BIOLOGICAL TESTING INVOLVING HUMAN SUBJECTS BY THE DEPARTMENT OF DEFENSE, 1977

HEARINGS

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

OF THE

COMMITTEE ON HUMAN RESOURCES UNITED STATES SENATE

NINETY-FIFTH CONGRESS

FIRST SESSION

ON

EXAMINATION OF SERIOUS DEFICIENCIES IN THE DEFENSE DEPARTMENT'S EFFORTS TO PROTECT THE HUMAN SUBJECTS, OF DRUG RESEARCH

MARCH 8 AND MAY 23, 1977

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TUESDAY, MARCH 8, 1977

U.S. Senate,
Subcommittee on Health and Scientific Research
of the Committee on Human Resources,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:07 a.m., in room 4232, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman of the subcommittee), presiding.

Present: Senators Kennedy and Schweiker.

Opening Statement of Senator Kennedy

Senator Kennedy. The Health Subcommittee will come to order.

In 1975 the Senate Health Subcommittee learned of serious deficiencies in the Defense Department's efforts to protect the human subjects of drug research. In 2 days of hearings, it was learned that consent forms were largely inadequate, that human experimentation review boards rarely met, that unwitting members of the civilian population had been test subjects, and that the Food and Drug Administration had inappropriately given up its responsibility for assuring that drug test subjects were fully protected. Today, we will learn what has been done in the ensuing 18 months to correct that situation.

We have also learned, for the first time, the extent of the Department of Defense activities in biological warfare. We will focus primarily on the biological warfare research program and the protection of witting and unwitting subjects of that program.

Recent revelations of simulant, open-air testing in civilian areas have alarmed many people. Their concern extends beyond the safety or hazards presented by the test organisms, however it goes to the heart of what a free society is all about. Should a democratic people cede to its Government the full responsibility of determining when secret tests on unwitting subjects are necessary to protect the Nation's security? How can public accountability be maintained when secrecy is a legitimate and necessary component of research on human subjects?

I intend to reintroduce legislation next week to extend the jurisdiction of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to cover all Federal departments and agencies. Similar legislation passed the Senate last year by unanimous consent. It died in the House of Representatives.

I believe the National Commission has earned the trust and respect of the American people. It has issued recommendations on fetal research and research on prisoners which has earned it the respect of scientists and laymen alike. I believe it is time for a nation with a scientific capability second to none to develop a uniform, national program for the protection of human research subjects second to none.

It is important, however, that the two subjects not be confused. The protection of subjects of research is a different problem than the decision as to whether or not to do the research at all. The two are related but not identical. I believe it is legitimate for the public to participate in both types of decisions.

In biological warfare, public suspicions about tests on unwitting subjects should not cloud public determinations about whether defensive biological warfare research is necessary at all. It is conceivable that had there been less unnecessary secrecy and more public input, tests on unwitting subjects might have been prevented while tests on witting volunteers might have been increased.

The public cannot and will not support what is does not understand and what it learns by expose. The interests of national security might have been better served by more public understanding and less concealment.

Before recognizing my colleague, Senator Schweiker, who has been so interested in this subject and has been so helpful to this subcommittee in both fashioning these hearings and focusing the attention on this issue, I want to say how much we appreciate the cooperation of the Department of Defense in these hearings today. There are a number of public policy issues that are raised by all this subject matter.

Our interest and the interest of this committee has been in the protection of the human subjects of our American civilians and in insuring the adequacy of that protection, the consent, and in fashioning the legislation to try and insure that that would be the case.

We have good legislation. We were interested in extending that legislation to the Department of Defense last year, and I am sure Senator Schweiker remembers that when we had the representatives of the various service organizations, all of them without exception supported the extension of that legislation to include the Department of Defense, but had to take a position negative to that because of some order of OMB, which we were never able to quite rationalize or justify or feel was warranted.

I find in my direct conversations with Secretary Brown an extremely positive and constructive attitude in this subject matter.

We realize you cannot at this time indicate a specific position on this since legislation is not before the committee. It will be introduced next week.

I can tell you how helpful your comments today will be in assisting us to achieve and accomplish our task and our job.

I further note that matters which he presented this committee go back many, many years. In tracing the history of development of this program, we find actions taken by those individuals involved in national security took place during the period of the fifties and sixties, and therefore we are really catching up in terms of history. I want to commend the Department for presenting this information to us in the

way that you will this morning and for the cooperation that you have had with the staff, in helping us, assisting us, to really come to grips with this issue.

We will have the open session at the start of the hearing. There are some matters which are classified. We will have that in a closed session.

Then we will work with the Department in trying to reveal as much of the hearing record as we possibly can for the public. I am completely satisfied that the thrust of this whole program will be laid out for the public today. I want to recognize Senator Schweiker at this time.

Senator Schweiker. Thank you, Mr. Chairman.

I am glad to have the opportunity to join in this hearing into the conduct of biological and chemical warfare testing by the Department of Defense. I was deeply disturbed by published reports that the Army had run tests in populated areas of the United States, apparently exposing large numbers of Americans to potentially dangerous substances. Since the Health and Scientific Research Subcommittee has a responsibility to take the lead in issues of research ethics and to protect the human subjects of research, I felt it necessary and appropriate for us to have hearings on the important issues raised by this testing program, and I want to thank Senator Kennedy for agreeing to my request for these hearings.

I also appreciate the work that the Department of Defense has put into the report released this morning. This is a positive and constructive step, and it will be most useful to us in drafting new legislation. I think our primary interest is looking ahead, developing policies for new legislation rather than unnecessarily rehashing the past, but I think also we can learn from the past. So I intend to review this report very carefully.

This is not the first time we have heard testmony on the propriety of Department of Defense research activities and the use of human subjects, and I intend to examine the report and today's testimony closely in light of what we heard before.

Many serious questions have been raised, particularly in regard to the biological simulant tests which have been widely reported in the press. Medical experts have told us that the Army was using simulant agents—live organisms which we know can infect human beings—in places like the New York subway system. There have been tests in my home State of Pennsylvania—in Mechanicsburg, in the Kittatinny and Tuscarora Tunnels on the Pennsylvania Turnpike and along Pennsylvania State Highway 16. Some experts have told me that the Army continued to use a certain bacterium long after it was known to cause infection. Officials from the Center for Disease Control have stated that many better alternatives to the known pathogenic fungus *Aspergillus fumigatus* exist. It has been suggested that the fact that the organisms used as simulants do naturally occur in the environment does not at all insure their safety—in fact, because they are normally regulated by the environment, their efforts may be harder to detect and control.

There may be honest disagreement about whether or not a substance is dangerous—and about when we can expect researchers to know about the potential danger. Perhaps more openness is needed, particularly in the biological area since we have renounced use of biological warfare

under any circumstances, to ensure that all available expertise in the public and private sector is brought to bear in each testing decision.

One thing seems clear: it is very risky indeed to assume that any living organism, reduced to germ warfare size and released in a populated area, is actually, theoretically, ever safe.

Another problem which arises in connection with any open-air testing is the problem of containment of any agent, be it a live organism, a chemical agent or simulant, or an anticrop or antianimal agent. Even though the spray may be in a confined, nonpublic area, how do we stop downwind effects and leakage? If anticrop and antianimal agents are tested in the open air, how can we be absolutely certain that nothing will get into our food supply?

I am looking forward to full disclosure of the extent of this program, the reasons for it, and the chain of responsibility involved. I would like to know how many tests there were and how controls were exercised, especially since it now appears that many tests were performed all over the country and some tests were done by private contractors. I want to know what justification there was for this endangering of the public health and apparent disregard of individual human rights. How was the need to do these experiments—if there was a need—verified for each individual test proposed? What followup was there on possible infections?

Perhaps most importantly, have the tests ended? If so, could they start up again?

All these questions are vital as we attempt to come to grips with the key issue in these hearings—the use of Americans as unwitting human subjects for open-air germ warfare testing conducted in the public domain by officials of our own Government.

Since the original news reports appeared, my office has received a number of letters from people who want to know if our own Armed Forces, charged with protecting us, could have injured them or their loved ones through indiscriminate open-air testing with disease-producing agents. They do not like the idea that they may have been guinea pigs in germ warfare experiments. In most cases, there is no reason at all to believe that the tests are implicated in these illnesses, and of course no direct proof exists. But I think it is tragic that in a free country like ours these sorts of questions have to occur to people at all. The American people have a right to know what is going on around them, and I hope this hearing will help resolve their lingering doubts.

Lastly, it is my understanding that in the near future we will have another day of hearings, at which time distinguished medical and scientific experts can offer their observations on this program.

Thank you, Mr. Chairman.

Senator KENNEDY. Thank you very much, Senator Schweiker.

Well, I think you understand now, as I know you do, Secretary Miller, what our interests are. We will proceed now with your testimony.

If you will introduce your associates, we will start out on your testimony.

STATEMENT OF EDWARD A. MILLER, ASSISTANT SECRETARY OF THE ARMY FOR RESEARCH AND DEVELOPMENT; ACCOMPANIED BY BRIG. GEN. WILLIAM S. AUGERSON, ASSISTANT SURGEON GENERAL FOR RESEARCH AND DEVELOPMENT; AND LT. COL. GEORGE A. CARRUTH, STAFF OFFICER, CHEMICAL AND NUCLEAR BIOLOGICAL CHEMICAL DEFENSE DIVISION, OFFICE OF THE DEPUTY CHIEF OF STAFF FOR OPERATIONS AND PLANS

Mr. Miller. Thank you very much, Mr. Chairman and Senator Schweiker.

We appreciate the opportunity to appear before you today to present testimony concerning the Army's biological and chemical warfare programs.

With me today on my right are Brig. Gen. William Augerson, Medical Corps, U.S. Army, who will testify on the human testing portion of the Army's program, and on my left is Lt. Col. George A. Carruth, who has spent the past 2 months assembling the report you have before you on the history of the Army's biological warfare program.

I would like first to take a few minutes to present some of the history of the Army's program on biological warfare.

It began in 1941 when the National Academy of Sciences, due to national concern, appointed a committee to make a complete survey of biological warfare (BW). In February of 1942, the committee completed its efforts and reported that BW as a weapon was not only feasible but that appropriate steps should be taken to establish a BW program for this country.

In August 1942, President Roosevelt approved the formation of the War Research Service (WRS), with George W. Merck, of the prominent Merck pharmaceutical firm, as its Director.

The first task undertaken by the War Research Service was the development of defensive measures against possible BW attack. Shortly after program inception, the WRS concluded that essential knowledge could be developed only with larger scale developmental operations.

In November 1942, the WRS requested the Chemical Warfare Service of the Army—which was redesigned the Chemical Corps in 1946—to prepare to assume responsibility for a large scale research and development program.

In 1944, the War Department, specifically, the Chemical Warfare Service, was assigned total responsibility for the U.S. BW program.

It became obvious early in the program that the United States was behind other nations in its chemical and biological warfare capabilities.

Senator Kennedy. Can you tell us where we are today, Mr. Miller, on that question?

Mr. Miller. I can comment first on chemical warfare capability.

I think that we have an aggressive defensive program going on in the Army with respect to protective clothing, masks, detection devices and so forth. I think that we are behind the Soviet Union in terms of capability to use chemical agents offensively.

I think that we are perhaps behind in some respects having to do with training and decontamination. The Russian maneuvers that we know about concentrate on large-scale decontamination training and so forth. They use positive pressure systems inside their tanks and inside their personnel carriers to preclude the entry of chemical agents.

Senator KENNEDY. That is on biological warfare?

Mr. MILLER. I am talking just chemical, Senator, at that point.

On biological, as you know, we have no offensive capability at all. We have turned over to the Pine Bluff, Ark., Arsenal Antipersonnel Agent Production Facility to another agency in the Government. We have no means of dispensing biological agents at the present time and our activity is entirely associated with defensive research with respect to immunization, with respect to protective clothing, masks, detection systems, and so forth.

Senator KENNEDY. Are there other countries now that are doing extensive research in both chemical and biological warfare?

Mr. MILLER. Certainly Russia and its satellite countries are doing extensive research to the best of our knowledge in both chemical and biological warfare.

Senator KENNEDY. Have you made any assessment as to the nature of their offensive capabilities in that area of biological warfare?

Mr. MILLER. We do not have any confirmed evidence that the Soviet Union has in fact destroyed its offensive biological warfare capabilities. They have signed protocol and indicated that they have discontinued production of biological agents, their production facilities have been dismantled and the stockpiles have been removed. However, we have no confirmation that that is the case.

With respect to the United States we have destroyed our stockpiles and permitted inspection and insurance that these stockpiles have in fact been destroyed.

Senator KENNEDY. What significance do you draw from that, or can you draw any conclusions from it?

Mr. MILLER. The significance that I would draw with respect, first, to chemical warfare is that the Soviets clearly intend to maintain an offensive capability, an ability to fight a war in a chemical environment.

With respect to biological warfare I have great concern that we are unable to confirm that they have in fact destroyed biological agents capable of being used on a large scale in an offensive way.

Senator KENNEDY. Your testimony is they may have. They may have destroyed these agents, but you have no evidence that they have?

Mr. MILLER. That is correct.

Senator KENNEDY. What can you tell us about the defenses that are available against biological warfare?

Mr. MILLER. Our own defense at the present time comprises essentially two elements. One is with respect to medicine, in which we are doing medical research on the effects of various known agents and the hardware program which is devoted to development of protective masks, detection schemes and protective clothing. This is of course focused on the needs of the military. It is focused on the needs of the Army as opposed to general population.

Senator KENNEDY. Could you go one step back, and could you give us what your assessment is about whether biological warfare is a usable and effective weapon at the present time?

Mr. MILLER. We believe that biological warfare could in fact be an effective weapon. There have been times, you may have read in our report in the past, where some question as to whether biological warfare would in fact be effective. Our present feeling is that it could be effective unless we are well protected against it.

Senator KENNEDY. We are really talking about a wide variety of different organisms or mechanisms under biological warfare, are we not?

Mr. MILLER. Yes; we are.

Senator KENNEDY. I think it is important to understand whether this is a real or potential problem, and I think we can put it into some historic context, and then understand what steps were being taken to try to deal with it. That is what we are really trying to shape here.

Just briefly, if you could, give us the parameters of the type of danger we are talking about, what we are talking about in layman's language, so that the people can understand what we are referring to.

Mr. MILLER. Let me ask General Augerson from the standpoint of medical and biological.

Senator KENNEDY. We want to establish this and then move on quickly. I think it is important that we get this.

General AUGERSON. If I might drop back to the question about is biological——

Senator KENNEDY. Bring the mike closer to you.

General AUGERSON. Before referring to the conscious work of men, nature has indeed examples of biological warfare, amply demonstrated in plagues and epidemics. The nature of the beast consists of what the targets might be: people, animals, or plants.

The agents cover both living organisms, such as bacteria or viruses, but also include toxins, and this is covered in the treaty, those toxic materials produced by the living organisms. An example would be some of the toxins such as botulinum toxin, a very potent material, even though it is not living.

Senator KENNEDY. There is a variation from that, as I understand, is there not?

General AUGERSON. The spectrum of possibilities range from diseases which are fairly rapidly fatal to agents which might merely render people or forces incapable of operating for a temporary period of time.

Senator KENNEDY. May not kill them in that instance?

General AUGERSON. That is right.

Senator KENNEDY. May neutralize their effectiveness for a period of time, as I understand it, is that correct?

General AUGERSON. Right. Some of the discussions in the past have been—although this potential endeavor has malignant potential—it also has potential possibility as seen by the people that advocated it, of rendering a portion of warfare less ghastly than some of the other alternatives available.

Senator KENNEDY. Let me just ask you about the recombinant DNA issue as it affects this particular question. We have been interested in this subject matter. The committee will have to deal with that in later

hearings, but as I understand, there is substantial research being done by the Soviet Union in the DNA area, recombinant DNA. What is the potential for recombinant DNA in this area of biological warfare? Is there significance to it?

General AUGERSON. Yes, sir. As with most important scientific accomplishments, it has the potential of great harm as well as great good. There are dangerous applications of genetic manipulation that one can imagine. I would hasten to add, sir, that the Department of Defense has conducted in the last year an inventory, if you will, of the work that we have in hand, and I am aware of no work in recombinant DNA——

Senator KENNEDY. You are not doing the work?

General AUGERSON [continuing]. We participate with the National Institutes of Health in the studies and development of guidelines and intend, if we ever do such work, to conform to the established policies and guidelines.

Senator KENNEDY. Just before leaving that subject matter, does the potential in the area of DNA research concern you, how it could be used in——

General AUGERSON. Yes, sir.

Senator KENNEDY [continuing]. In an adverse way?

General AUGERSON. Yes, sir; potentially very powerful way of altering the way living organisms work.

Senator KENNEDY. Do you know of any defenses against it?

General AUGERSON. I think that has to be answered on a case-by-case threat-by-threat basis, sir.

Senator KENNEDY. Now, let me ask just about the nature of the dissent, getting back to the general question about biological warfare. How do you assess the vulnerability of the United States now in terms of that subject matter, Mr. Miller?

Mr. MILLER. We of course have looked at it largely from the standpoint of vulnerability of the military, the ground forces of the Army, in particular. We feel that without appropriate protective mechanisms, without appropriate masks, protective clothing, detection systems and so forth that our ground forces would indeed be vulnerable.

We are looking I think aggressively, we are working at the pace that satisfies us so we are overcoming those problems with respect to the known agents.

As you know, we are not working on even our defensive program on development of any new or presently unknown agent.

Senator KENNEDY. As I understand from your answer, your responsibility is related to the military, is that correct?

Mr. MILLER. Yes, sir.

Senator KENNEDY. Who is protecting the general public?

General AUGERSON. The overall responsibility for plants and animals resides with the Department of Agriculture.

Senator KENNEDY. Department of Agriculture?

General AUGERSON. Yes, sir. That is my understanding.

Senator KENNEDY. That is my understanding, too. What do we know about what they are doing in this area? Do we know whether they are doing anything at all?

General Augerson. I apologize, sir, I am not familiar with their program.

Mr. Miller. I am not familiar with their programs.

Senator Kennedy. Colonel Carruth?

Colonel Carruth. I do not know exactly what their program is, sir. But when the Army closed out its biological laboratories at Fort Detrick, the aspect of the Corps Division, Environmental Sciences part, was turned over to the Department of Agriculture. That is personnel, facilities, and all the equipment.

The Army's budget or the Defense budget that was provided for plant pathology in a study of plant diseases was transferred to the Department of Agriculture. They are continuing a program.

Senator Kennedy. The Department of Agriculture is?

Colonel Carruth. Yes, sir.

Senator Kennedy. But the military does not have the responsibility, as you understand it, other than the protection of the military forces; in terms of crops and animals, that responsibility is the Department of Agriculture's. As I understand it, in terms of the rest of the population, it is the Public Health Service?

Mr. Miller. I believe that is right.

Senator Kennedy. Is there anything you can tell us about what is being done by those agencies? I suppose we ought to hear from them, and we will, but I am just trying to get some sense as to where we are just generally on that issue.

General Augerson. I think it would be better to deal with them.

Senator Kennedy. Before we get back to your statement, Mr. Miller, if you would please review when biological warfare has been used. There have been a few instances in the course of military history, and I think it is probably appropriate in trying to establish the scene here, that you tell us what instances you know about when biological warfare or chemical warfare has been used in modern times.

Mr. Miller. We believe that the Japanese used chemical agents against the Chinese in that area. Then Yemen——

Senator Kennedy. That was approximately what time? You can submit this for the record.

Mr. Miller [continuing]. I will submit the date for the record. In 1941, Japan used mustard against China in Manchuria.

Senator Kennedy. That was the Second World War, though?

Mr. Miller. Yes, sir.

Senator Kennedy. Just before the Second World War?

Mr. Miller. It is about that time, late thirties, early forties.

Senator Kennedy. We will get the date.

What else?

Mr. Miller. Yemen, in internal or civil war, we understand chemical agents were used. We also understand that Italy used chemical agents in its warfare with Ethiopia.

General Augerson. I think from a biological side, Senator, there is historical example of the deliberate use of blankets contaminated by smallpox during the French and Indian war where contaminated blankets were given to the Indians.

Senator Kennedy. Could you run that by me again?

General Augerson. Yes, sir. I may regret it.

