the Board of Appeals of the US Patent Office (Case 291, serial no. 533,264) June 27, 1947. Universities, pharmaceutical houses, and private investigators conducted numerous studies in both animals and man on LSD. There were hundreds of reports in the scientific literature of these studies, and it was decided at Edgewood Arsenal to test the substance from the standpoint of whether it was capable of disrupting military operations. Studies were begun at Edgewood Arsenal in 1955. Pharmacological studies were conducted in animals in an attempt to determine the mechanism of action of the drug. Studies conducted in human subjects (Volunteers) were oriented toward learning what the effects of different doses, given by different routes, would be; how these doses would affect military performance; and how predictable the effects are. Included in these studies were clinical laboratory methods of detection of LSD in blood, tissues, and urine. Studies of analogues of the compound, such as BOL (Bromlysergic acid) were conducted to see whether protective measures could be taken with these compounds to give the person some prophylactic protection against the more potent members of the series. Much of this has been reported in the open literature. Throughout the period we used every known study on cells, tissues, and organ culture in order to assess the potential hazard to humans from a tissue or genetic standpoint. Although human chromosome breaks had been reported by others, we found them much more frequently from caffeine and many other common substances. We were unable to demonstrate any damage by LSD to any system used. This has been a continuing project on all chemical substances which may be introduced into the body, so it is not unique to this compound. We have done the same studies on every chemical which is standard in CW, every therapeutic compound used to treat any compound of interest, every riot control agent--everything. In no instance was a human subject who did not volunteer used, and in every instance of human exposure, the individual knew in advance that he would be given a drug that had psychotomimetic properties. He did not necessarily know when or how he would be given the drug to avoid responses that would be invalid because of the power of suggestion.

These studies were conducted intermittently over the period of 1955 to 1967 when all work on LSD at Edgewood Arsenal was concluded.

Prior to the establishment of the volunteer program at Edgewood Arsenal, Dr. Amadeo Marrazi, M.D., now at University of Minnesota, was in charge of medical research. From 1956 on, Dr. Van M. Sim has been responsible for the program. He has served under the following Directors of the Laboratory:

1956-1959: COL Albert Dreisbach
1959-1962: COL Douglas Lindsey
1962-1963: COL Frank Bauer
1963-1974: COL Joseph Blair
1974-present: COL Claude McClure

Because of the organization structure of the post and the laboratory, COL Nicholas Bottiglieri, COL Henry Uhrig, and COL Frank Leitnaker served as Directors of the Laboratory during the time that COL Blair was Deputy Director of Chemical Research and Development Laboratory from 1963 until 1971.

All work on LSD at this installation carried a military security classification until March of 1970, when it was declassified. Immediate action was taken to screen all documents on LSD and declassify those which did not contain information on other agents that still carried a military classification.

PROCEDURES USED IN CLINICAL AND FIELD TESTS

1. All human subjects were volunteers; all were told they would be given a compound and, in general, what they might expect and the duration of effects. In all field tests adequate numbers of controls (without drug) were part of the program.

2. The normal procedure of signing a statement of willingness to participate before a witness was carried out on the clinical program. In the group trials, this procedure was accomplished by the unit.

3. Extensive physical and psychological tests, including predictive personality indexes, were employed througt. In addition, specific psychological tests such as McQuarrie Mechanical Ability, reading tests, arithmetic tests, drawing and picture tests were employed. The physical examination, history, clinical examination, and clinical laboratory studies, both before and after tests, were standardized from the onset of clinical testing. Psychiatric interviews and total review of each subject were made before they were allowed to go on test.

4. Followup procedures to determine that there were no residual effects of the drug were instituted. These were reviewed by a Committee of the National Academy of Sciences for the Surgeon General in 1973. There was no recommendation that further followup programs would be of any value.

5. The laboratory methods for identification of the material, the clinical diagnosis of the individual who might be poisoned, the treatment of the individual, and the problems of mass casualty handling were all a part of the program.

Senator KENNEDY. We want to thank you very much for coming. It has really been amazing that you are prepared to talk in such detail about various programs that have been going on from 1967 to the present. That was the nature of our inquiry to the Department of Defense. They were very unresponsive in terms of answering that.

You have been very forthright in terms of time, numbers, people, and figures, and have indicated that you have supplied reports to the Surgeon General, so it mystifies me why they were so reluctant to comment on what you have been quite willing and prepared to comment upon this morning.

I think you understand our primary interest is in the area of notification and consent, supervision and followup on these matters, and I think your willingness to work with the Commission on Human Rights and Subjects is extremely helpful and useful in the kinds of consent programs and notification, so that, at any time in the future, where the Department of Defense is involved, I am going to, as I mentioned to you, ask the Commission itself if they will work with you in the development of protocols to insure that kind of notification, because, quite clearly, the ones that you do have, I feel, are inadequate.

Just before we recessed the hearing, there was a part of Mr. Ablard's testimony that I will read. It appears on page 16, when he said:

> In view of the results of the clinical experimentation at Edgewood Arsenal and recognition of the limited capability to structure realistic interrogation situations in the laboratory environment using volunteers, the proposal was submitted by the U.S. Army Intelligence Center in coordination with the Chemical Warfare Laboratory to conduct field experimentation—this is now referring to LSD—in conjunction with actual interrogation situations.
>
> This proposal was approved by the Army's Assistant Chief of Staff for Intelligence and subsequently two series of field tests were conducted.

Do you know anything about that?

Dr. SIM. Sir, as I say, the only part of this that we provided was some local support, and I think they have given all this to another committee, and I am not privy to it.

Senator KENNEDY. I have asked the Department of Defense for an explanation, and they have said this was classified information, but they would discuss this matter with the committee members this afternoon at 3 o'clock.

So we are going to recess until 3 o'clock and listen to the explanation in executive session to the two series of field tests being conducted.

I think it is very important to us to find out about that matter.

The subcommittee stands in recess.

(Whereupon, at 11:45 a.m., the subcommittee adjourned.)