My historian friends will hold me to task. I have been told by historical associates that there was strong suspicion that during the French and Indian wars that blankets known to be contaminated by material from smallpox patients, that blankets so contaminated were given to Indians thought to be hostile.

Senator KENNEDY. Let us continue.

Mr. MILLER. I will continue with my prepared statement.

It became obvious early in the program that the United States was behind other nations in its chemical and biological warfare capabilities. General Creasy, one of the past chief chemical officers, testifying before the House Science and Astronautics Committee in 1959 stated:

> It is a publicly known fact that the Germans did have nerve gases, (and) they had issued the orders to use them in Normandy, on D–Day. At that time we had only a vague inkling that such things existed. We did not have any protection against them; our masks would have been completely useless; and had they been used, it is my personal judgment we would never have gotten ashore.

The Germans decided against using nerve gases only after being convinced that the Allies had equal or better capabilities in this area. In reality, all we had at the time was mustard gas.

It was also discovered at the end of World War II that the Japanese had an extensive BW program involving 2,500 people and that they had developed effective BW weapons.

The Korean and cold war years did little to lessen this concern, and the United States became involved in a program that was designed to avoid strategic or tactical surprise or disadvantage in the BW field.

From 1942 until November 1969, when President Nixon banned BW weapons, the biological warfare program proceeded under the watchful eye of congressional committees, boards and advisory councils. Those were generally external to the Army and had broad representation from the Federal Government, academic and scientific communities. Their roles were to insure that the program was conducted in a safe and scientific manner and that useful technology was developed. At one time, the President of the United States had his scientific advisory committee to keep him informed on overall BW efforts, and accepted their recommendations for program changes.

During the active life of the BW program, biological warfare materials were developed, produced and stockpiled. Tests were conducted with both agents and simulants. Most were done on Government installations, under controlled conditions; however, testing was also conducted off Government installations.

Biological simulants were used in testing to determine how far the material would disperse and how much of it would be living at the end of the journey—in other words, how vulnerable was the United States to attack.

Senator KENNEDY. Could we move to appendix 1 to annex E of volume 2 of the report? It is the flow sheet.

Maybe we could just walk through this chart, which I think is probably the heart of the testimony. Maybe Colonel Carruth would do it, if you would like to do it, and I would hope Secretary Miller would make whatever comment he would so we could get some kind of an understanding.

As I understand it, you have the three different areas here. One is the chamber, which probably we are not as concerned about here today. We are concerned about the protection of the subjects within the chamber, obviously, and the notice and consent that they have.

Obviously it would be an area that any panel would be interested in.

The second title is the field.

The third one is the lab.

We are concerned with notification to people and consent in all those areas. In the field now we get the simulants and the pathogens, as I understand it.

Let me give you my understanding.

Then you have the Conus, which is Continental United States; and Oconus, which is outside the United States.

Mr. MILLER. Outside.

Senator KENNEDY. Up at the top you have simulant, which I understand is to be non——

Mr. MILLER. Pathogenic.

Senator KENNEDY. And pathogens which are to some degree of danger.

In the simulant you found, there were some organisms which were actually used which later turned out in a limited area. And those people already had some sickness or illness which may or may not have had some complicating factor. As I understand, there are some statistics in that area, although it is not conclusive.

Mr. MILLER. I think may or may not is a correct assessment.

Senator KENNEDY. There was some statistical increase in some areas, but in the review for Center for Disease Control they could reach no conclusion on that?

Mr. MILLER. No positive conclusion.

Senator KENNEDY. Then we go down to the chart that is underneath it, which is the public domain and military installations.

Colonel CARRUTH. That is correct.

Senator KENNEDY. Let us take, for example, the number of tests under field, simulant tests in the United States, Conus, and then come back over to the public domain. If you could tell us just about how many tests were conducted in those areas and give us a description of that.

Is that possible?

Colonel CARRUTH. Maybe not in total all of them, sir. The records indicate that there were 19 tests. Nineteen tests conducted in public domain using biological simulants. I will make a distinction, Senator, between biological simulants and nonbiological materials, for instance particles and other materials which were released to check dispersion patterns, but were not living materials. There were 27 of those tests conducted in the public domain.

The tests that were conducted——

Senator SCHWEIKER. Twenty-seven of what kind again, Colonel?

Colonel CARRUTH. Nonbiological simulants.

Senator SCHWEIKER. In view of what you've just said, why were only eight tests listed in Army's response to the initial inquiry that Newsday made? I believe Army came up with a list of some eight tests.

Why the discrepancy between eight tests and the number of tests you just mentioned that are listed in the report?

Colonel CARRUTH. Senator Schweiker, the question from Newsday was how many tests had been conducted using the simulant *Serratia marcescens*. In December when the question was asked, we had not compiled this report.

We spent some two months, and went through—well, I do not know how many thousands of linear feet of files trying to pull this data from a program started in 1942 and was not terminated until 1969.

It was a difficult task getting all the data. That was the initial data that we had available at the time the Newsday request came in.

Senator SCHWEIKER. Using which simulant?

Colonel CARRUTH. *Serratia marcescens*.

Senator SCHWEIKER. The New York subway test was listed in the information you provided to Newsday for that article, and SM was not used in that test, as I understand it from your report. So in that very statement you were talking about two different strains of bacteria, not just *Serratia marcescens*?

Colonel CARRUTH. The problem with the subway test, it was not until the actual test report was taken out of the Archives and reviewed that we then were able to determine that SM was not used in the subway, and biological simulant *Bacillus globigii* had been used.

Senator SCHWEIKER. When was it that you determined that SM not used in the subway?

Colonel CARRUTH. In January, sir, of this year, while compiling the the report.

Senator SCHWEIKER. You were mistakenly under the impression that—you gave a report or someone did, I realize you gentlemen are dealing with a lot of material, a lot of past history—but someone gave a report to the Senate Intelligence Committee on which I served about the test in the New York subway system. I am a little bit surprised that those people who reported the details of the test to my other committee did not have to go to the Archives. Why wouldn't they have found out exactly which bacteria was used then? Why did it take another year to get this out when our inquiry in the Intelligence Committee was very much to the heart of the same issue?

Colonel CARRUTH. I cannot answer that question, sir. I was not involved in that hearing.

Senator KENNEDY. Let us review the basic issue that we are talking about here, and that is simulant tests conducted in the public areas. That is what we are talking about here, are we not?

Colonel CARRUTH. The majority of the simulant tests were conducted on military installations.

Senator KENNEDY. We are not talking about the military installations, we are talking about public domain in those areas. How many did you say were conducted?

Colonel CARRUTH. Nineteen, sir.

Senator KENNEDY. Maybe you could just sort of describe the procedures a little bit to the best of your knowledge, and how they were collected and what actually happened in these areas, what you were trying to deal with?

Colonel CARRUTH. The early tests that were conducted were specifically designed to determine the vulnerability. The initial tests conducted and listed in the report were ones in Washington, and these were to test the vulnerability of the Pentagon to simulated biological attacks.

They were testing to determine whether or not it could be done covertly, thereby infecting the members of the military services and knocking out our headquarters.

The next test that was conducted was one to determine the vulnerability of our Navy ships at sea to a biological attack. A test in San Francisco was to determine whether or not an enemy could conduct a biological attack at sea and infect the population of our cities.

I might say that with the simulants used, and the San Francisco test was done in 1950, the evidence that was available at that time indicated that both simulants, both *Serratia marcenscens* and *Bacillus globigii*, were nonpathogenic. Since they were simulants, we did not expect to find any effect on the human population.

The only way we sampled was the use of mechanical sampler to determine the number of living organisms that were disseminated over the area.

Senator SCHWEIKER. May I ask a question on that very point, Mr. Chairman?

Senator KENNEDY. Yes.

Senator SCHWEIKER. I have an article, which I guess by now you are more than familiar with, which appeared in the AMA Archives of Internal Medicine in 1951, called Infection Due to Chromobacteria, by Dr. Wheat and others.

And going back to the same time frame of the San Francisco testing that you just described, it calls to the attention of the medical profession some 11 cases of infection with the SM organism, which is the same organism that you used in that test.

It goes on to say, in essence—I do not want to characterize too much the wording—but basically the authors are reporting what they consider to be a very unusual numerical outbreak of SM infection in the hospital. One person died.

I wonder, when did the Army become familiar with the fact that a medical article had been written that some unusual incidence of SM infection occurred in the bay area around the time of the testing? When did this come to the attention of the Army authorities?

General AUGERSON. I believe in terms of documentation, Senator Schweiker, there is in the files from the biolaboratory at Fort Dietrick some record of the meeting called in 1952 where an expert panel, civilian, medical biological consultants, was called in by the occupational safety officer at Fort Dietrick to consider the report in the Wheat article and other matters, and to advise the Army as to what the hazard was.

Senator SCHWEIKER. What year was that?

General AUGERSON. 1952.

There is a document that records the meeting, so presumably the awareness followed the article and preceded——

Senator SCHWEIKER. In fact, did I understand the report to say that the safety officer was so concerned about it then that he ordered that

no tests would be conducted near hospitals and other facilities where people might be endangered, is that correct?

General Augerson. That is my understanding, sir.

Senator Schweiker. What I am confused about, and what deeply troubles me, is here is an American Medical Association journal article which obviously indicates some danger signals. Here is the Fort Detrick safety officer, who is obviously concerned—and I appreciate your bringing that out. That was in 1952.

Yet the Army kept on using this same material at least up through 1968.

In your report here, which you have—well, I am beginning to deal with classified information, so I will have to withdraw that part—I will phrase it in another way.

I believe, notwithstanding the safety officer and notwithstanding the AMA Journal report about SM, you ran these tests up through 1968, some 16 years after the Fort Detrick safety officer had determined he felt there was a serious problem and 17 years after the AMA article said they caused a death.

That is what I have the most trouble with.

General Augerson. I can well understand how that looks to you, sir, and I can well understand the public concern.

The technical issue on the dangers of this organism is somewhat more complicated. I am not going to try to make it complicated here.

But it was not until 1969 in Lancet and in 1970 in the Journal of the American Medical Association that editorials were written bringing to the attention broadly of the medical profession the hazard of this organism. This followed a period of several years when many hospitals across the country far removed from any work that the Army did experienced growing difficulty with serratia as a source of infection in debilitated hospital patients, patients who had intravenous or urinary catheters in place.

There were unexplained outbreaks in the civilian hospitals far removed from any of our tests. There were examples of investigators in 1957, and I think in some later years, deliberately putting in—in good conscience, because they did not believe it was a pathogen, putting serratia into or on people in order to follow the movement of what they thought were benign organisms, so that although I can well understand how the situation looks, sir, the main weight of opinion was that it was not dangerous.

Senator Schweiker. You do concede now that the main wave of opinion is that SM can be dangerous if a person has some genetic characteristic that makes him susceptible to pulmonary or pneumonia diseases; or if he is in a rundown condition and might be more susceptible because he has had an operation and or has some kind of pre-existing disease or infection that other bacteria caused. If a person is in that kind of rundown condition, we now know it would be very dangerous for him to be exposed to SM bacteria, is that a fair statement, General?

General Augerson. There would certainly be some danger, and it is not the sort of thing in the light of today's knowledge that we would consider doing under the circumstances that took place in the past.

There are still circumstances where that organism can be properly and may well be used under controlled situations.

Senator Schweiker. You do have in your unclassified information a statement that infections with this group of organisms, Serretia bacteria, were rare and until the 1950's the SM organism was considered to be essentially nonpathogenic.

Here you are saying, in your report entitled "Information for Members of Congress" which was issued in January, that up until the 1950's this was considered essentially nonpathogenic.

By the same token again, we continued testing with the organism up until 1968, some 18 years after that time.

General Augerson. I believe Colonel Carruth may have some information as to what changes in test procedure were taken under the advice of this ad hoc advisory group.

Colonel Carruth. In the ad hoc committee report, there were two points that were brought out. One was the fact that they considered the use of SM in even overpopulated areas allowable within the context, if required for advancement of the BW program, and made a further recommendation that if we did conduct any further tests in populated areas, that we should have a subsequent and a followup program in the hospitals to determine if the cases in San Francisco were coincidental.

However, following that, and as you have correctly stated, the safety director at Fort Detrick did establish controls. His guidance was that SM would not be released over areas where debilitated or aged people were located, such as hospitals and sanitariums.

He established rather stringent controls for pretests that were required in those areas before the bacteria Serratia marcescens could be released.

Senator Schweiker. It is my understanding that in connection the San Francisco Bay test in September 1950, a series of monitoring stations were set up, and when the material was actually dumped in the ocean, aerosolized by the surf and blown inland which was the purpose of the project, to determine how effective the impact of an offensive weapon would be against the coast and some sources familiar with the testing procedure have indicated that the monitoring stations picked up the bacteria as far as 50 miles inland.

Can you give us any information about how far the bacteria traveled in tests such as that?

Colonel Carruth. Sir, our records do not indicate that was an Army test.

However, the 1950 test——

Senator Schweiker. I did not say it was an Army test.

Colonel Carruth [continuing]. I do not have knowledge of that test.

Senator Schweiker. I believe it was a Navy test. I think you folks participated indirectly in it, but it was a Navy test, as I understand it.

But you do not have knowledge of it?

But there were records kept. There was a very detailed recordkeeping system, monitoring the air and monitoring the dispersion of bacteria, and we have heard from some pretty good sources in the lab itself that they were actually detecting some of the bacteria as far away as 50 miles inland. This again was back in the 1950's.

Are you saying you do not have records, or you do not know, or you dispute that?

Colonel CARRUTH. The only knowledge I have, sir, is that *Bacillus globigii* was the organism used. I do not have a test report. I do know that our test in 1950, we used a spray device to disseminate organism. and it was not something that was done with surf, sir.

Senator KENNEDY. We do want to move on. I do not think that there is any question in the minds of the American people that open air testing is basically repugnant to our American system; that in many instances, at least some important instances, tests were conducted in the public domain—well, we are talking now about the type of testing that is in the public domain—but there were determinations made subsequently that some of these particular organisms were dangerous to the public and were actually withdrawn.

We know with the expansion of knowledge that we may determine in the future that some of the others that were used had some kind of potential or real danger to people, and that the American people were not really notified or informed, the community was not, unlike even where we see the DNA program in our community of Cambridge, Mass. We are informed to make some judgments about these things.

I hope you would agree, at least with myself, and I think the overwhelming majority of the American people, that in that area there should not be any further testing of any of these devices in the public domain.

Can we agree on that? I know you are speaking as a professional person, but would that not certainly be your conclusion based upon the study in this area?

Mr. MILLER. That is the conclusion I would reach.

Senator KENNEDY. We have also in the area of pathogens the situation, as I understand it now, where there were some organisms which were tested in the public domain, which, after a period of time, you found presented significant health hazards.

Senator Schweiker has reviewed the SM. They were not pathogens at the time. They were simulants at the time. But you found out later, so there were populations that were put at some risk without their understanding, without their consent, without their awareness of it.

That is something which I think all of us agree is wrong. It has ceased, as I understand it, and it has been ended since 1969.

Am I correct in that?

Mr. MILLER. That is correct.

Senator KENNEDY. In the area of pathogens, there was use of these which are the more dangerous, obviously, bacteria. There was some testing that was used in various military installations, in open air, and in your report today you are revealing where those were and the times that they were held and how many there were.

How many were there, Colonel?

What does your report show?

Colonel CARRUTH. I will have to count them, sir, I do not have the exact number.

Senator KENNEDY. There were a number. They are listed here.

But for the point of our hearing today, the fact is that even being used on military installations, on those military installations, do you know whether there were families that were living on those installations, whether there were women and children and dependents on those military installations, to your knowledge?

Colonel CARRUTH. At Dugway Proving Ground, yes, there are dependents that live at Dugway.

Senator KENNEDY. So they would have been put at some risk, would they not?

Colonel CARRUTH. Not with the monitoring systems, the controls that were put on there.

I might mention that Dugway Proving Ground is approximately the size of the State of Rhode Island. It is a rather large installation, and the biological test facility is some miles away from the populated areas.

Senator KENNEDY. How many other areas were there?

There were 8 series of tests, is that correct, and 54 agents used? That is what your report shows. This is what is here [indicating].

In those series of tests, were there others that were exposed?

At least in the area, were dependents in those areas, were there civilians working in any of those?

Colonel CARRUTH. The only other areas in which tests were conducted, were two with antianimal agents, early in the biological program. The antianimal research program was terminated in 1954. One test at Eglin Air Force Base was done with antianimal agent against swine, and a test at the University of Wisconsin was with the Newcastle disease, which is a virus that infects chickens.

Senator KENNEDY. The military being infected within this area, were they being informed that these tests were taking place?

Colonel CARRUTH. The people who were conducting the tests knew what the test was about, sir.

Senator KENNEDY. That is not what I am asking. I am asking whether any of the people in any of the vulnerable areas were made aware of the tests?

Mr. Miller, do you know?

Mr. MILLER. I think the answer is only those who had official capacity with respect to the tests were informed.

Senator KENNEDY. I understand your position is obviously that if there were going to be any kind of tests, that the military personnel should be informed of the dangers of any of these, the risk-benefit ratio, am I correct, Mr. Miller?

Mr. MILLER. You are correct.

Senator KENNEDY. And that in these instances that was not the case?

Mr. MILLER. I think with everything we know today as compared with what we knew then, if we are going to do any more open air biological testing on military installations, we will assure that the general public is safe.

Senator KENNEDY. Do you have any plans for any further open air testing?

Mr. MILLER. We have a plan under formulation to do open air biologic tests at Dugway of the XM–19 alarm system. We believe it is necessary to test the alarm system against the simulant to insure its suitability.

Senator KENNEDY. That is a detection system?

Mr. MILLER. Yes, sir; it is a detection system, detection and alarm.

Senator KENNEDY. Colonel Carruth, do you have an opinion as to the nature of the vulnerability of the United States in terms of bio-

logical testing in the nature of our preparedness or our ability to deal with biological warfare?

Colonel CARRUTH. I think the basic answer to that, Senator, we should probably cover in the closed session.

However, some generalities. Since biological agents are not that difficult to manufacture, since they can be introduced without a signature, it can be released without being easily detected, most aspects of our way of life are vulnerable to biological attack.

Senator KENNEDY. So you see the necessity for some continued, testing I suppose from a national security point of view?

Colonel CARRUTH. When the biological program was terminated, there were several groups and areas in which the emphasis was to be placed in our biological defense program.

Secretary Miller has already covered basically all of them. That was in physical protection, to be able to protect the personnel. Medical defense, which is an area General Augerson has expertise in, and another area is in vulnerability assessments. Basically vulnerability assessment is the utilization of the data which we have gathered from the previous tests to analyze the vulnerability of our forces to potential enemy biolgical attack.

There may be some time in the future that we are going to have to analyze whether there is a specific area of vulnerability that takes additional tests. But, at this time, we have none planned.

Senator KENNEDY. Senator Schweiker.

Senator SCHWEIKER. Thank you, Mr. Chairman.

I would like to address a couple of questions to you about a test that occurred at Fort McClellan, Ala., in 1952. I guess to do that I have to read a few statistics here.

I might say these statistics come from Dr. Thomas Chester, who is a Center for Disease Control employee assigned to the Alabama Health Department, Bureau of Preventable Diseases. These are official Alabama Health Department statistics, and pneumonia is a reportable disease in Alabama, although the reporting system is not perfect.

1952 was the year the simulant test was conducted in Fort McClellan, using both SM and BG. I am addressing myself to the SM aspect of the test.

The interesting thing is, if you isolate Calhoun County, some very significant figures show up.

In 1951, pneumonia cases in Calhoun County represented 4.6 percent of the statewide total of pneumonia cases. In 1952, the percentage jumped to 12.3 percent, three times the rate of the preceding year. And in the year after the test, 1953—the year of the flu epidemic, I might add—in 1953, the rate dropped back down to 4 percent, and then continued to level off, at 4.2 percent in 1954.

I am disturbed about a couple of things. I want to make clear I do not necessarily claim there is a cause and effect relationship because that is very difficult to say. But it does strike me as unusual that in a 5-year period, the averages are pretty consistent, except for the year that the test was conducted at Fort McClellan. In that year, for that particular county area only, the number of pneumonia cases tripled.

I think what concerns me more is that I believe supposedly there should have been some sort of monitoring system set up. I guess my

question is, what is your reaction to these statistics, No. 1; and, No. 2, did in fact the people responsible for these tests establish a monitoring system to check on whether pneumonia-like illnesses occurred in test areas such as this, where the rate tripled in the test year, compared to years before and years after the test?

General Augerson. I am probably as well prepared to answer that as any.

As far as I know, Senator, I am not aware of any special surveillance system established to monitor the changes in the incident of various conditions in surrounding communities as part of that program. There may have been, but I am not aware of it.

I would observe, however, that it is very difficult dealing with statistics, such as this. For example, in the year when the pneumonia figure tripled between 1951 and 1952, as I recall, I believe also the influenza cases in the county also tripled.

It is hard for me to see how this is a relationship between our testing and influenza.

Senator Schweiker. I thought 1953 was the big flu impact, not 1952.

General Augerson. There was a much larger number of cases of influenza in 1953. However, the number of cases of influenza, I do not have the notes here in front of me, I do recall that the influenza cases went up sharply in that county as did pneumonia cases. But it is hard to prove negatives.

As I say, it is very difficult.

Senator Schweiker. In your survey of these tests, did you find any rationale or explanation as to why some kind of specific monitoring system was not set up, to protect the population?

General Augerson. As you know, I was not involved——

Senator Schweiker. I realize all three of you are in very difficult positions. I understand that.

General Augerson [continuing]. But trying to reconstruct this, I think the assumption was that under the conditions established, there was not a threat to the public.

I do not believe you mentioned today the rather extensive consultation that took place in the matter of testing with responsible individuals in the public health community to include in many of these cases informed local health officials.

Senator Schweiker. I can accept that. But I have trouble relating that to why the Public Health Service, of all people, would not have said let us monitor what you are dealing with, so we will know what any effects of this may be.

It would seem to me the Public Health Service, frankly, as well as the Army or whoever did the tests, would feel some responsibility to do this.

General Augerson. As I say, it may well be that it was merely—everyone made an assumption of the innocence of these organisms.

Senator Schweiker. Yet there was an AMA article back in 1951, 1 year after the San Francisco tests, an article in Journal of the AMA saying there was a great danger here with this disease. So, surely, the Public Health Service would be familiar with that situation, if not the Army?

General Augerson. Even the AMA article you refer to, sir, indicated that these were not thought to be highly infectious organisms, and people who were infected in that 11 cases were in rather special circumstances.

Senator Schweiker. One person did die, though.

General Augerson. Yes, sir.

Senator Schweiker. The other question is, do you know exactly when the Florida test in Key West, the Monroe County area, was conducted?

All I have is the year 1952.

Do you have a date on that test? I do not believe it is in any of your lists. You may not have that date.

Colonel Carruth. I do not have the exact date of that test. We could not find the test report.

We found only fragmentary data.

Senator Schweiker. The other statistics I want to bring out, and I want to make it clear that this is very speculative, but it is disturbing in view of the Alabama figures, relate to the Key West test. A lot depends on when the test was conducted, because the Florida State Health records show that 1953 is the only year in which Monroe County's rate of pneumonia cases per 100,000 population exceeded the statewide rate.

I guess my big question is, when did the test occur?

If it occurred toward the end of the calendar year, it could obviously have had an impact reflected in these figures.

At this point, are you going to be able to get that information?

Colonel Carruth. I could not find the exact date, and I could not find the test report. I found fragmentary evidence that the tests were to be conducted starting April 14, 1952. A quarterly report for the period April 1 to June 30, 1952 contained information that the test had been conducted.

Senator Kennedy. Secretary Miller, I think we covered the thrust of your testimony.

If there is anything further, we will include it all in the record.

Mr. Miller. Biological simulants were used in testing to determine how far the material would disperse and how much of it would be living at the end of the journey—in other words, how vulnerable was the United States to attack.

Release of these simulants in populated areas was not done to study the effects of those materials on human beings, but to develop knowledge necessary to prepare defensive measures.

Biological simulants released were chosen because they were believed harmless in the way they were used. They had no known harmful effect on human beings.

Release in and near cities, in real world circumstances, were considered essential to the program because the effect of a builtup area on a biological agent cloud was unknown.

One example of simulant use was the test conducted in a New York subway. That test was conducted to determine how vulnerable a mass transit system was to covert attack. It was designed to test how widely biological material would be disseminated by releasing it at a single point in the subway.

The simulated user *Bacillus subtilis*, more commonly known as *Bacillus globigii* or GB, was believed to be, and is still believed to be, perfectly harmless.

There probably is some BG in this room right now, not because we brought it with us, but because it is found in most places naturally.

Throughout the biological warfare program, the Army has been as candid as possible without making classified material public.

Classified material, however, has been available to Congress, and much of it provided over the years in closed sessions. In addition, there has been extensive publication in scientific journals, and more recently unclassified reports to Congress have been reprinted in the Congressional Record.

Since 1969, the Army has busied itself with undoing the efforts of the preceding 27 years to establish a BW offensive capability. Total destruction of all DOD BW stocks and munitions was accomplished between May 1971 and February 1973. The BW facility at Pine Bluff Arsenal was then turned over to the Department of Health, Education, and Welfare for use as the National Center for Toxicological Research, and the biological laboratories at Fort Detrick are being used by the National Cancer Institute.

Today, the Army does limited testing in restricted areas to maintain an adequate defensive posture. We are interested in developing personal protective clothing and masks that protect against all types of known biological agents as well as alarm systems and detection devices.

We are maintaining an active program in vulnerability assessment and one in medical diagnosis, prevention and treatment.

I have furnished each member of the subcommittee a copy of a comprehensive unclassified report on the Army's BW program. Your chairman was furnished a classified copy of the report earlier.

I would like to ask that the unclassified report be made a part of the record.

[The report referred to follows:]

UNCLASSIFIED

U.S. ARMY ACTIVITY

IN THE U.S.

BIOLOGICAL WARFARE PROGRAMS

VOLUME I

24 FEBRUARY 1977

UNCLASSIFIED

CONTENTS

Volume 1

Purpose and Definition

This report provides a comprehensive review of the U.S. Army's role in the Biological Warfare (BW) program so that Congress and other government officials can assess accurately BW issues which are being raised continually. The report is limited to the BW technical program and the policies and governmental controls which guided the program.

The acronym BW will be used throughout to connote biological weapons and defense programs. It also encompasses the terms "bacteriological" and "bacterial" which were used interchangeably in the early periods. BW is defined as the use of microorganisms ("germs"), such as bacteria, fungi, viruses, rickettsiae, and substances (toxins) derived from living organisms (as distinguished from synthetic chemicals used as gases or poisons) to produce death or disease in humans, animals, or plants. For BW purposes, the most effective and efficient route of entry of disease microorganisms into the human and animal body is normally by breathing into the lungs. For plants deposition on external surfaces is usually sufficient to cause infection.

Preface

In preparing a comprehensive review of the Army BW programs, it is crucial that the activities be portrayed in the context of the times and circumstances in which they occurred. For this reason, the events have been related to the appropriate period of national security activity. It has been difficult, at times, to provide finite data as some of the detailed working papers have since been destroyed; however, much data is available and every attempt has been made to use primary documents or the most credible derivative data.

The policy of the United States regarding biological warfare between 1941 and 1969 was to first deter its use against the United States and its forces, and secondly to retaliate if deterrence failed. Fundamental to the development of a deterrent strategy was the need for a thorough study and analysis of our vulnerability to both an overt and covert attack while concomitantly examining the full range of retaliatory options. Recognition by American scientists of the potential of BW and concern about the United States lack of preparedness prompted the start of the U.S. program in World War II. From its inception, the program was characterized by continuing in-depth review and participation by the most eminent scientists, medical consultants, industrial experts, and government officials.

As a result of President Nixon's ban on BW weapons in November 1969 we have destroyed our limited BW weapon stocks. Because a potential BW threat still exists, the U.S. still maintains a defensive BW program in accordance with the 1969 Presidential policy statement. This program seeks to develop effective warning and detection devices, protective clothing and equipment and continues to assess the vulnerability of the U.S. and its forces to enemy BW attack. The problems of biological defense are greater today than at any time in the past because of the technological advances in the biological sciences.

Chapter 1

Introductory Survey of United States Army Biological Warfare Programs (U)

World War II

In the fall of 1941, opinions differed on the potential effectiveness of BW. Sufficient doubt existed so that reasonable prudence required that a serious evaluation be made as to the dangers of a possible attack. Secretary of War Henry L. Stimson therefore requested the National Academy of Sciences to appoint a committee to make a complete survey of the BW situation (two months prior to the attack on Pearl Harbor). After careful study, the committee concluded in February 1942 that BW was feasible and urged that appropriate steps be taken to reduce U.S. vulnerability to BW attack. Secretary Stimson then recommended to President Roosevelt the establishment of a civilian agency for this purpose. With approval by the President, the War Reserve Service (WRS) was formed in August of 1942 with George W. Merck of the Merck Company, a pharmaceutical firm, as Director. WRS was attached to the Federal Security Agency and served as a coordinating agency using the resources of existing government and private institutions to carry out the BW program. Scientific advice was received from a committee of prominent scientists set up by the National Academy of Sciences and the National Research Council. An exchange of information was also inaugurated with the United Kingdom and Canada.

The first task undertaken by WRS was the development of defensive measures against possible BW attack. Its major achievement was the organization of a research and development program (R&D now referred to in the Department of Defense as research, development, test and evaluation, RDTE) to extend the paucity of knowledge about BW. It was concluded that significant knowledge could not be gotten without larger scale developmental operations.

Therefore, in November 1942, WRS requested the Chemical Warfare Service (CWS) of the Army (redesignated the Chemical Corps in 1946) to prepare to assume responsibility for a larger scale research and development program, including construction and operation of laboratories and pilot plants. Up until this time the Army had only been involved in the coordinating Committee activities of the WRS. The Army chose Camp Detrick, Frederick, Maryland, a small National Guard Airfield, as the site for new facilities and construction started in April 1943. WRS turned over to the Army CWS all operational projects but continued to exercise general supervision over the entire BW program.

The Office of Strategic Services alerted the Joint Chiefs of Staff in December 1943 to indications that the Germans might be planning to use BW. The BW program was accordingly stepped up and, in June 1944, the complete program was transferred by direction of the President to the War Department. At the direction of the Secretary of War, the Chemical Warfare Service was made responsible for work on BW agents, for BW intelligence, and for BW defense. The Army Surgeon General was directed to cooperate with the CWS on matters of BW defense. The program continued as a joint effort with Navy and other Federal department participation. The R&D program was greatly accelerated with the addition of field testing facilities and a production plant. When the War Department assumed full responsibility, Secretary Stimson appointed Mr. Merck as a special consultant on BW. He also established the United States BW Committee in October 1944 with Mr. Merck as Chairman and with senior representatives from the military services.

At its peak, the Special Projects Division of the Army CWS, which was the main element for carrying out the program, had 3,900 personnel, of which 2,800 were Army, nearly 1,000 Navy, and the remaining 100 civilian. The work was carried out at four installations: Camp Detrick was the parent research and pilot plant center; field testing facilities were set up in the summer of 1943 in Mississippi, another field testing area was established in Utah in 1944; and a production plant was constructed in Indiana in 1944. All work was conducted under the strictest secrecy. In addition to the coordination with the United Kingdom and Canada, a joint program was undertaken by an American-Canadian team to develop defenses against rinderpest disease of cattle.

During World War II, the policy of BW use implicity paralleled the policy for Chemical Warfare (CW); that is, retaliation only. While the United States had not ratified the Geneva Gas Protocol of 1925 which prohibited CW and BW, President Roosevelt and Prime Minister Churchill announced this policy in unilateral statements in the spring of 1942.

End of World War II

At the end of World War II, the construction activities and the testing programs were terminated and the remainder of the activities gradually phased down to a research status. The production plant, Vigo Ordnance Works, constructed at Terre Haute, Indiana to provide a retaliatory capability using aerial bombs, ceased operation before infectious BW agents production began. Only a harmless simulant biological agent (Bacillus globigii or BG) was produced. The project was terminated and the plant was subsequently sold to

the Charles A. Pfizer and Company for commercial use.

By the end of World War II, a wide variety of disease agents effective against man, animals, and plants had been studied and limited field testing conducted. Extensive work on safety measures to perform BW research and development had been necessary as no comprehensive procedures, methodologies or equipment had been available at the start. Even so, infections occurred. These were later reported publicly in the extensive War Department press release on BW in January 1946. The release was the first notification to the nation and the world of United States work in BW. It reported, in part, that:

> "In all work on biological warfare carried on in the United States, extreme care was taken to protect the participating personnel from infection. Many new techniques were devised to prevent infection and proved highly successful. Hospitals and dispensaries were maintained at all installations, staffed with both Army and Navy personnel and were equipped to treat accidental infections. As the result of the extraordinary precautions taken, there occurred only sixty cases of proven infection caused by accidental exposure to virulent biological warfare agents which required treatment. Fifty-two of these recovered completely; of the eight cases remaining, all are recovering satisfactorily. There were, in addition to the sixty proven cases, 159 accidental exposures to agents of unknown concentrations. All but one of these received prompt treatment and did not develop any infection. In one instance, the individual did not report exposure, developed the disease, but recovered after treatment."

Although remarkable achievements were made, the potential of BW had by no means been completely measured; and Mr. Merck in his final report to the Secretary of War recommended that the program be continued on a sufficient scale to provide an adequate defense. A summary of accomplishments stated in the report are shown at Annex A.

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Chapter 2

Research and Planning Years After World War II (1946-49) (U)

Responsibility and Authority

When World War II ended, the CWS had as its major mission preparedness for CW and BW in the context of a policy of retaliation only. The BW program of the Chemical Corps was justified annually to Congress along with other Army programs. During the hearings in 1946 before the Subcommittee of the Committee on Appropriations, House of Representatives, on the Military Establishment Appropriations Bill for 1947, the Chief Chemical Officer discussed the BW program including the accomplishments applicable to public health and welfare and the potential effects of biological warfare. In the 1947 hearings to the same subcommittee, a question was raised as to why the Chemical Corps should be retained as a separate branch of the Army. General Waitt defended its retention on the basis of its past contributions and the future need for its technical military expertise. This issue was seriously debated in the Army at that time and was resolved in favor of continuing the separate Army Chemical Corps. A summary of the extent to which Congress was aware of the BW program is at Annex B.

With the establishment of the Office of the Secretary of Defense (OSD) in 1947, overall technical direction of the BW R&D program was vested in the "Research and Development Board" of OSD which was constituted at the same time. The Board had a Committee on Chemical and Biological Warfare which carried out this responsibility. The Committee consisted of a full-time three man executive staff and eminent consultant members from science, industry and government.

The authority channel of management control was from the Secretary of Defense through the War Department (renamed the Department of the Army) to the Chief Chemical Officer and on to Camp Detrick. Military command at Camp Detrick was limited to administration of the installation service and support activities; direction of the technical program in the laboratories was the assigned responsibility of the Technical Director. Both the Commanding Officer and Technical Director were under the Chief Chemical Officer.

Scope of BW Program

The BW work was primarily confined to Camp Detrick with a small number of contracts in universities and industry. Activities were concentrated on BW agent research and defensive aspects; some applied research on dissemination devices; the collation and digestion of the large scale R&D effort carried out during World War II; and the formation of sound research and development program frameworks. The research and development program is discussed in more detail in Annex C.

In response to concerns about the vulnerability of the United States to covert attack, the Research and Development Board, OSD, requested its Committee on BW to consider the implications of BW in sabotage in extension of a study by a Special "Ad Hoc Panel on Sabotage." In October 1948, the Committee submitted a "Report on Special BW Operations" concluding that: BW was well adapted to subversive use; U.S. was particularly susceptible to attack by BW operations which presented a grave danger, and the current BW R&D program did not meet the requirements to defend against subversive BW operations. The Committee provided a blueprint on goals, objectives, organization, and examples of projects. One of their defensive project examples was conduct of vulnerability tests on " . . . test ventilating systems, subway systems,

and water supply systems with innocuous organisms . . .". Their recommendations were subsequently approved and became the genesis of open air vulnerability tests and covert R&D programs conducted by the Army, some of which were in support of the Central Intelligence Agency (CIA). As a result of the study recommendation a Special Operations (SO) Division was established at Camp Detrick, MD in May 1949.

While most of the BW R&D program concentrated on the antipersonnel aspects of BW, there are also smaller programs in antianimal and anticrop BW as outgrowths of the World War II effort. The antianimal program was closely linked to the antipersonnel program since certain diseases produced effects in humans and animals, and the scientific disciplines involved are identical or very similar. The anticrop R&D program differed significantly in that agricultural sceintific disciplines were required. Additionally, the anticrop program at Camp Detrick also included R&D on chemical substances which could be used against plants for either defoliation or crop destruction. The latter was considered CW but was performed at Camp Detrick as a matter of scientific economy. As with the antipersonnel R&D programs, the antianimal and anticrop activities were heavily research oriented during this period.

From the end of World War II until 1950, no production was carried out for purpose of operational readiness and no facilities were available for such work. Laboratory scale research and pilot plant development proceeded as a natural extension of the research programs. New facilities for pathogenic BW agent pilot plant production were also planned during this period. (Annex C and D).

Testing

At the end of World War II, all the field test sites with the exception of Dugway Proving Ground, were abandoned and the primitive Granite Peak BW

test site at Dugway Proving Ground, Utah was inactivated. Pathogenic agent testing at Camp Detrick was confined to closed laboratory size chambers and was directly related to agent evaluation and medical defensive aspects. In this period, no control experimentation on humans had yet been conducted at Camp Detrick even though such experimentation was an acceptable practice in the development of vaccines within the U.S. medical community. Small scale outdoor testing with two biological simulants (BG, a spore forming microorganism; Serratia marcescens, a vegetative organism commonly referred to as SM) and inert material such as talc, were conducted at Camp Detrick. These materials were considered to be totally harmless by scientific and medical experts. In 1949, construction of an enclosed one million liter test sphere (the largest in the world) was built at Camp Detrick and BW explosive munition tests with pathogens were started.

The first open air sea tests with biological simulants were conducted in 1950 aboard U.S. naval ships in the Atlantic Ocean off Norfolk, VA. Simulant clouds were released to envelop ships so as to assess their vulnerability and to test prototype BW electronic detection devices. Annex E provides a chronological listing of the open air tests conducted and Annex F discusses some of the tests which have appeared in the news recently.

Open air testing of infectious biological agents was considered essential to an ultimate understanding of BW potentialities because of the many unknown factors affecting the degradation of microorganisms in the atmosphere. However, the primitive test experience in World War II, revealed that too little was known on how to assure absolute control of infectious organisms in the open air from a safety and environmental

standpoint. Safety and medical aspects in BW R&D as well as testing were always of overwhelming concern; and adequate safety procedures and controls had to be operative prior to the initiation of any new R&D BW projects. Annex G summarizes the BW safety program.

Support to Other Government Agencies

In addition to its internal BW technical work, the Army provided what was tantamount to "contract services," to other military services and government agencies since it had the most comprehensive and largest BW program. From its formation, the mission of SO Division was to carry out research on potential methods of enemy covert BW attack and also to assess the BW implications of the growing concern about sabotage in the cold war. Activities of SO Division in support of CIA were investigated and recorded in the 1975 Report of the Hearings in September 1975 before the Senate Select Committee, chaired by Senator Church, to study Governmental Operations with Respect to Intelligence Activities and, therefore, will not be discussed in detail in this report.

Program and Policy Reviews

The military significance of BW and the need for a BW program were constantly reviewed at the highest levels of OSD between 1948 and 1950. In July 1948, a comparative study of BW, CW and radiological warfare (RW), was made by the Research and Development Board at the request of the Joint Chiefs of Staff (JCS). Subsequent studies were made periodically to evaluate comparative military aspects, time to accomplish R&D, system costs and technical feasibility. In March 1949, the Secretary of Defense

established a committee to report on the status of the BW program. The committee report in July 1949 indicated that the U.S. BW defense posture needed improvement.

The general United States policy for use of CBR warfare, i.e., only in retaliation against its use by an enemy, was reevaluated at the highest military and civilian levels in 1949. This culminated in February 1950 when the President approved continuation of the retaliation only policy.

In October 1949, at the direction of the Secretary of Defense, the Research and Development Board established an Ad Hoc Committee on CBR Warfare to investigate all the technical and strategic aspects of the subject.

In June 1950, after extensive research, the Committee submitted a report recommending changes in CBR weapons policy, establishment of a BW production facility, that field tests of BW agents and munitions be conducted, and all aspects of BW research programs be expanded.

Chapter 3

Expansion of the BW Program During the Korean War (1950-53)

Attainment of BW Retaliatory Capability

At the onset of the Korean War on 25 June 1950, the report of the Ad Hoc Committee on CBR Warfare was under review by the Secretary of Defense. The Korean War spurred efforts to again develop a BW retaliatory capability based on the ominous threat of USSR involvement but there was reluctance to publicize the program.

On 27 October 1950, the Secretary of Defense formally approved all of the Ad Hoc Committee on CBR Warfare recommendations except one relative to changing U.S. BW retaliatory policy, and directed their implementation. The U.S. Army Chemical Corps assumed prime responsibility for carrying out the Committee recommendations. The Army was authorized to construct a BW production facility at Pine Bluff Arsenal (PBA, near Pine Bluff Arkansas). Design of the facility was accelerated and ground was broken in February 1951.

The first limited BW retaliatory capability was achieved in 1951 when an anticrop bomb was developed, tested and placed in production for the Air Force. Anticrop Agent production sites were carefully selected for safety with the coordination and approval of the U.S. Department of Agriculture.

Expanded Program

The BW test program was also accelerated in this period. (Annex E). In late 1949, vulnerability tests with simulants were started in response to the Report on Special BW Operations which pointed out the U.S. susceptibility to covert BW attack. The first large area vulnerability test

was conducted in San Francisco Bay in September 1950 using the simulants BG, SM and fluorescent particles. (Annex E). Small scale pathogenic field testing at Dugway Proving Ground was resumed in 1950 after a five year lapse and expanded in 1951. (Annexes H and I). The first anti-animal BW test was conducted in July 1951 at Eglin Air Force Base, Florida. In 1954, the antianimal BW program was discontinued because it was concluded that it lacked military worth. This is covered in more detail in Annex C.

In September 1951, the JCS assigned priorities to the Army for the development of specific BW agents. Also, the state of CBR readiness was reviewed by the Secretary of Defense in November 1951 with the conclusion that a higher degree of readiness and more manpower was required in the development of CW and BW munitions. A directive to improve CBR readiness was issued to all elements of the Defense Department on 21 December 1951.

In early 1952, the Pine Bluff Arsenal BW antipersonnel agent plant was 40 percent complete (Annex D) and the total cost was estimated at $69 million. Production was scheduled for October 1952 but did not begin until December 1953. Production readiness to meet estimated requirements was achieved in the spring of 1954. The final total cost of the plant was $90 million.

Major research facilities to support the expanded BW R&D program were constructed at Camp Detrick and in 1953 over $10 million worth of laboratory and pilot plant facilities were completed.

With the expansion of the BW retaliatory program, there was also an increase in the defensive work, e.g., the research program in protection against BW was almost doubled in 1952. Much data were developed in

personnel protection, decontamination, and immunization. Early detection research was started but progress was also because of the complexity of the technical problem.

The preceding acceleration actions during the Korean War were, in part, caused by the concerns of the field commanders. They became very apprehensive over the possibility of the enemy initiating CW and/or BW because of the intensive propaganda campaign accusing the U.S. of using BW. It was recommended that the United Nations Forces should maintain retaliatory capabilities and defensive preparedness in CW and BW.

Readiness

In response to the December 1951 DOD Directive to improve CBR readiness, the Secretary of the Army established a committee to evaluate Army efforts in CW and BW. The resulting report indicated a need to improve management of the CW and BW effort by reorganizing to separate BW and CW elements on a vertical basis. The report was reviewed by a panel of General Officers. The panel supported the basic thrust of the Committee and proposed "Contractor operation" of the BW program with a small government management staff for supervision, paralleling the AEC management approach. As a result, an Assistant Chief Chemical Officer for BW was appointed in the early fall of 1953 and the BW elements of the Chemical Corps were consolidated under him in October 1953. This action was a preparatory measure prior to signing a contract with a large commercial chemical firm. In late December 1953, while final negotiations were in progress with representatives of the contractor, the firm advised that they no longer wanted to contract operate the program and withdrew from further participation. The BW program was then continued, as reorganized, with government personnel.

In June 1953, a month before the Korean War ended, The Secretary of Defense, expressed concern over the state of CBR readiness and stated that each Service, singly or in combination, should be prepared to employ CBR weapons when directed. After a review of the Services' capabilities, it was concluded that BW capabilities were, indeed, limited for a variety of reasons but primarily by knowledge gaps in the biological sciences.

Chapter 4

Cold War Years - Reorganization of Weapons and Defense Programs (1954-1958) (U)

Continuation of Technical Programs

As previously described, by the end of the Korean War in July 1953, construction of the BW production plant at Pine Bluff Arsenal (PBA), was nearing completion. Production of hardware for antipersonnel BW agent cluster bombs began early in 1953 and by the end of the year had been delivered to PBA for filling to support Air Force requirements. In December, the plant entered the shakedown test phase with pathogenic organisms. It became operational in the spring of 1954 with the first production of Brucella suis (the causative agent of undulant fever). Large scale production of the lethal agent Pastuerella tularensis (tularemia) began a year later.

The growth of BW R&D capabilities continued at Fort Detrick. Between August 1954 and July 1958, an additional $15.6 million worth of laboratory construction was completed. Safety continued to be of major concern, particularly where shipment of larger quantities of BW agent were contemplated. (Annex J). In January 1955, and continuing until December 1958, the vaccine research program at Fort Detrick was supplemented by a major contractual effort at Ohio State University Research Foundation. The program included the use of human volunteers. (Annex K).

Policy Revision

A thorough review of the basic U.S. policy of "retaliation-only" with CBR warfare was precipitated in May 1954 by the Chief of Staff of the Army. The question of CBR policy was ultimately referred to high level

national security advisors. Based on Soviet military doctrine expressed by Marshal Zhukov in a speech to the 20th CPSU Congress on 20 February 1956, and repeated three days later by the Commander-in-Chief of the Soviet Navy, our national policy was realigned. The Soviet pronouncements clearly stated the tenet that CW and BW weapons would be used for mass destruction in future wars. In 1956, a revised BW/CW policy was formulated to the effect that the U.S. would be prepared to use BW or CW in a general war to enhance military effectiveness. The decision to use BW or CW would be reserved for the President.

Special Studies

In May 1958, the JCS again reviewed the BW and CW situation at the request of the Secretary of Defense and concluded that progress on offensive BW and CW was slow because of budget limitations. While the Air Force has some capability, Army offensive BW systems were still under development. Although there was a firm military requirement for CW and BW defense materiel, defensive capabilities were not effective because of technical difficulties.

In December 1958, a BW/CW Symposium was convened by the Defense Science Board at the Headquarters of the Rand Corporation. This symposium examined the military and political impact of BW and resulted in recommendations that the Secretary of Defense acquaint the JCS of the results of the symposium, develop weapons requirements, increase the CW and BW research effort, develop weapons systems use doctrines, and attempt to gain public acceptance and support for BW and CW weapons systems.

The Defense Science Board approved the conclusions and recommendations resulting from the symposium and forwarded them to the Director of Defense Research and Engineering (DDR&E). The recommendations were sent to the JCS with the report, and an Ad Hoc Committee on Biological and Chemical Warfare was established to prepare a research, development, test and evaluation program based on the recommendations.

Chapter 5

The Limited War Period - Expanded Research Development, Testing and Operational Readiness (1959-1962) (U)

Program Definition and Expansion

In mid-1959, the DDR&E briefed the Secretary of Defense on the potentialities of CW and BW and recommended a 5-fold expansion of the RDTE effort over a five year period. The Secretary of Defense sought advice on expanding the CW/BW weapons program and asked that employment doctrine be identified. He was advised that present retaliatory capabilities were out of date and needed modernization; a U.S. operational capability should be maintained as a deterrent; U.S. forces must be capable of operating in a toxic environment; an increased RDTE program directed to qualitative operational requirements was needed, and the Service Chiefs should be requested to identify qualitative operational requirements.

In late October 1959, the Chief Chemical Officer was directed by the Chief of Army Research and Development to prepare an expanded five year program. The DDR&E also revived the Army's anticrop program which had been phased out in 1957 because of the decreased interest of the Air Force, the prime user.

By the end of 1959, the Chemical Corps mission reached a height of emphasis unprecedented since WWII. The military Services were submitting requirements for BW munitions, which included dissemination means for artillery, missiles, drones, and other lesser weapon systems. (See Annex

C, Research and Development). To further the emphasis the Secretary of Defense set up a Biological and Chemical Defense Planning Board, to establish program priorities and objectives. The Board had eminent scientists, engineers, and R&D managers from industry, academia, and government. In the report of June 1960, the board recommended, inter alia, major emphasis in the BW retaliatory and defensive programs. The DDR&E approved the recommendations in August 1960 and the Services were directed to increase their funding to attain identified BW/CW objectives. The cold war years of possible direct nuclear confrontation (U.S. vs USSR) had been ameliorated by the Korean War which had been fought with conventional weapons. In about the same period, the Soviet Union was beginning limited harassment tactics, e.g., the closing off of highway access to Berlin, resulting in the Berlin Airlift. The advent of limited war and small scale conflict evoked a need for weapons which could assist in controlling conflict with minimum casualties. Controlled temporary incapacitation, therefore, became an RDTE weapons objective, and CW and BW weapons offered the most promising technical possibilities. The BW program was then shifted to emphasize incapacitation.

In the summer of 1960, the CW/BW national policy of "preparedness for use at the discretion of President" which had been revised from "retaliation only" in March 1958 was revalidated. Congress became interested in CBR disarmament at about the same time and the Senate Subcommittee on Disarmament held hearings and published a report (See Annex B). Stimulated by this initiative, the Department of Defense conducted extensive studies through 1961, concluding that for the "time periods 1962-65 and 1965-70 no single

inspection procedure or combination of procedures were available that would offer a high level of assurance against militarily significant violation of BW arms limitations;" and that "there was no inspection procedure that would insure against clandestine use of these weapons."

An immediate major Defense thrust of the Kennedy Administration was a reassessment of BW/CW. In May 1961, the Secretary of Defense asked that the JCS: evaluate the potentialities of BW/CW, considering all possible applications; prepare a costed plan for development of an adequate BW/CW deterrent capability. This project was Number 112 of about 150 which the new Defense leaders were emphasizing. The JCS, using primarily the August 1960 report of the Defense Biological Planning Board and an Army Chemical Corps special submission, sent their study to Secretary of Defense McNamara in early June, accepting the Board's basic findings and generally supported additional emphasis. The JCS estimated that the cost for obtaining Secretary of Defense McNamara's complete spectrum BW/CW capability was about 4 billion dollars.

The Acceleration Plans

Within OSD, the JCS study was referred to the Director of Defense Research and Engineering for review prior to submission to the Secretary of Defense. The DDRE made a finite review of the JCS recommendations. Overall, he strongly concurred in the JCS view that these weapons had great potential; however, he felt that they could be considered operational only in the most limited sense and that the task of measuring their impact accurately still had to be done. The DDR&E recommended that his office, in cooperation with the JCS, come up with a phased approach for achieving the required capabilities.

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The Secretary of Defense accepted the JCS recommendations as modified by the DDRE and in July 1961, a DOD task group titled, "Project 112 Working Group" was set up by the DDRE, with Joint Staff and Service representatives. They then prepared a comprehensive plan for execution which was submitted in September 1961 to DDRE. The plan laid out precise tasks, target dates and assigned action. The lack of adequate field testing was also highlighted with the recommendation that a Joint Task Force (similar to the nuclear testing Joint Task Force) be established under JCS control, which would conduct service tests. Overall, the project resulted in large increases in U.S. Army BW programs, since the Army Chemical Corps was responsible for conducting BW agent research for all military Services.

Reorganization of Chemical Corps Functions

The Army Chief Chemical Officer was notified by the Office of the Deputy Chief of Staff for Logistics (DCSLOG) on 14 November 1961, that he was responsible for carrying out the major portion of Army Project 112 actions. At this juncture, the Chief Chemical Officer was under the direct jurisdiction of the DCSLOG with technical channels to other General and Special Staff elements of the Army, notably the Army Chief of Research and Development where the primary Army focal point for Project 112 was located. The Assistant Chief Chemical Officer for BW (established in 1953) was shortlived and had been abolished in 1954 when the new Chief Chemical Officer realigned the Chemical Corps to the traditional functional approach. With modest changes, it remained that way through 1961.

In 1962, the Army had a major reorganization which abolished the Chiefs of Technical Services to include the Chief Chemical Officer, His technical operating functions were integrated into the newly formed Munitions Command of the Army Materiel Command. Selected non-technical staff functions were assigned to a new office within the Office of the Deputy Chief of Staff for Operations (DCSOPS), with the Chief Chemical Officer as its Director, initially with a staff of 70. Within the Munitions Command, the BW program subsequently was centered at Fort Detrick which had operational control of BW production activities at Pine Bluff Arsenal. In 1962, BW testing was assigned to a separate Testing and Evaluation Command.

Program Accomplishments

The BW program in 1962 reflected the objectives established by Project 112. An anticrop weapons system for the Air Force resumed in 1962 with the production of agent. Within the increased program, $20.1 million was approved for modification and expansion of the production facilities at Pine Bluff Arsenal. The development of vaccines for Q fever and Tularemia enabled development work on Q fever and tularemia to proceed to standardization as BW agents. $2.3 million was authorized for procurement of broad spectrum antibiotics for BW casualties.

Deseret Test Center

As a result of Project 112, the Army activated a BW/CW testing organization in May 1962. Deseret Test Center (DTC) was established at Fort Douglas in Salt Lake City, Utah. It was authorized 227 military and civilian personnel and was jointly staffed and supported by the Army, Navy, Air Force, and Marine Corps. Liaison was maintained with the US Public Health

Service. Its mission, organization, and functions were approved by the Secretary of Defense. DTC was to coordinate the requirements for, plan, conduct, and evaluate testing of biological (and chemical) weapons and defense systems. While reporting through the Army Chief Chemical Officer and Army Chief of Staff, DTC had to obtain approval of the JCS for conduct of tests, to include materiel, personnel, and funds. In addition, review and approval by OSD (DDR&E) and the President (President's Scientific Advisory Committee (PSAC)) were required. The Secretary of the Army also participated since he submitted the proposed test programs to the Secretary of Defense on a parallel basis with the Army Chief of Staff submissions to the JCS. For example, on 21 August 1962, the Secretary of the Army provided recommendations with supporting detailed rationale for the DTC tests. Coupled with the Deputy Secretary of Defense approval of only part of the tests, these documents demonstrate the extreme care taken to assure the ultimate in safety, the highest level of review and approval, and appropriate government coordination. These reviews of proposed BW/CW tests focused on the need to place governmental controls on any experiment that could have adverse effects onthe environment; and precipitated a statement on national policy on 17 April 1963. This statement required that the President give prior approval for any scientific or technological experiments which might have protracted effects on the physical or biological environment. OSD implemented this policy on 30 April 1963 by issuing a DOD Instruction titled, "Large Scale Scientific or Technological Experiments," which spelled out precise controlling procedures.

Chapter 6

Adaptation of the BW Program to Counterinsurgencies - The Vietnam War Years (1963-68) (U)

Technical Programs

Throughout the Vietnam War, the BW program was guided essentially by the requirements delineated in Project 112.

The overall emphasis in Defense programs during this period was on supporting the Vietnam War and the BW program was limited accordingly. The primary retaliatory BW efforts were directed toward meeting production requirements of antipersonnel and anticrop agents. Production facilities at Pine Bluff Arsenal were completed and between 1964 and 1967, the plant produced several different BW agents. Various types of BW munition hardware were delivered to Pine Bluff Arsenal, filled, and stored there. These munitions were never shipped anywhere, except for test purposes. Production of anticrop agent was accelerated in 1963 and continued until August 1969. Anticrop agent cultivating methods, originally developed at Fort Detrick, were subsequently refined under a contract beginning in 1963. The agent was subsequently produced and delivered to Fort Detrick at the termination of the contract in June 1966.

Chemical Herbicides

Based on the special scientific advisory efforts of the OSD Advanced Research Projects Agency to South Vietnam and supported by special funds provided by them, the United States Army and Air Force were requested to conduct chemical herbicide spray experiments in South Vietnam. The purpose was to determine their operational suitability for defoliation of jungle vegetation to prevent ambush along key travel routes, and for destruction of field crops grown by the insurgents in remote areas. The technical work

on the herbicides and dissemination devices was done by Fort Detrick personnel and the US Air Force provided aircraft and pilot support. These actions were not BW but some confusion resulted because Fort Detrick carried out the RDTE activities as a part of their overall scientific program. Subsequent U.S. introduction of herbicides operationally in 1963 and rapid increase in their use until termination in 1970, resulted in North Vietnamese accusations that the U.S. was using CW and Even BW. The impact of these actions on the U.S. ban of BW in 1969 are treated in detail in Chapter 7.

Incapacitating BW Agents

In 1964 RDTE on enterotoxins from bacteria of the Staphylococcus group, which causes severe short term incapacitation (known as food or ptomaine poisoning), had progressed to the point where development of weapon systems appeared feasible. As a result, work on this potential agent was accelerated. Enterotoxins are not living microorganisms and are not contagious in any way. They are complex chemical substances produced by microorganisms which can not be readily synthesized chemically; and were included in the Fort Detrick BW program as a matter of scientific economy, much like the chemical herbicides were part of the BW anticrop program. Staphylococcal enterotoxins were particularly attractive as agents because much less enterotoxin is required to produce incapacitation as compared to standard CW agents. President Nixon's statement in November 1969 did not specifically ban biological toxins and extensive discussion ensued on whether to include toxins in the U.S. declaration. The inclusion of toxins in the ban occurred in February 1970 and all Staphylococcal enterotoxin work stopped. The details of R&D, production, human volunteer testing, and field testing are in Annexes C, D, E and K.

Some living microorganisms, such as Q fever and VEE, were also considered but were not as desirable as toxins because of the concern about possible

spread, the predictability of effects on the target population, and available knowledge about their long term effects on the environment. Other associated programs were also carried out and are described in the annexes listed above. No serious consideration was given to their use in the Vietnam War although hypothetical analyses were made to assess their potential.

Defensive Programs

Defensive BW developments in this period emphasized rapid detection systems, extension of available vaccines and improved therapy and prophylaxis. Also, a test was conducted to determine the vulnerability of personnel in an urban subway system to covert BW attack. A series of trials were conducted in three major north-south subway lines in mid-Manhattan, New York City, in June 1966. A harmless simulant biological agent (BG) was disseminated within the subway tubes and from the street into the subway stations. The simulant data when translated into equivalent covert attacks with pathogenic agents during peak traffic periods indicated that large numbers of people could be exposed to infectious doses. With the need for increasing money to support the U.S. Army's increased involvement in the Vietnam War and the mounting efforts in the United Nations (UN) to achieve some type of disarmament agreement in CW/BW, the funding support of Army BW programs gradually dropped from $38 million in FY 66 to $31 million in FY 69 when President Nixon banned U.S. BW weapons. In FY 73, when the Army biological defense program had stabilized, the amount had dropped to $11.8 million.

Chapter 7

Disarmament and Phase Down (1969-72) (U)

Presidential Ban of BW

On 25 November 1969, President Nixon announced a major policy decision on the United States chemical and biological warfare program. With respect to CW, he renounced the first use of lethal and incapacitating chemicals and he stated that he would resubmit the Geneva Protocol to the U.S. Senate for ratification. With regard to the BW program, President Nixon renounced the use of lethal bacteriological (biological) agents and weapons and all other methods of biological warfare, and he directed the Defense Department to make recommendations for the disposal of existing BW weapons. He further stated that the U.S. would confine its biological research to defensive measures such as immunization and safety measures. Questions remained, however, on whether the policy applied to biological toxins. On 14 February 1970, a White House announcement extended the policy to biological toxins regardless of their means of production.

The Presidential announcement was culminated by several major reviews of U.S. policy concerning chemical and biological warfare by national security experts. However, as indicated in Chapter 6, the origin of the policy change dates from criticism of U.S. application of chemical herbicides and riot control agents in the Vietnam War beginning in the mid-60's. In addition, studies of a coordinated U.S. policy on BW and CW were initiated by the Defense Department and the State Department in October 1963. These studies continued into 1965. On 5 December 1966, the General Assembly of the United Nations passed a resolution for all States to observe the principles of the Geneva

Protocol of 1925. In December 1966, a recommendation was made that the United States should announce a policy of "no first use" of biological weapons but no action was taken.

United Nations Disarmament Efforts

International attention on chemical warfare was heightened in January 1967 by the reported use of toxic material in the Yemen Civil War. The effectiveness of the Geneva Protocol was questioned and there was considerable debate at the United Nations on the necessity to develop new instruments to extend the Geneva Protocol. A case was made by the United Kingdom to separate BW and CW to facilitate disarmament progress in this area. In 1968, the Eighteen-Nation Committee on Disarmament (ENCD) recommended that the Secretary General appoint a group of experts to examine the dangers to mankind represented by employment of CW and BW. The group was subsequently appointed following a UN General Assembly resolution to this effect on 20 December 1968. They met in February, April and June and submitted their report to the Secretary General of the UN in late June 1969. In July 1969, the Secretary General accepted the report and urged a halt to the development, production and stockpiling of all CW and BW agents and proposed elimination from the stockpile. He also appealed to all States to accede to the Geneva Protocol and to apply its provisions to all chemical and biological warfare agents. In November 1969, the World Health Organization submitted a separate report to the UN on the health aspects of chemical and biological weapons. Both reports emphasized the unpredictability, risk in, and lack of control of BW in a major military employment. At the UN, there was general agreement that no new instrument other than the Geneva Protocol was needed to preclude the use of CB weapons

but that a new agreement would be needed to prohibit their development, production, and stockpiling.

The UK continued to push for a separation of CW and BW and on 10 July 1969, they submitted to the Conference of the Committee on Disarmament (CCD)* a draft Convention for the prohibition of the development, production and stockpiling of bacteriological (biological) and toxin weapons. (The UK draft was revised to include toxins at the suggestion of the U.S. and was resubmitted on 18 August 1970.) The USSR submitted a competing disarmament Convention encompassing CW and BW to the UN General Assembly in September 1969. It was in this framework of international debate that President Nixon made his preemptive announcement of unilateral BW disarmament by the United States.

United States Demilitarization Program

In preparation for the President's announcement, the Department of the Army in August 1969, was directed to immediately cease all production of toxins and biological agents and filling of dissemination devices. Guidelines for BW demilitarization plans were formulated and plans were initiated for disposal of all antipersonnel agents and munitions at Pine Bluff Arsenal and all anti-crop material at Fort Detrick, Rocky Mountain Arsenal and Beale Air Force Base. The plans emphasized operational safety and control, total accountability for all materiel, and absolute verification of destruction in the form of incontrovertible data. The plans were reviewed extensively by Army experts and by U.S. Departments of Health, Education and Welfare; Interior; Agriculture; the Environmental Protection Agency; and appropriate state and local officials. Accompanying environmental impact statements were filed with the President's Council on Environmental Quality.

*On 26 Aug 1969, the Eighteen Nation Committee on Disarmament was renamed "The Committee on Disarmament (CD)" to reflect expansion of its membership. The name of the conference was changed accordingly.

Total destruction of DOD antipersonnel BW stocks and munitions was accomplished between 10 May 1971 and 1 May 1972. The facilities at Pine Bluff Arsenal were completely decontaminated and turned over to the Food and Drug Administration to become the National Center for Toxicological Research. Total destruction of DOD anticrop agents and decontamination of facilities at the three storage points was accomplished between 19 April 1971 and 15 February 1973.

The offensive BW experimental program was also terminated in 1969 with a complete inventory of all BW materiel at Fort Detrick and Dugway Proving Ground and destruction of all items except those essential to defensive BW research. The BW production facilities were decontaminated and assigned to the Army Health Services Command pending formal transfer to the National Cancer Institute (NCI). The NCI has performed work through a contractor at the former biological laboratories since 1972 under an interim agreement; final transfer should be completed in 1977. Finally, BW defense program management and operations were transferred to Edgewood Arsenal. Details of the BW demilitarization program are contained in Annex L.

Biological Warfare Convention and Geneva Protocol

In March 1971, while the U.S. BW demilitarization program was in progress, the East and West stalemate regarding separation of BW and CW weapons was broken and a mutually acceptable draft convention applied to BW alone was submitted to the General Assembly. The convention was approved by the Assembly in December, signed in Washington, London, and Moscow on 10 April 1972. Ratification by the U.S. Senate was delayed by their consideration of the Geneva Protocol and the question of adding herbicides and riot control agents to the definition of CW agents.

The question was resolved by President Ford in the latter part of 1974 when the Administration renounced as a matter of policy the first use of

of riot control agents and herbicides in war except under specific conditions of defense to save lives. The Senate approved both the Protocol and the Convention on 16 December 1974 and President Ford signed documents of ratification on 22 January 1975.

Chapter 8

The Biological Defense Research Program (1973-77)

Program Realignment

Since the President's ban on offensive BW in November 1969 (extended by the ban on biological toxins in February 1970), the Army has confined its BW technical program to demilitarization and to defensive development involving physical protection and medical procedures. The demilitarization programs have been discussed in the previous chapter and elaborated in Annex L.

On 1 April 1972, Fort Detrick was transferred from the U.S. Army Materiel Command (AMC) to the Office of The Surgeon General. As a result of the shift in ownership of Fort Detrick, the Analytical Science Office and the Biological Defense Materiel Division were transferred from Fort Detrick to Edgewood Arsenal, Maryland. On 1 July 1973, Fort Detrick and the U.S. Army Garrison was reassigned to the U.S. Army Health Services Command also under The Surgeon General. Civilian personnel, equipment and facilities of the Plant Sciences Directorate of Ft Detrick were transferred to the U.S. Department of Agriculture to continue the work on defense technology against crop disease in accordance with a PSAC recommendation.

The U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)* located at Fort Detrick is the center of the Army's program on the medical aspects of BW defense. The physical defense program is conducted by the Biological Defense Group, with approximately forty personnel, assigned to the Directorate of Development and Engineering at Edgewood Arsenal. Field test support of the Edgewood Arsenal effort is provided by Dugway Proving Ground. Under an RDTE Project (Technical Assessment of Foreign Biological Threat), Dugway Proving Ground has the mission of examining the U.S. and its Armed Forces' vulnerability to biological attack. This function is

*Approximately 461 assigned personnel.

assigned to a total of seven analysts in the Studies Division who examine available intelligence reports, current laboratory research, and results of vulnerability testing with an overall assessment of these activities. Vulnerability assessments normally involve study and evaluation rather than laboratory R&D; however, simulant tests may be conducted when additional basic data is required.

Funding for the total RDTE effort has varied from $10.2 million in FY 73 to $14.4 million in FY 76. Most of the funds (approximately 65% of $14.1 million in FY 77) have been applied to The Surgeon General's medical defense programs.

Physical Defense Program

The Biological Defense Group has responsibility for basic research and development of biological detection and alarm devices, development of high volume aerosol sampling and collection equipment, as well as development and evaluation of devices, systems, methods, and protocols for physical protection and decontamination. The major thrust of the physical defense program during the 1972 to 1976 time frame has been towards the end item development of a Biological Detection and Warning System for the field Army.

The current program for basic research on biological detection has emphasized studies on remote detection concepts. This research has consisted of theoretical analyses of the feasibility for detecting microbiological aerosol clouds in the atmosphere area scanning methods. No experimental studies have yet been conducted.

The hardware development program was accompanied and supported by an active program of system analysis to provide a logical basis for the

establishment of performance characteristics for the proposed systems. Studies included threat analysis, target analysis, field alarm array studies and the impact of detector arrays on casualty reduction, system logic studies, and related concept of use studies leading to a better definition of system requirements. Coupled with the detector development was the parallel development of a large volume field sampler which would be triggered by an alarm to collect a sample.

Exploratory development of biological agent decontamination continued throughout the 1972-77 period. A contract package was prepared for the exploratory development of a decontamination system for biological contaminated personnel, equipment, and enclosures. This would be a four year technical effort planned for FY77 through FY80.

Basic research in this area is directed at evaluating the concept of decontaminating microbiological aerosols with a counter-aerosol of a chemical disinfectant such as lactic acid.

In the area of physical protection, peripheral leakage tests on two new mask prototypes will be completed, and evaluation of the leakage characteristics and performance of individual and collective protection equipment under development for the Army will be continued.

Medical Research Program

The objective of the medical research program is the development of an effective, integrated medical defense against biological weapons and highly infectious agents. New and classical techniques in virology, immunology, and pathology are employed to develop methods for the early diagnosis, prevention and/or treatment of biological agent casualties, and rapid laboratory identification of BW agents as well as other extremely infectious diseases of importance in military operations. A major effort of research

is the development, production and stockpiling of vaccines that can be used by US military troops deployed anywhere in the world against known and potential BW agents. The only national resource for vaccine development of any magnitude for the US Armed Services, Merrill National Laboratories, is utilized for mass production of candidate vaccines. This multifaceted program utilizes the most efficient methods and technology for prevention and treatment, aerosol immunization, diagnosis, and vaccine production for BW agents and other militarily important highly infectious diseases.

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IN THE U.S.

BIOLOGICAL WARFARE PROGRAMS

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U. A. ARMY ACTIVITIES
IN THE
UNITED STATES BIOLOGICAL WARFARE PROGRAMS
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FOR RELEASE AT 7:30 P.M., EST. JANUARY 3, 1946

BIOLOGICAL WARFARE

REPORT TO THE SECRETARY OF WAR BY MR. GEORGE W. MERCK,
SPECIAL CONSULTANT FOR BIOLOGICAL WARFARE

Note to the Editors: Intelligence reports of investigation conducted by Military Intelligence agencies in Japan after the occupation and received there after Mr. Merck had prepared his report to the Secretary of War show that Japan had made definite progress in biological warfare. From these investigations it is known that the Japanese Army fostered offensive developments in this field from 1936 until as late as 1945.

Intensive efforts were expanded by Japanese military men toward forging biological agents into practical weapons of offensive warfare. Modifications of various weapons developed through research in their laboratories were fieldtested at Army proving grounds where field experiments were also conducted in the use of bacteria for purposes of sabotage. These efforts were pursued with energy and ingenuity. While definite progress was made, the Japanese had not at the time the war ended reached a position whereby these offensive projects could have been placed in operational use.

There is no evidence that the enemy ever resorted to this means of warfare. Whether the Japanese Army could have perfected these weapons in time and would have eventually used them had the war continued is of course not known. However, defenses against biological warfare were the subject of an active research and development program in this country.

This report sets forth the combined efforts of American scientists and industry working with the armed forces and in cooperation with similar agencies in the United Kingdom and Canada to develop defenses to enemy attacks by biological warfare.

While the military developments cannot be disclosed in the interest of national security the research contributed significant knowledge to what was already known concerning the control of diseases affecting humans, animals and plants. Arrangements have been made whereby this information of value to humanity as a whole will be made available to the public from those sources responsible for the work. This will be accomplished through reports before scientific bodies, publication in scientific journals and other means by which advances in science and medicine are disseminated in peacetime.

Dear Mr. Secretary:

The military strength of a nation in war depends not only on the weapons which it actually brings to bear on the enemy but also on the thoroughness with which the nation prepares for all eventualities. This basic military doctrine was followed by the United States in waging war against the Axis.

A type of warfare that might have been employed in World War II - a potential avenue of attack by our enemies - was biological warfare. Biological warfare may be defined as the use of bacteria, fungi, viruses, rickettsies, and toxic agents from living organisms (as distinguished from synthetic chemicals used as gases or poison) to produce death or disease in men, animals, or plants. This type of warfare was not unknown in World War I, although it was employed only on a very limited scale. There is incontrovertible evidence, for example, that in 1915 German agents inoculated horses and cattle leaving United States ports for shipment to the Allies with disease-producing bacteria.

In the years between World War I and World War II a general interest in the possibilities of biological warfare was maintained by scientists and military men in many countries, and many came to believe that this type of warfare was possible or even probable in the future. As the inter-war period drew to a close, opinion in the United States as to the possibility of biological warfare was by no means united, but common prudence dictated to those responsible for the nation's defense that they give serious consideration to the possible dangers in this field. The counsel of those alert to the possible danger was formally brought to the attention of the War Department in the fall of 1941, whereupon Secretary Stimson promptly requested the National Academy of Sciences to appoint a committee to make a complete survey of the current situation and of future possibilities.

After careful study, this committee - known as the WBC committee - drew the conclusion in its report of February 1942 that biological warfare was distinctly feasible and urged that appropriate steps be taken for defense against its use. The report stated in part:

> "The value of biological warfare will be a debatable question until it has been clearly proven or disproven by experience. The wide assumption is that any method which appears to offer advantages to a nation at war will be vigorously employed by that nation. There is but one logical course to pursue, namely, to study the possibilities of such warfare from every angle, make every preparation for reducing its effectiveness, and thereby reduce the likelihood of its use."

With these conclusions before him, Secretary Stimson recommended to President Roosevelt the establishment of a civilian agency to take full charge of all aspects of biological warfare. Upon the approval of the President, the War Research Service with Dr. George W. Merck as Director was organized in the summer of 1942 and was attached to the Federal Security Agency. In the interests of efficiency, economy, and secrecy War Research Service remained a small organization. It served primarily as a coordinating agency and drew on the facilities, personnel, and experience already existing in the Government and private institutions. Its recommendations were implemented by orders and directives issued by the various branches of the Armed Services, particularly the Medical Services of the Army and the Navy and the Chemical Warfare Service of the Army. Appropriate liaison was maintained with the Armed Services, the U.S. Public Health Service, the Department of Agriculture, and the Department of the Interior. Intelligence was obtained from the Army, the Office of Naval Intelligence; and public relations matters were handled in cooperation with the Bureau of Public Relations of the War Department, the Office of War Information, and the Office of Censorship. A Committee of prominent scientists -- known as the ABC Committee -- was set up by the National Academy of Sciences and the National Research Council to advise War Research Service on its special research problems.

The exchange of information on this subject which had been inaugurated some months before with the United Kingdom and Canada was continued and provision was made for the interchange of biological warfare personnel between the three countries.

The first major task undertaken by War Research Service was the development of defensive measures against possible biological warfare attack. Measures were taken in cooperation with the Armed Services to protect the supply of water, food, and milk on the mainland; in Hawaii, the Caribbean Area, particularly the Canal Zone; and finally all overseas theaters.

An extensive program for the collection of intelligence on biological warfare was established, making use of the intelligence collection agencies of the Armed Forces, the OSS, and the FBI, and arrangements were made to send specially trained intelligence officers into operational areas to stimulate the collection of intelligence on biological warfare.

The major achievement of War Research Service, however, was the organization of a program of research and development to extend the boundaries of knowledge concerning the use of pathogenic agents as a weapon of war and the means of protection against possible enemy use of these agents. All known pathogenic agents were subjected to thorough study and screening by scientists of the highest competence in their respective fields to determine the possibilities of such agents being used by the enemy. Those disease-producing agents which seemed to offer some promise were assigned to various university and private research laboratories for

extensive experimentation to determine their lethal properties, means of production, and methods of protection or antidotes against their use. As the program progressed, however, it soon became clear that exhaustive investigations of biological warfare agents, their use as weapons, and means of protection against them could not be achieved without larger scale developmental operations.

In November 1942 War Research Service requested the Chemical Warfare Service of the Army to prepare to assume responsibility for a larger scale research and development program involving the construction and operation of specially designed laboratories and pilot plants. The site chosen for these facilities was at Camp Detrick, Frederick, Maryland, where construction was begun in April 1943. When these facilities were put into operation, research projects which had been developed under sponsorship of War Research Service were turned over the Chemical Warfare Service for further development at Camp Detrick. War Research Service continued to exercise general supervision over the entire field and continued to sponsor fundamental research studies in universities and private institutions and to help secure scientific personnel and equipment for the Camp Detrick operations.

In December 1942, the Office of Strategic Service reported to the Joint Chiefs of Staff that there were some indications that the Germans might be planning to use biological warfare agents. While the evidence that the Germans might use such agents was inconclusive, there was considerable concrete information available from work which had been carried on in the United States, the United Kingdom and Canada that attack by biological agents was feasible. Accordingly, it was decided in January 1944 to step up all work in this field, particularly in terms of the protection of troops against possible enemy use of these weapons, and to transfer a large part of the responsibility for the biological warfare program to the War Department. The complete transfer was accomplished by direction of the President in June 1944 when the Chemical Warfare Service was made responsible for the program in the War Department with the cooperation of the Office of the Surgeon General on certain important defensive phases. The Navy Department continued to make important contributions to the program and continued to work in close collaboration with the War Department in this field. The research and development program was greatly accelerated, although it was directed that no biological warfare agents should be produced in quantity without specific approval of the Secretary of War. In fact, no large stocks of these agents have ever been accumulated.

Upon assumption of the War Department of full responsibility in this field, the Secretary of War appointed the Director of War Research Service as his Special Consultant on Biological Warfare and established the United States Biological Warfare Committee, with Mr. Merck as chairman, to advise him on policy matters and to maintain close liaison with the British and Canadian groups concerned with biological warfare. This Committee was composed of representatives of the Chemical Warfare Service, the Office of the Surgeon

General, U.S. Army; [illegible] Medicine, U.S. Navy; Bureau of Ordnance, U.S. Navy; Army Service Forces; New Development Division, War Department Special Staff; [illegible] Office of Strategic Services. A new Committee -- designated the OSRD Committee -- was formed by the National Academy of Sciences and the National Research Council to advise the War Department on the scientific aspects of the subject.

At the height of its development, the Special Projects Division of the Chemical Warfare Service of the Army, which carried the main responsibility for the program after June 1944, had a total personnel, nearly 3900, of which some 2800 were Army personnel, nearly 1000 Navy, and nearly 100 civilian. The projects carried on by the Special Projects Division at its four installations were combined operations -- with Army, Navy, and civilian personnel working together in the closest cooperation. They worked under high pressure and the strictest secrecy. Their achievements have been most remarkable.

The first installation, established by the Special Projects Division in April 1943 was the parent research and pilot plant center in Maryland; the second, Field testing facilities established in the summer of 1943 in Mississippi; the third a plant designed for the investigation of larger scale production acquired early in 1944 in Indiana; and the fourth field testing facilities established in the summer of 1944 in Utah. These installations were unique in many respects requiring, as they did, special designing to meet the completely new problems under investigation. The need for great precision and rigid safety requirements created many complex engineering problems. Special equipment had to be designed, constructed, and installed to handle processes never before exploited and on a scale of operation never before undertaken.

While it is not possible to reveal at this time the specific agents on which intensive work was done at those installations, the general nature of the problem and the type of information that was obtained in this field can now be told. It should be emphasized that while the main objective in all these endeavors was to develop methods for defending ourselves against possible enemy use of biological warfare agents, it was necessary to investigate offensive possibilities in order to learn what measures could be used for defense. It was equally clear that the possibility of retaliation in kind could not be disregarded in the event such agents were used against us. Accordingly, the problems of offense and defense were closely interlinked in all the investigations conducted. This is implicit in the discussion which follows.

A wide variety of agents pathogenic for man, animals, and plants was considered. Agents selected for exhaustive investigation were made as virulent as possible, produced in specially selected culture media and under optimum conditions for growth, and tested for disease producing power on animals or plants. Intensive investigations were conducted on many aspects of this field, including studies of how well various organisms of high disease-producing power would retain their virulence and how long they would remain alive under different storage conditions; biological, physical, and

chemical protective measures; the number of organisms required to produce infection; the effectiveness of antibiotics and chemo-therapeutic agents; the incubation period of various diseases; and the effectiveness of certain chemicals (or coagents) when used with pathogenic agents or toxins in influencing their disease producing powers. From these and other studies has come much new information which, when published in scientific journals, will make significant contributions to the advancement of knowledge. Extensive studies of biological and chemical agents which might have been used in attacking our crops resulted in certain discoveries which will undoubtedly prove of great value to agriculture.

Studies were made of methods and means by which biological warfare agents might be employed against us. This involved not only the perfection of antisabotage measures -- information on which was made available to appropriate civilian and military authorities -- but also studies of the various types of munitions that might be employed for the dissemination of biological warfare agents. A strong intelligence program was instituted which operated very effectively in all theaters of operation with the result that a thorough knowledge of German activities in this field was also obtained. Similar investigations of Japanese activities (are now being) were conducted. When these investigations are completed it will be possible to evaluate fully the work carried on in this field by our enemies. All evidence to date indicates that the Axis powers were behind the United States, the United Kingdom and Canada in their work on biological warfare. It is also known that after early 1942 Germany obtained no information concerning United States activity in biological warfare, and that no serious leaks of information on this subject occured in this country. The intelligent and whole-hearted cooperation of the press and radio of the nation, working in conjunction with the Office of Censorship, helped very materially in this regard.

In all work on biological warfare carried on in the United States, extreme care was taken to protect the participating personnel from infection. Many new techniques were devised to prevent infection and proved highly successful. Hospitals and dispensaries were maintained at all installations, staffed with both Army and Navy personnel and well equipped to treat accidental infections. As the result of the extraordinary precautions taken, there occured only sixty cases of proven infection caused by accidental exposure to virulent biological warfare agents which required treatment. Fifty-two of these recovered completely; of the eight cases remaining, all are recovering satisfactorily. There were, in addition to the sixty proven cases, 159 accidental exposures to agents of unknown concentrations. All but one of these received prompt treatment and did not develop any infection. In one instance, the individual did not report exposure, developed the disease, but recovered after treatment.

Obviously none of these cases were brought about intentionally, and were not, therefore, "controlled" experiments, but in any event certain valuable information was obtained from their treatment, particularly with

regard to new antibiotics, chemotherapeutic agents and immunizing procedures, which, but for those cases of accidental infection, could otherwise have been tested only on animals. Considering the variety of highly pathogenic agents handled, the scale of operations employed, and the relatively large number of people involved, the safety record of our biological warfare program is truly remarkable.

The activities of the United States in the field of biological warfare, undertaken under the good of necessity and aimed primarily toward securing for this nation and its troops in the field adequate protection against the possible use by our enemies of biological warfare agents, were carried on with that teamwork which has characterized so many of our efforts in wartime. The branches of the Army and Navy, many civilian scientists, university and private research institutions, and several Departments of the Government all worked together to the common end. This was a matter of great urgency, and many of the problems were unique and most complex. The objective was attained; adequate defenses against a potentially dangercus method of warfare were devised, the possibility of surprise from this quarter was forestalled. Apart from the military objectives attained, however, much information of great lasting value for human welfare was obtained. Unique facilities were established for research and experimentation on pathogenic agents on a scale never before possible. These facilities will be of inestimable value to future military and civilian biological investigations. In general terms, these were some of the more important accomplishments of the program:

1. Development of methods and facilities for the mass production of microorganisms and their products.

2. Development of methods for the rapid and accurate detection of minute quantities of disease-producing agents.

3. Significant contributions to knowledge of the control of airborne disease-producing agents.

4. Production and isolation, for the first time, of a crystalline bacterial toxin, which has opened the way for the preparation of a more highly purified immunizing toxoid.

5. Development and production of an effective toxoid in sufficient quantities to protect large scale operations should this be necessary.

6. Significant contributions to knowledge concerning the development of immunity in human beings and animals against certain infectious diseases.

7. Important advances in the treatment of certain infectious diseases of human beings and animals, and in the development of effective protective clothing and equipment.

8. Development of laboratory animal propagation and maintenance facilities to supply the tremendous number of approved strains of experimental animals required for investigations.

9. Applications of special photographic techniques to the study of airborne microorganisms and the safety of laboratory procedures.

10. Information on the effects of more than 1000 different chemical agents on living plants.

11. Studies of the production and control of certain diseases of plants.

Steps are being taken to permit the release of such technical papers and reports by those who have been engaged in this field as may be published without endangering the national security. It is important that this be done, for much of the information developed in the course of this undertaking will be of great value to public health, agriculture, industry, and the fundamental sciences.

III

While it is true that biological warfare is still in the realm of theory rather than fact, in the sense that it has not actually been used in military operations, the findings of the United States in this field along with the findings of groups engaged in similar work in the United Kingdom and Canada have shown that this type of warfare cannot be discounted by those of this nation who are concerned with the national security. Our endeavors during the war provided means of defending the nation against biological warfare in terms of its presently known potentialities, and explored means of retaliation which might have been used, had such a course been necessary. Although remarkable achievements can be recorded, the metes and bounds of this type of warfare have by no means been completely measured. Work in this field, born of the necessity of war, cannot be ignored in time of peace; it must be continued on a sufficient scale to provide an adequate defense.

It is important to note that, unlike the development of the atomic bomb and other secret weapons during the war, the development of agents for biological warfare is possible in many countries, large and small, without vast expenditures of money or the construction of huge production facilities. It is clear that the development of biological warfare could very well proceed in many countries, perhaps under the guise of legitimate medical or bacteriological research.

In whatever deliberations that take place concerning the implementation of a lasting peace in the world, the potentialities of biological warfare cannot safely be ignored.

Respectfully yours,

GEORGE W. MERCK
Consultant

Annex F

Congressional Awareness

World War II. The strict secrecy and urgency imposed during World War II (WWII) on the BW program prohibited public knowledge and resulted in only cursory Congressional review. However, key Congressional leaders were kept generally aware of the program through Secretary of War Stimson and his consultant for BW, George W. Merck. At the end of WWII, an official report (an unclassified version of Mr. Merck's secret report to the Secretary of War) was released and published. This report, entitled "Implications of Biological Warfare," was included in a volume of U. S. Scientific Atomic Energy Information transmitted to the United Nations Atomic Energy Commission in June 1946 by Bernard M. Baruch, the United States Representative. Concommitantly, selective BW work was authorized for publication in scientific journals. During the period 1946 to 1972 over 1,600 scientific papers by Fort Detrick scientists were published in the open literature.

Post World War II. During the period 1946 to 1952, information on the BW program was provided to members of the House Armed Services Committee and the Defense Subcommittee of the House Committee on Appropriations. Because of the classified nature of the discussions, a number of the portions of the hearings are not reflected in the Congressional records. In the 1946 hearings the Chief Chemical Officer discussed the BW program in detail including accomplishments applicable to public health. In the hearings before the Defense Subcommittee of the House Committee on Appropriations for 1951, Mr. George M. Mahon, Texas, Chairman, reflected the view expressed at times by other Congressional members when he decried the "Change of our

policy last year in making public the scope and nature of biological warfare which we are undertaking. . . . I regret that the Department of Defense is now making public the amounts of money which we are spending for biological warfare or that we spend money for such purposes . . . I do not see that any useful purpose has been served."

Post Korean War. In hearings before the Defense Subcommittee of the House Committee on Appropriations for 1953, the record shows the need for an increased funding level to pay for new biological laboratories that were scheduled to begin operations in 1953.

With these actions and the need to justify funds for a continuing Army BW program, Congressional oversight was expanded to the level of scrutiny afforded other military programs having security implications and gradually extended to the point where special Congressional Committee comprehensive reviews were conducted starting in 1959. The House Committee on Science and Astronautics held a two-day hearing in June 1959 on Chemical, Biological and Radiological Warfare Agents, chaired by Congressman Overton Brooks and included, among others, Congressmen John W. McCormack, Joseph W. Martin, and Olin E. Teague. A study on CBR Warfare and Its Disarmament Aspects was prepared in August 1960 by the Subcommittee on Disarmament of the Committee on Foreign Relations of the United States Senate. The Chairman was Senator Hubert H. Humphrey and includes, among others, Senator John F. Kennedy and Senator Frank Church.

These special reviews augmented the annual Army budget justification submissions and testimony to the Congress in which the Army BW programs were specifically identified and were, at times, the subject of extensive discussion. In hearings before the Defense Subcommittee of the House Appropriations Committee in 1959, Congressman Robert L. F. Sikes, Florida, asked Secretary

o. Defense McElroy for a review of the chemical and BW programs because "they are both operating now on a meager basis." On 26 March 1956, Major General William M. Creasy appeared as a witness before the aforementioned subcommittee. General Creasy's testimony totals 20 pages in the Congressional Record and covers an extensive number of areas relating to the overall chemical and BW programs including the testing program and the necessity to use human volunteers. Budgetary requirements, public information needs, security aspects, offensive and defensive BW, and other areas of Congressional interest are reflected in hearings before the Subcommittee of the House and Senate Committees on Appropriations for 1959, 1960 (H.R. 7454), (Part 6), and 1961 (Part 6) (H.R. 11998, Part 2). Certain congressmen also maintain a continuing awareness as a result of regional and personal interest. For example, Senator Charles M. Mathias has had general knowledge of the Fort Detrick BW programs at Frederick, Maryland because of its location in his home town and his past participation in its U. S. Naval Reserve Unit as well as his constituency interests as the past District Congressman and subsequently as U.S. Senator. Key committee members also visited the installations involved in the BW program. In 1959, Representatives Norrel, Teague and Mahler toured the production facility at Pine Bluff Arsenal and received a classified briefing on its mission and operations

Biological Ban. In early November 1969, the BW program again became the focus of Congressional scrutiny as 108 Members of Congress called upon the President to take actions to review chemical and biological warfare. On 18 November 1969, the House Subcommittee on National Security Policy and Scientific Developments of the Committee on Foreign Affairs started extensive hearings on United States policy with respect to chemical and

biological warfare. On 25 November 1969, President Nixon's statement banned U. S. use of BW and made a statement supporting a universal outlawing of BW. Since then Congressional review has been constant and at times intense. The policy reviews continued in 1971 with the Senate Committee on Foreign Relations hearings on the Geneva protocol.

In retorspect, all aspects of U. S. Army funded activities in the U.S. BW Program have been either reviewed or made known to the appropriate and designated elements of Congress. The only aspect which could be viewed as an exception was the technical work done by the U. S. Army for the Central Intelligence Agency (CIA). Under the authoritative "ground rules" enforced by CIA, this was their responsibility since they provided the funds. The same arrangement obtained with the other military Services and Federal agencies when they requested technical assistance from the Army in BW activities pertaining to their responsibilities.

In September 1975 the CIA connection with the BW program at Fort Detrick was thoroughly reviewed by the Senate Select Committee to Study Government Operations with Respect to Intelligence Activities. It was during these hearings that the question of BW vulnerability testing including the New York subway tests, was raised by Senator Hart. Details of this aspect of the program are covered in the Senate Select Committee report.

Biological [illegible] Development

Introduction. Research and development of offensive and defensive aspects of BW was initiated shortly after the entry of the United States into WWII as a result of intelligence reports indicating an offensive capability by the Axis powers. As discussed in Chapter 1, responsibility for implementation of the R&D program was assigned to the Chemical Warfare Service (CWS) in November 1942 and construction of Camp Detrick, the principal BW R&D center, was initiated in April 1943. The research effort at Fort Detrick began eight months later under the Special Projects Division of the CWS. Fort Detrick remained the center of BW research and development and was aided by many academic and industrial agencies, until termination of the BW offensive program in 1969. (Appendix I) Scientists working at Fort Detrick published 1616 articles in scientific and technical journals.

BW Offensive Research and Development. The BW offensive program was concerned principally with antipersonnel and anticrop agents and associated delivery capabilities and to a much lesser degree with antianimal agents. Antipersonnel agent research covered a wide range of highly infectious pathogenic bacteria, rickettsial, viruses and fungi and extremely toxic products of biological origin (toxins). Research efforts were directed toward selection and preservation of the most virulent strains, establishing human dosages, enhancing storageability, and survival when released as an aerosol. Technology for large scale production of the most promising agents was developed. To assist production, development, and testing efforts, harmless simulant agents were selected and efforts expended to obtain improved simulants. During the twenty-six years of BW offensive

research, only eight antipersonnel agents were standardized.

Anticrop research at Fort Detrick concerned BW agents as well as CW agents, i.e., chemical herbicides and defoliants. The latter will not be discussed further as they were not part of the BW microbial program. Research on BW agents included strain selection, evaluation of nutritional requirements, development of optimal growth conditions and harvesting techniques and preparation in a form suitable for dissemination. Extensive field testing was done to assess the effectiveness of agents on crops. Many candidate anticrop BW agents were screened resulting in five standardized BW anticrop agents.

Research and development on BW munitions started by adaptation of burster type bombs available from the British and was extended to improved burster type munitions, submunitions, gas explusion bombs, various types of line source spray tanks and highly specialized projectiles and generators as well as insect vectors. In the early years, the research and development essentially paralleled the experience gained in the development of CW munitions during WWII. Research activities included optimizing configurations, testing performance and developing hardware production and filling technology.

Antianimal research began in 1942 and was initially concerned with developing methods for portecting our large livestock population against BW attack. This research resulted in the development of vaccines to protect against rinderpest, a deadly cattle disease and Newcastle disease, a serious poultry affliction. Researeh was carried out at Camp Detrick initially but when there was a need for larger scale research, a facility was established at Camp Terry on Plum Island, New York. Two field tests of potential antianimal agents were conducted using hog cholera virus and Newcastle

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virus. The program at Camp Detrick was terminated in 1954. By agreement between the Secretary of Defense and the Secretary of Agriculture, the Department of Agriculture assumed responsibility for the defense of our livestock against BW attack, and the Plum Island facilities were transferred to that agency.

Defensive BW Research and Development. The biological defense program included safety, physical and medical protection. The safety program pervaded the entire BW research and development effort to provide protection of both employees and the surrounding community. The program included personnel and laboratory safety practices commensurate with the extremely hazardous agents involved, design criteria for site operating equipment and facilities, facility monitoring devices, and assessment of handling procedures for BW munitions.

The physical protection program was directed toward detection identification and warning systems, protective devices and decontamination methods. Detection and warning efforts started in 1948 have led to engineering development of a fast-response antipersonnel BW detector system which has not been standardized. At the present time, there is no field BW detector, and only conventional biological identification techniques are available. Research on protective masks, particulate filters, protective clothing and shelters was closely integrated with the chemical defense programs. Many compounds were screened for use as decontaminants and decontaminant dispensers were developed for field use. However, some chemicals which are the most effective decontaminants are also toxic and/or carcinogenic. Research in this area is continuing to find safer decontaminants.

R&D efforts on medical aspects of protection related to BW have been extensive throughout the history of the program and have involved close cooperative efforts between Army, USPHS, and other HEW agencies. Major accomplishments in this program include development of vaccines, rapid identification procedures and treatment methods which have been responsible for the excellent safety records.

Biological Defense Research Today. The current biological defense technology program is divided into two major areas: Detection and Warning Investigations and Decontamination and Protection. Effort in detection and warning is of an exploratory nature and is directed toward concepts, principles and approaches for rapid detection of biological aerosols and evaluation of candidate devices. Concepts under consideration include group specific immunological methodology, remote and/or area alarms, background interference elimination methodology and computerized pattern recognition techniques.

Decontamination and protection research is directed toward concepts, principles and approaches for the decontamination of biological materials, personnel protection and biological evaluation of other materiel under development. Concepts under consideration include anti-aerosol and protective cloud technology, decontamination agent generators, individual and group collective protectors, and a continuing chemical screening program for new less toxic vapor-phase decontaminants for closed spaces.

Throughout the research and development process, there is a requirement to test hypothesis and developmental equipment items. In the BW program, this necessitated the use of BW simulants and agents in a wide variety of tests.

Appendix I to Appendix C

FORT DETRICK RDTE TYPE CONTRACTS

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
Aerojet-General Corp.	29	Oct 1956	Jun 1958
		Apr 1958	May 1965
		May 1963	Aug 1963
		Jun 1963	Feb 1964
		Jun 1964	Sep 1966
		Sep 1964	Jan 1966
		Sep 1964	Oct 1965
		Jun 1959	Jun 1960
		Jul 1959	Jan 1960
		Feb 1966	Apr 1967
		Jun 1966	Aug 1967
		Mar 1962	Apr 1962
		Oct 1969	Nov 1969
		Nov 1965	Mar 1967
		May 1963	Dec 1965
		Jun 1964	Dec 1967
		May 1965	Apr 1968
		Apr 1967	Aug 1968
		Apr 1967	Sep 1969
		Nov 1967	Jul 1969
		Apr 1968	Feb 1969
		Apr 1968	Aug 1969
		May 1968	Jun 1969
		Nov 1968	Mar 1970
		Jan 1969	Oct 1969
		Jan 1969	Dec 1969
		Jan 1969	Mar 1969
		Mar 1969	Oct 1970
		Jun 1969	May 1970
Aeroprojects Inc.	9	Sep 1950	May 1951
		May 1951	Feb 1952
		Mar 1952	Aug 1953
		Jun 1955	Jul 1956
		Jul 1956	Apr 1957
		May 1957	Jun 1958
		Sep 1951	Feb 1953
		Nov 1952	Feb 1954
		Apr 1968	Jan 1970
Aerotec Corp	1	Jun 1955	Oct 1956
Agricultural Aviation Engr Corp	1	Mar 1963	Oct 1963
Agricultural Specialty Co	1	Jun 1963	Mar 1965

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
Aircraft Armaments, Inc	4	Oct 1951	Feb 1954
		May 1962	Feb 1963
		Jun 1963	Mar 1965
		Nov 1964	Mar 1965
AAI Corp	2	Jun 1966	May 1968
		Jan 1967	Apr 1968
AiResearch Mfg. Co.	2	Apr 1964	Sep 1964
		May 1965	Apr 1967
Allied Research Associates Inc.	1	Aug 1957	Jun 1958
Allied Chem. Corp.	3	Apr 1967	Jun 1968
		Apr 1964	Apr 1967
		Dec 1958	Jun 1959
Allied Helicopter Service, Inc.	1	Apr 1967	Sep 1967
Amchem Products, Inc.	1	Aug 1959	Jan 1961
American Cyanamid Co.	2	Apr 1964	Nov 1965
		Jul 1957	Jul 1958
American Institute of Crop Ecology	2	Jun 1963	Jun 1965
		Apr 1955	Dec 1957
American Type Culture Collection, Inc.	1	Jun 1964	May 1967
Ansul Chemical Co.	2	Mar 1967	Aug 1969
		Jun 1962	Dec 1963
American Type Culture Collection	1	Jun 1952	Jun 1953
Anstice Co., Inc	1	Jun 1951	Aug 1951
Applied Science Laboratories Inc.	1	Jun 1961	Jul 1962

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
Univ. of Arizona	2	Jun 1961	Jul 1970
		Jun 1963	Dec 1965
Univ. of Arkansas	3	Sep 1954	Nov 1955
		Nov 1955	Nov 1956
		Nov 1956	Nov 1957
Armour Research Foundation of IIT	5	Nov 1951	Sep 1953
		Jun 1952	May 1954
		May 1953	Apr 1955
		Jun 1955	Dec 1955
		Jul 1955	Jun 1956
Arthur D. Little, Inc.	4	Apr 1950	Mar 1951
		Aug 1950	Jun 1952
		Jan 1951	Sep 1952
		Dec 1952	Oct 1955
Associated Nucleonics, Inc.	3	Feb 1960	Dec 1960
		May 1961	Apr 1962
		Jun 1961	Aug 1962
Atlas Powder Co.	1	Nov 1966	Jul 1956
Auburn Research Fndn.	1	Mar 1953	Dec 1957
AVCO Corp.	5	Sep 1958	Sep 1959
		Jun 1961	Jun 1963
		Sep 1964	Jun 1967
		Jun 1968	Oct 1970
		Apr 1969	Jun 1970
Baltimore Biological Laboratory	1	Apr 1963	May 1966
Battele Memorial Institute	11	Apr 1952	Oct 1952
		Apr 1952	Mar 1954
		Mar 1953	Mar 1954
		Apr 1953	Mar 1954
		Jul 1954	Aug 1955
		Oct 1954	Feb 1956
		Jun 1956	Sep 1958
		Apr 1957	Jul 1958
		Dec 1962	Jan 1966
		Sep 1964	Feb 1966
		Jun 1965	Aug 1965
Baylor College of Medicine	1	Aug 1966	Jun 1972
Ben Venue Labs, Inc.	2	Sep 1953	Jun 1954
		Oct 1954	Oct 1955

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
Beckman Instruments, Inc.	3	Feb 1966	Apr 1968
		Jun 1968	Nov 1969
		Nov 1968	Mar 1970
Bete Fog Nozzle, Inc.	1	Jun 1951	Jun 1952
Bendix Corp.	2	Jun 1962	Jun 1964
		Sep 1964	Jul 1965
Bionetics Research Laboratories	2	Mar 1966	May 1967
		Jun 1967	Sep 1968
Biosearch Co.	1	Feb 1962	Mar 1963
Bio-Search & Development Co.	1	Apr 1962	Sep 1963
Bjorksten Research Laboratories	1	Jan 1964	Jul 1965
Black Mfg. Co.	1	Jun 1951	Jun 1952
Booz-Allen Applied Research, Inc.	5	Feb 1957	May 1962
		Jul 1962	Sep 1962
		Apr 1963	Jun 1964
		Oct 1964	Oct 1965
		Oct 1965	Mar 1968
Boyce-Thompson Inst.	3	Jun 1963	Jun 1964
		Jun 1964	Aug 1965
		Oct 1968	Nov 1969
Brooklyn College	1	Mar 1960	Sep 1961
Bucknell Univ.	2	Apr 1952	Jun 1953
		Jul 1953	Aug 1954
Buffalo Electro-Chemical Co., Inc.	1	Feb 1951	Dec 1951
State of California	2	Jul 1951	Sep 1952
		Jan 1953	Dec 1953
Univ. of California	12	Apr 1950	Sep 1953
		Sep 1950	Aug 1951
		Mar 1951	Jul 1953
		Aug 1951	Aug 1952
		Aug 1952	Oct 1954
		Oct 1954	Oct 1955
		Jul 1962	Dec 1965

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
cont'd		Mar 1963	Dec 1963
		Mar 1964	Feb 1965
		Jun 1965	May 1966
		Jun 1966	Nov 1967
		Dec 1967	Nov 1968
Cambridge Technology, Inc.	2	Jun 1967	May 1968
		Jun 1967	Jun 1968
C-E-I-R, Inc.	1	Aug 1958	Mar 1959
Univ. Of Chicago	13	Jul 1955	Mar 1957
		May 1956	Sep 1963
		Oct 1950	Feb 1953
		Jun 1951	Jun 1953
		Dec 1951	Dec 1953
		Jun 1952	Jul 1954
		Jun 1952	Mar 1954
		Dec 1953	Dec 1956
		Aug 1962	Aug 1965
		Oct 1963	Oct 1964
		Nov 1964	Oct 1965
		Apr 1960	Apr 1963
		Mar 1966	Jul 1966
University of Cincinnati	5	Sep 1950	Sep 1951
		Sep 1951	Aug 1953
		Sep 1951	Sep 1953
		Apr 1953	Apr 1955
		Jun 1955	Jun 1956
Columbia University	1	Dec 1952	Jun 1954
Commercial Solvets Corp.	1	Apr 1963	Dec 1965
Continental Oil Co.	1	Sep 1962	Dec 1964
Control Data Corp. (Formerly C-E-I-R, Inc.)	2	Jun 1964	Feb 1968
		Jan 1968	Mar 1970
Cordis Corp.	1	Oct 1964	Oct 1965
Cornell Aeronautical Lab., Inc.	1	Oct 1960	Dec 1962
Cornell Univ.	2	Apr 1951	Mar 1953
		Apr 1953	Mar 1955
Cyclo Chemical Corp.	2	Jun 1964	May 1969
		Jun 1969	Dec 1970

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
Danielson Manuf. Co.	1	Mar 1953	Jun 1968
Daniel, Mann, Johnson & Mendenhall	1	Jun 1967	Jul 1968
Day & Zimmerman	1	May 1955	Oct 1955
DeBell & Richardson Inc.	1	Jun 1955	Dec 1957
Dorr-Oliver, Inc.	1	Aug 1962	Jul 1964
Doughnut Corp. of America	1	Dec 1952	Jan 1953
Dow Chemical Co.	5	May 1963 Jun 1967 Feb 1964 Nov 1958 Apr 1967	Aug 1964 Jun 1970 Jan 1966 May 1959 Dec 1967
Dry-Freeze Corp.	2	Feb 1951 Mar 1952	Sep 1951 May 1952
Duke Univ.	5	May 1951 May 1951 May 1954 Jun 1956 Feb 1964	May 1954 May 1953 Jun 1956 Feb 1964 Dec 1968
Allen B. DuMont Labs, Inc.	2	Jun 1953 Mar 1954	Mar 1956 Mar 1956
Edo Corp.	1	Jun 1964	Sep 1965
Emory Univ.	1	Dec 1954	Jun 1957
Everedy Co.	1	Mar 1951	Feb 1952
Environmental Rsch. Corp.	2	Jun 1967 Jun 1967	Sep 1968 Jan 1971
Ethyl Corp.	1	Jun 1962	Jun 1966
Fairchild Engine & Airplane Corp.	1	Aug 1959	Jan 1960
Fairchild Stratos Corp.	4	Aug 1962 Jan 1964	Apr 1964 Apr 1964

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
cont'd		Apr 1960	Jun 1961
		Jul 1961	Sep 1961
Falcon Plastics	1	Dec 1958	Jun 1959
Farrand Optical Co.	2	Jun 1956	Apr 1958
		Dec 1957	Sep 1958
Fawn Plastics Co., Inc	1	Mar 1961	Aug 1962
Fletcher Enamel Co.	1	Dec 1950	Dec 1951
Univ. of Fla.	6	Jun 1956	Jun 1957
		Jun 1955	May 1956
		Jun 1963	Jun 1965
		Jun 1968	May 1970
		Apr 1952	May 1954
		Jan 1953	Sep 1953
Florida State Univ.	3	Mar 1951	Sep 1951
		Sep 1951	Jun 1953
		Jul 1953	Jun 1956
FMC Corp.	4	Jun 1964	Dec 1965
		Jan 1965	Jun 1967
		Jun 1966	Mar 1967
		Sep 1969	Feb 1970
Fordham Univ.	2	Mar 1966	Feb 1967
		Jan 1965	Feb 1966
Fostoria Presses Steel Corp.	1	Jul 1966	Mar 1956
Foundation for Research on the Nervous System	2	Dec 1963	Apr 1968
		Apr 1968	Oct 1969
Franklin Electronics, Inc.	1	May 1966	Jun 1966
Franklin Inst.	2	Jun 1968	Jan 1970
		Apr 1969	Oct 1970
Gelman Instrument Co.	1	Apr 1964	Apr 1969
General American Transp. Co.	2	Oct 1961	Jun 1966
		Jun 1962	Jan 1963
General Aniline & Film Co.	1	Jun 1963	Oct 1964
General Dynamics Corp.	1	May 1955	Apr 1956
General Electric Co.	5	Nov 1960	May 1961

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
cont'd		May 1963	Jul 1963
		Jun 1963	Dec 1964
		Sep 1963	May 1964
		Feb 1966	Dec 1967
General Mills, Inc.	7	Apr 1950	Jan 1951
		Jul 1950	Dec 1950
		May 1952	Jun 1954
		Dec 1952	Nov 1955
		Dec 1955	Dec 1957
		Aug 1956	May 1957
		Nov 1956	Nov 1957
George Washington Univ.	2	Nov 1952	Apr 1956
		May 1956	Mar 1959
Georgia Tech Rsch Inst.	5	Jun 1950	Jun 1951
		Jun 1951	Jun 1953
		Mar 1953	Jun 1954
		Jun 1954	Jun 1955
		Jun 1956	Jun 1957
B. F. Goodrich Co.	2	Jul 1953	Aug 1954
		Jan 1955	Jan 1956
Grinnell Co., Inc.	1	Jan 1954	Nov 1958
Hahn E. Mann Medical College & Hospital	2	Oct 1953	Jan 1954
		Nov 1954	Apr 1956
Harvard College	5	Jul 1951	Sep 1952
		Jul 1949	Aug 1961
		Aug 1951	Jun 1955
		Sep 1955	Aug 1956
		Jun 1963	Sep 1968
Hawaii, Univ. of	2	May 1967	Jun 1968
		Jun 1968	Jun 1970
Henry Ford Hospital	2	Jul 1951	Jul 1952
		Oct 1952	Jul 1953
Hills-McCanna Co.	1	Jan 1957	Jan 1958
Holmes & Narver, Inc.	1	Jun 1968	Nov 1969
Honeywell Regulator Co.	5	Jan 1955	Dec 1956
		Jun 1955	Apr 1957
		Feb 1957	Apr 1958
		Jun 1961	Nov 1962
		Dec 1961	Apr 1962

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
Hooker Chemical Corp.	1	May 1964	Aug 1965
Hyland Labs, Inc.	1	Jun 1964	Feb 1966
IIT Research Inst.	10	Sep 1962	Jan 1963
		Nov 1962	Jul 1966
		Jun 1955	Dec 1956
		May 1963	Jun 1964
		May 1964	Feb 1967
		May 1965	Feb 1965
		Feb 1958	Sep 1962
		Feb 1963	Apr 1965
		May 1965	Sep 1966
		Jan 1966	Aug 1970
Illinois, Univ. of	7	Oct 1950	Dec 1951
		Jun 1951	Jun 1954
		Sep 1952	Jun 1956
		Apr 1956	Dec 1957
		Jun 1959	May 1960
		Oct 1963	Jan 1967
		Jun 1966	May 1968
Indiana, Univ. of	4	Mar 1953	Apr 1955
		May 1951	Apr 1953
		Apr 1963	Mar 1966
		Sep 1964	Mar 1966
Industrial Corp.	1	Jun 1962	Apr 1963
Insect Control & Rsch, Inc.	3	Jun 1964	Jun 1966
		Oct 1963	Jun 1964
		Dec 1960	Sep 1963
International Business Machines	1	Jun 1968	Mar 1969
Internation Minerals & Chemical Corp.	2	Sep 1966	Jun 1968
		May 1964	Jun 1965
Bioferm, Inc.	3	Dec 1962	Nov 1963
		Mar 1963	Apr 1963
		Nov 1963	Nov 1963
Iowa State College of Agric.	6	Jan 1949	Jan 1951
		Jun 1950	May 1952
		Jul 1951	Jul 1953
		Dec 1951	Jun 1953
		Sep 1954	Jun 1956
		Jun 1952	May 1954

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
John Hopkins Univ.	12	Jul 1955	Feb 1963
		Mar 1956	Sep 1958
		Jun 1950	Jul 1951
		Mar 1951	Aug 1953
		Apr 1951	Oct 1952
		Aug 1951	Oct 1952
		Oct 1952	Oct 1954
		Nov 1952	Oct 1953
		Mar 1953	Mar 1955
		Apr 1955	Mar 1956
		Apr 1963	May 1971
		Jun 1965	Jun 1970
S. C. Johnson & Son, Inc.	1	Sep 1960	Nov 1962
Kansas State Univ. of Agric. & Applied Science	5	May 1956	Jun 1958
		Dec 1962	Jul 1963
		Oct 1959	Aug 1960
		Aug 1960	Aug 1961
		Sep 1961	Sep 1962
Univ. of Kansas	4	Apr 1949	Jun 1951
		Jul 1951	Jun 1952
		Jun 1952	Jun 1953
		Jul 1953	Jun 1954
Duane Kennedy Co.	1	Jul 1959	Jul 1960
Kent Manuf. Corp.	1	Apr 1950	Mar 1951
Kentucky Research Fdn.	1	May 1954	Jun 1956
Walter Kidde & Co., Inc.	1	Jan 1955	Apr 1958
Knapp-Monarch Co.	1	Sep 1952	Aug 1953
Kuljian Corp.	1	Nov 1954	Mar 1956
Lambert Pharmaceutical Co.	1	Jun 1950	Jun 1951
Lehigh Univ.	1	Jan 1953	Dec 1953
Litton Systems, Inc.	14	Jun 1960	Sep 1965
		Nov 1962	Feb 1964
		Mar 1964	Nov 1965
		Sep 1964	Jan 1966
		May 1965	Oct 1965
		May 1965	Jan 1966
		Jun 1965	Sep 1965
		Mar 1966	Apr 1966
		Apr 1966	Jul 1966

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
cont'd		Jun 1962	Jun 1964
		Aug 1966	Dec 1966
		Nov 1966	Jan 1968
		Mar 1967	Mar 1967
		Nov 1967	Nov 1967
Lockheed Aircraft Corp.	3	Jan 1965	Dec 1965
		Aug 1966	Sep 1967
		Mar 1968	Dec 1969
Long Island Biological Association	6	Oct 1950	Sep 1951
		Oct 1951	Sep 1952
		Oct 1952	Sep 1953
		Oct 1952	Sep 1953
		Sep 1953	Sep 1954
		Sep 1954	Sep 1955
Lovell Chemical Co.	3	Oct 1950	Sep 1951
		Feb 1952	Apr 1952
		May 1953	May 1954
Lux Clock Manuf. Co.	1	Jul 1953	Dec 1953
Machine & Tool Design Co.	1	Jun 1954	Nov 1954
Magna Corp.	1	Jun 1962	Aug 1963
Glenn L. Martin Co.	1	Aug 1950	Nov 1950
Martin Marietta Corp.	1	Mar 1953	Jul 1955
Md., Univ of	8	Mar 1953	Jul 1955
		Jun 1955	Jul 1956
		Oct 1956	Oct 1959
		Jun 1951	May 1952
		Jun 1952	May 1953
		Mar 1953	Feb 1954
		Mar 1954	Mar 1955
		Mar 1969	Dec 1969
Mass., Univ of	1	Nov 1954	Nov 1955
Mathieson Cml Corp.	2	Mar 1953	Jun 1954
		Jun 1952	Apr 1953
Maxon Electronics Corp.	1	Jun 1961	Aug 1963
Marquette School of Medcine	1	Jun 1969	Aug 1970

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
MB Associates	5	Jun 1964	Oct 1966
		Jun 1966	Aug 1967
		Jan 1967	Sep 1967
		Jun 1967	Jul 1969
		Mar 1969	Nov 1969
Mellon Inst. of Ind. Rsch	4	Aug 1950	Aug 1951
		Aug 1951	Aug 1952
		Aug 1952	Feb 1954
		Jun 1954	Aug 1955
Melpar, Inc.	6	Jun 1961	Jul 1963
		Jun 1962	Jun 1963
		May 1963	Oct 1965
		May 1964	Nov 1964
		Jun 1964	Aug 1965
		Jun 1964	Jul 1965
American Std., Inc. (Melpar Div)	2	Oct 1965	Jan 1967
		Feb 1966	Jul 1967
Merck & Co., Inc.	2	May 1955	Dec 1956
		Apr 1960	Jun 1961
Meteorology Rsch, Inc.	1	Jun 1965	Feb 1967
Metronics Associates, Inc.	2	Apr 1966	May 1966
		May 1968	Jun 1970
Metal Matic, Inc.	1	Aug 1954	Oct 1954
Michigan, State of (Dept of Health)	1	Jun 1965	Jul 1967
Michigan State College	5	Jun 1954	May 1956
		Oct 1950	Sep 1952
		May 1951	Oct 1951
		May 1952	Jan 1953
		Oct 1952	Sep 1954
Michigan State Univ.	3	May 1956	Sep 1967
		Dec 1965	Nov 1968
		May 1960	May 1961
Michigan, Univ. of	7	Jul 1951	Jun 1952
		Apr 1953	Sep 1955
		Aug 1959	Jun 1964
		Aug 1962	Jun 1964
		Jun 1964	Nov 1965
		Mar 1967	Jun 1969
		Jun 1969	Jul 1961
Midwest Rsch Inst.	4	Jun 1961	Jul 1963
		Jul 1961	Apr 1964

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
cont'd			
		Jun 1965	Jun 1971
Metronics Associates, Inc.	2	Mar 1965	Oct 1968
		Jun 1968	May 1970
Univ. of Miami	1	Apr 1969	Sep 1970
Millipore Filter Corp.	1	Jun 1954	Dec 1955
Mine Safety Appliances Co.	5	Jun 1955	Jan 1957
		Jun 1957	Apr 1959
		Sep 1959	Oct 1960
		Mar 1961	Nov 1963
		Jun 1963	Jun 1964
Minneapolis-Honeywell Regulator Co.	3	Feb 1953	Dec 1954
		Feb 1953	Sep 1955
		Dec 1952	Feb 1956
Univ. of Minnesota	18	Jun 1950	May 1952
		Jul 1953	Sep 1956
		Jul 1951	Jun 1952
		Jun 1952	May 1954
		Jun 1952	Jun 1954
		Jun 1952	Jun 1953
		Oct 1952	Dec 1953
		Apr 1953	Mar 1955
		Apr 1953	Sep 1953
		Jul 1953	Jun 1955
		May 1953	Jun 1954
		May 1954	Jan 1955
		Sep 1956	Sep 1957
		Jun 1964	Dec 1965
		Jun 1962	Dec 1965
		Jun 1959	May 1964
		Feb 1965	Apr 1966
		Mar 1967	Jun 1970
Mississippi State College	2	May 1951	Apr 1953
		May 1953	Apr 1955
Univ. of Mississippi	3	Jul 1951	Sep 1952
		Nov 1951	Jun 1953
		Sep 1952	May 1955
Univ. of Missouri	1	May 1950	Apr 1952

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
Molded-Resin Fiber Co.	1	Dec 1951	Feb 1953
Monomer-Poylmer, Inc.	1	Nov 1951	Mar 1952
Monsanto Chemical Co.	1	Dec 1958	Jun 1959
Monsanto Research Corp.	4	Jan 1963 Jun 1966 Apr 1967 Jun 1968	Dec 1965 Apr 1968 Dec 1967 Feb 1969
Montana State Univ.	1	Jun 1967	Nov 1970
MTD Research & Development	1	Jul 1960	Aug 1961
Douglas M. McBean, Inc.	1	Jun 1953	Jul 1957
McDonnell Douglas Corp.	1	Jun 1960	Mar 1965
National Academy of Sciences	1	Dec 1957	Dec 1962
Nation Research Corp.	1	Feb 1961	Mar 1961
Univ. of Nebraska	2	Sep 1951 Nov 1948	Apr 1954 Aug 1951
New Mexico College of Agriculture & Mechanic Arts	1	Jun 1960	Dec 1962
New Mexico State Univ.	1	Jun 1964	Dec 1968
New York Univ.	1	Jan 1954	Jun 1956
Research Fndn. of State Univ. of New York	3	Oct 1952 Jun 1963 Jun 1969	Mar 1965 Jun 1967 Jul 1969
North American Avaiation, Inc.	2	Dec 1957 Jan 1962	May 1959 Apr 1962
North Carolina State of Univ. of N.C.	2	Aug 1963 May 1964	Sep 1963 Jun 1964
North Dakota Agricultural College	2	Apr 1960 Apr 1961	Sep 1960 Sep 1961
Northrop Corp.	1	Jan 1966	May 1967
Univ. of North Carolina	1	Oct 1951	Jan 1954

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
Northwestern Univ.	3	Sep 1950	Oct 1951
		Nov 1951	Oct 1952
		Dec 1952	Jun 1954
Univ. of Notre Dame	1	Dec 1951	Mar 1954
New York Univ.	1	Nov 1951	Nov 1953
Univ. of Notre Dame	6	Jun 1953	Jul 1954
		Jan 1950	Mar 1951
		Mar 1951	Jul 1954
		Sep 1954	Sep 1955
		Sep 1959	Aug 1960
		Nov 1962	Jan 1965
G. O. Noville & Associates Inc.	1	Aug 1953	Jul 1957
Ohio University	2	Feb 1955	Jan 1957
		Jan 1957	Jan 1958
Ohio State Univ. Research FNDN.	8	Oct 1952	Oct 1955
		Jan 1955	Dec 1958
		May 1955	May 1957
		Oct 1959	Sep 1960
		Oct 1962	Oct 1965
		Mar 1963	Dec 1965
		Jun 1963	Sep 1965
		Jun 1969	Jul 1969
Okanagan Copter Sprays Ltd.	1	Jun 1967	Jun 1967
Oklahoma Agric. & Mechanical	1	Sep 1951	Feb 1953
Oklahoma State Univ.	2	Mar 1963	Jun 1963
		Feb 1968	Aug 1969
Olin Mathieson Chem. Corp.	2	Sep 1955	Feb 1958
		Sep 1955	Feb 1958
Optics Technology, Inc.	2	May 1963	Nov 1964
		Jun 1965	Jun 1966
Ordnance Engrg. Corp.	1	May 1955	May 1956
Oregon State Univ.	2	Jan 1964	Dec 1968
		Jan 1969	Apr 1970
T. G. Owe Berg, Inc.	1	Jun 1966	Aug 1967
Parke, Davis & Co.	7	Jun 1951	Nov 1954

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
cont'd		Jan 1953	Apr 1955
		May 1953	Feb 1958
		May 1955	Feb 1958
		Dec 1954	Oct 1955
		Oct 1955	Oct 1956
		Apr 1957	Oct 1958
Park Thompson	1	Dec 1950	Aug 1951
Ralph M. Parsons Co.	10	Oct 1951	Oct 1951
		Dec 1951	Mar 1952
		Jun 1952	Feb 1954
		Jun 1952	Aug 1955
		Apr 1952	Jul 1963
		Jun 1952	May 1956
		Sep 1954	Nov 1955
		Jun 1951	Nov 1951
		Aug 1951	Dec 1953
		Sep 1953	Jan 1954
Pennsalt Chem. Corp.	3	Jun 1962	Dec 1965
		Jan 1969	Sep 1970
		Jan 1969	Sep 1970
Pennsylvania State College	3	Jul 1951	Aug 1953
		Sep 1953	May 1970
		Mar 1969	Apr 1971
Pennsylvania, Univ. of	4	May 1955	Nov 1957
		Feb 1958	Jun 1958
		Jun 1958	Sep 1961
		Jul 1961	Aug 1967
Pfizer, Charles & Co., Inc.	3	May 1963	May 1964
		Mar 1965	Jan 1967
		Jun 1963	Jun 1964
Philco Corp.	1	Jun 1961	Nov 1964
Photomechanisms, Inc.	2	Sep 1958	Feb 1962
		Oct 1961	May 1962
Pittsburgh, Univ. of	1	Apr 1951	Jun 1953
Planning Research Corp.	1	Apr 1960	Dec 1961
Plax Corporation	1	Mar 1952	Sep 1952

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
Pneumo-Dynamics Corp.	1	Jun 1963	Jan 1964
Polaroid Corp.	6	Feb 1951	Jun 1952
		Jun 1952	Jun 1953
		Jun 1953	Aug 1954
		Sep 1954	Dec 1955
		Jan 1956	Apr 1957
		Apr 1958	Apr 1960
Prengle, Dukler & Crump	1	May 1961	Mar 1964
Prime, Inc.	3	Jul 1950	Oct 1950
		May 1953	Apr 1954
		Aug 1953	May 1955
Princeton Univ.	1	Jun 1967	Oct 1969
Puerto Rico, Univ. of	1	Jan 1952	Jun 1952
Purdue Research Fndn.	6	Jun 1952	Nov 1954
		Jan 1955	Mar 1956
		Jul 1963	Jan 1966
		Jun 1966	Aug 1968
		Feb 1969	Aug 1970
		Jun 1963	Dec 1969
Rheem Manufacturing Co.	1	Mar 1952	Apr 1954
Rhode Island State College	1	Jan 1951	Mar 1952
Rhode Island, Univ. of	1	Mar 1953	Mar 1955
Rutgers College	1	Oct 1950	Sep 1951
Rutgers Univ.	1	Oct 1951	Sep 1953
Rutgers, The State Univ.	2	Jun 1957	Aug 1960
		Sep 1962	Aug 1965
Ryan Aeronautical Co.	1	May 1963	Jul 1963
Sharpley Laboratories, Inc.	1	Mar 1963	Mar 1966
Shell Chemical Corp.	1	Nov 1958	May 1959
Sierra Engrg. Co.	1	Jun 1964	Jul 1965
Smithsonian Inst.	4	Apr 1951	Apr 1953
		Apr 1953	Apr 1955
		Jul 1955	Apr 1956
		Oct 1962	Jun 1969
Southern Calif., Univ of	2	Oct 1952	Jan 1955
		Jan 1955	Sep 1957

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
cont'd		Jan 1955	Sep 1957
Southern Research Inst	16	Apr 1951	Jan 1952
		Jun 1951	Jun 1952
		May 1952	Dec 1952
		May 1952	Sep 1953
		Jun 1952	Jun 1953
		Jun 1953	Jul 1954
		Oct 1953	Sep 1954
		Feb 1953	Nov 1955
		Jun 1954	Dec 1955
		Oct 1954	Jan 1956
		Aug 1954	Sep 1955
		Jan 1956	Mar 1958
		Jul 1956	Aug 1957
		Feb 1960	Apr 1961
		May 1960	Sep 1963
		Dec 1961	Jun 1962
Southwest Research Inst.	1	Apr 1957	Jul 1957
Sperry Piedmont Co.	1	Jan 1965	Aug 1965
Sperry Utah Co.	2	Apr 1963	May 1965
		Jun 1964	Mar 1965
Specialized Instruments Corp.	2	May 1952	Aug 1952
		Jan 1954	Jul 1954
Spraying Sys Co.	1	Jul 1951	Aug 1952
Squibb, E. R. & Sons	1	Jun 1952	Apr 1953
Stanford Research Inst.	2	Aug 1957	Aug 1958
		Jun 1954	Jun 1955
Stanford, Leland Jr. Univ.	4	Jun 1954	Jun 1955
		Jul 1955	Aug 1956
		Oct 1951	Apr 1954
		Aug 1956	Sep 1959
Stanford Research Inst.	1	Mar 1964	Jan 1966
Syracuse Univ.	2	Nov 1967	Jan 1969
		Jan 1969	Apr 1970
Taller Y Cooper, Inc.	1	Jun 1955	May 1957
Tennessee, Univ. of	2	Jun 1951	Oct 1952
		Nov 1962	Oct 1965
Texas Agric. Mechanical Col.	5	Jul 1953	Dec 1954

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
cont d		Jun 1954	Jun 1955
		Jun 1955	Aug 1956
		Aug 1956	Aug 1957
		Jun 1968	Dec 1970
Texas. Univ. of	8	Oct 1951	Oct 1954
		Oct 1952	Jul 1955
		Sep 1955	Jul 1958
		Jun 1957	Aug 1958
		Feb 1951	Feb 1953
		Aug 1958	Aug 1960
		May 1963	Oct 1965
		Jun 1968	Jun 1970
Tex. Rice Improvement Assoc.	1	Mar 1958	Nov 1958
Thompson Helicopters, Inc.	1	May 1964	May 1964
Townsend Engineered Products Inc.	1	Aug 1963	Jul 1957
Tracerlab, Inc.	6	Dec 1951	Dec 1952
		Jan 1953	Dec 1953
		Sep 1949	Dec 1951
		Jan 1954	Mar 1955
		Jun 1955	Feb 1957
		Apr 1957	Dec 1958
Travelers Research Corp.	1	Jun 1966	Jan 1968
Trident Eng g Assoc. Inc.	1	Mar 1965	Aug 1965
Trio-Cml Works Inc	4	Sep 1967	Oct 1967
		Aug 1967	Sep 1967
		Mar 1969	Mar 1969
		Jul 1969	Dec 1969
Edward L. Trudeau Foundation	1	Jun 1952	Sep 1953
U.S. Industrial Corp	1	Apr 1965	Jun 1965
U.S. Rubber Co.	1	Jun 1964	Jul 1965
U.S. Steel Co.	1	Mar 1958	Mar 1959
Univ. Match Corp.	3	Feb 1954	May 1955
		Sep 1955	Jun 1956
		Nov 1956	Nov 1957
Utah,Univ of	6	Jan 1951	Feb 1953
		Mar 1953	Feb 1954
		Mar 1954	May 1955

CONTRACTOR	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
cont d		Nov 1953	Nov 1954
		Nov 1954	Jun 1956
		Jul 1955	Jul 1959
Virginia, Univ. of	2	Jun 1965	Apr 1967
		May 1967	Feb 1969
Vitro Eng g Co	1	Dec 1961	Mar 1962
Wahl-Henius Inst	2	Jun 1952	Oct 1952
		Jun 1953	Jun 1954
Warner Lambert Pharmaceutical Co.	1	Jun 1953	Jun 1955
Wash. St. Univ.	4	May 1967	Sep 1968
		Aug 1959	Nov 1964
		Dec 1964	Nov 1968
		Jan 1969	Jun 1970
Wesleyan Univ.	2	Feb 1953	Apr 1955
		Apr 1951	Apr 1953
West Va. Univ	14	Jun 1949	Sep 1951
		Jun 1952	Jun 1953
		Dec 1952	Feb 1955
		Jun 1953	Jun 1954
		Jun 1953	Jun 1954
		Jun 1954	Jun 1955
		Oct 1954	Sep 1955
		Feb 1955	Jan 1957
		Jul 1955	Jun 1956
		Jul 1956	Jul 1959
		Feb 1957	Jan 1958
		Jan 1963	Sep 1964
		Feb 1963	Apr 1966
		Sep 1964	Mar 1966
Western Reserve Univ.	3	Mar 1951	Feb 1952
		Jun 1951	May 1952
		May 1952	May 1953
Wiegand, Edwin L. Co.	1	Aug 1955	Apr 1956
Wisconsin, Univ. of	21	May 1950	May 1952
		Jun 1950	May 1952
		Jun 1950	Jan 1952
		Jun 1952	Jan 1954
		Sep 1952	Sep 1953
		Mar 1953	May 1955
		Apr 1951	Aug 1956
		Feb 1954	Sep 1956
		Dec 1954	Oct 1963

CONTRACTORS	NUMBER OF CONTRACTS	CONTRACT DATE	TERMINATION DATE
cont'd		Jul 1956	Jul 1957
		Nov 1956	Jun 1961
		Jun 1966	Oct 1969
		Sep 1950	Sep 1951
		Oct 1950	Oct 1951
		May 1951	May 1953
		Jun 1951	Jun 1952
		Sep 1951	Sep 1952
		Oct 1951	Feb 1953
		Feb 1952	Sep 1953
		Jun 1952	Jan 1954
		Jun 1952	May 1953
Wistar Inst. Of Anatomy	3	Jun 1963	Oct 1965
		May 1966	Jan 1968
		May 1960	Apr 1962
Worchester Fndn. for Experimental Biology	1	Dec 1962	Nov 1963
Yale Univ.	2	Jun 1963	Aug 1965
		Jun 1966	Oct 1967
H.L. Yoh & Co., Inc.	2	Jun 1955	Feb 1956
		Jun 1955	Mar 1956

Annex D

Production of Biological Warfare Agents and Munitions

Background. Production of all BW agents including antipersonnel and anticrop material, was based on technology developed in laboratory and pilot plant facilities at Fort Detrick. The first pilot plant, intended for the production of botulinum toxin, was completed in October 1943. A second plant was built in March 1944 to produce anthrax spores and the anthrax simulant. From these beginnings until cessation of offensive BW operations in 1969, Fort Detrick produced test quantities of a large number of antipersonnel and anticrop BW agents and developed the production process eventually employed at the Vigo and Pine Bluff Arsenal production facilities. A wide variety of process equipment, some of which was developed for the first time to support the unique requirements of BW production, constituted the numerous pilot plant facilities at Fort Detrick.

Antipersonnel agent and munition production. The first large scale BW munition production facility was constructed at the Vigo Ordnance Plant, near Terre Haute, Indiana, beginning in May 1944. The Vigo Plant was intended to produce biological agents and vaccines and to fill and assemble biological munitions beginning with anthrax-filled bombs. The Vigo Plant was in a test operation phase producing BC, a harmless simulant of anthrax, when the end of WWII terminated plant operations. The plant was deactivated and eventually excessed by the Army in 1946.

The only facility operated for large scale production of antipersonnel BW agents was located at Pine Bluff Arsenal with construction completed in November 1953. The plant later became permanently identified as the Directorate of Biological Operations (DBO). The initial capability of producing bacterial agents was later expanded to include capabilities for producing

toxins in addition to viral and rickettsial agents and the unique capacity for growing and infecting mosquitoes with viral agents. The complex of buildings included those designed for agent fermentation, munitions filling/production and laboratory support operations. The entire facility was designed and constructed to provide both absolute safety to operating personnel and absolute containment of the highly toxic and infectious materials produced there. Between 1954 and 1967, the facility produced the following biological agents and toxins: Brucella suis, Pasteurella tularensis, Q fever rickettsia, Venezuelan Equine Encephalomyelitis, Bacillus anthracis, botulinum toxin and staphylococcal enterotoxin. Bulk agents and antipersonnel munitions filled with these various agents and toxins were produced and stored at DBO as a deterrent capability. DBO operations were terminated in November 1969, and all stocks of antipersonnel biological munitions, agents and toxins were subsequently destroyed in accordance with approved demilitarization plans. The facility was then decontaminated and deactivated, and on 15 May 1972, the complex (including land, buildings, and equipment) was turned over to the Food and Drug Administration, an agency of the Department of Health, Education and Welfare, who operate it as the National Center for Toxicological Research (NCTR).

Anticrop Biological Agent Production. Three anticrop biological agents were produced between 1951 and 1969. These included both stem rust of wheat and rye, and rice blast. Between 1951 and 1957, wheat stem rust spores and rye stem rust spores were produced from innoculated crops at planting sites located on Government installations.

The harvested spores were shipped to Edgewood Arsenal, Maryland for classification, drying and storage. This operation was terminated in 1959 by the Air Force. Between 1962 and 1969, wheat stem rust spores were grown at Government sites. The crude material was transferred to Rocky Mountain Arsenal where it was cleaned, classified and placed in cold storage. All wheat rust spores were destroyed by February 1973.

Rice blast was produced by a submerged culture process under a contract. The production contract was awarded in March 1965. Agent production was terminated in June 1966 after initial delivery of acceptable material. The final agent was packaged and stored at Fort Detrick. The total rice blast stock was destroyed between 17 January and 18 May 1972.

ANNEX E

Testing

General. Testing is an integral part of research and development. It is primarily concerned with the acquisition of data to evaluate and confirm or negate postulates and theories devised in the laboratory, instrumentation design parameters, and mathematical modes.

Rationale for biological testing. BW testing, like all elements of the BW program, was at its inception, unique. The artificial study of biological material disseminated into the atmosphere, now known as aerobiology, was not a practiced or organized scientific discipline at the start of the BW program. Little or no knowledge was available regarding the biological and/or physical decay factors of micro-organisms in normal weather fluctuations, the amount necessary to cause infections, nor the methodology or hardware to effect dissemination. It was, therefore, essential to conduct testing to acquire the necessary scientific and technical information to substantiate theories and fill knowledge gaps and to determine vulnerability to attack.

Categorization of biological testing. Biological testing can be divided into three categories, laboratory (small scale), closed chambers (medium scale), and open air field (large scale). Each of these categories can be further divided into testing with simulants and pathogens. The open air field testing can be further categorized into continental and extra contininental and that performed on public and non-public domain (military installations). Within this realm further

characterization can be delineated into the target of the test, i.e., mechanical devices such as detectors or biological samplers, and living targets such as humans, animals or crops.

In addition to the above testing another form may be categorized under the general heading of immunological testing in humans and animals which was done to evaluate vaccines, toxoids and skin tests.

Appendix I is a pictorial representation of biological testing.

Liaison. The US Public Health Service closely followed the progress of BW research and development from the very start of the program because of its civil defense responsibilities. In 1950 a USPHS liaison officer was assigned to Ft. Detrick on a permanent basis to maintain even closer contact for emergency health planning, and awareness and mutual exchange of information on new detection methodology, epidemiology, disease control, safety, and vulnerability of the US to hostile BW attack.

In 1951, the Department of Agriculture assigned a permanent liaison officer to closely follow the BW program as related to crops and animals.

Active liaison was also maintained from the very beginning of the program with the other military services. The Surgeon General of the Army maintained his close liaison with medical personnel right on the scene working within the research and development laboratories. In 1956, as a result of a Joint Medical Service and Chemical Corp Agreement, the Army Medical Unit was established at Ft. Detrick with the mission to conduct defensive R&D including prophylactic and therapeutic measures, more rapid and effective diagnostic and identification procedures and to evaluate the threat of BW to the military from a medical point of view.

The US Naval Unit, Ft. Detrick was established on 8 February 1944 with the mission to promote modern medical research in public health concerns, vapor phase disinfectants control of airborne diseases, and to provide the Naval Establishment with information for its defense.

Naval personnel were integrated into all aspects of the laboratories, and operational elements of the past.

The US Air Force began to station liaison officers at Ft. Detrick in the late 1940's. The mission was to coordinate BW munition development, supply support for field testing, and to maintain and operate a meterological station.

General Safety and Medical Considerations. The safety and medical aspects of testing with biological material were of overwhelming concern to management from inception of the BW program, primarily because of the many unknown factors, and the potential severe danger to employees as well as the local community. A major safety organization was always established along with the operational organizations and its importance can be attested to by the fact that the Safety Director reported directly to the Commanding Officer and Technical Director. Since many of the early aspects of the Safety/medical program were of necessity experimental, it was necessary to confer with and have the approval of the Surgeons' General of the military services for much of its operations. U.S. Public Health Service maintained cognizance of the program and provided advice on public health.

To this end, the Safety/medical program developed specialized operating features for laboratories to include negative pressure isolation cabinets, glove ports and gloves for working within the cabinets, and exhaust ventilation system incorporating air incineration chambers,

water and water decontamination systems and protective clothing and masks to ensure that no contaminated material contacted the workers or was discharged to the environment.

These pioneering efforts subsequently became the foundation for infectious disease safety procedures, techniques and equipment throughout the scientific and industrial communities in the world.

The concern for safety/medical aspects is further noted by the deliberations of various external/advisory committees such as "The US Biological Warfare Committee" (Merck Committee) in 1942, and the Committee on Biological Warfare of The National Military Establishment Research and Development Board (Baldwin) in 1948. With advent of the requirement to determine the field environment effects such as varying temperature, humidity, terrain, to include structures, sunlight, winds, etc., on BW agents, independent external advisory committees were formed to review, comment upon, and make recommendations concerning test protocols. These committees were "The Ad Hoc Committee on BW Testing" (Scheele Committee) 1953, and "The Interegency Survey Committee on BW Testing" (Price Committee) 1959. The members of these committees were eminent authorities in their fields of biological and medical sciences and were drawn from various universities, and Federal and state agencies. It is to be noted that these committees did in fact make strong recommendations for safety/medical requirements and specified certain pathogenic microorganisms which should be utilized for open-air testing. The Army considered these latter recommendations binding.

The increased testing program which arose from DOD Project 112 generated a detailed safety review procedure for each test. "The Deseret Test Center (DTC) Medical Advisory Committee" (Davis Committee) 1962-1969 provided the first level of review. Since DTC was a joint organization the proposed test programs were reviewed and approved by the Joint Chiefs of Staff and the Office of the Secretary of Defense. A national policy directive was issued by the President on 17 April 1963 requiring Presidential approval of all tests which might have significant or protracted effects on the physical or biological environment. The Department of Defense issued an instruction in April 1963 on Large Scale Scientific or Technological Experiements which outlined the procedure to be used for obtaining Presidential approval. DTC test plans and the Medical Advisory Committee recommendations were forwarded to the President's Science Advisory Committee for approval.

Conduct of testing. In the conduct of testing, specialized sampling and analysis aspects were employed to determine the various parameters of the test requirements as well as the downwind travel distances. These were supplemented by rather complete meteorological data gathering systems to define meteorological conditions. Meterological conditions were an absolute control factor in whether or not a test was permitted to start or continue.

Simulant Testing. Every effort expended in open-air testing was first directed towards the utilization of simulants to obtain the necessary data for evaluation. Biological simulants are defined as living microorganisms, not normally capable of causing infection, representing the physical and biological characteristics of potential microbiological agents and considered medically safe to operating personnel and surrounding communities. In addition, certain selected inorganic materials such as flourescent particles, were also utilized to obtain aerosol dissemination data.

The two most commonly used biological simulants were Serratia marcescens (SM) and Bacillus subtillis variant niger, normally referred to as Bacillus globigii (BG). The most commonly used flourescent particle was an inorganic complex, zinc cadmium sulfide (Zn CdS).

Bacillus globigii (BG). BG is considered ubiquitous in nature. It can be readily cultured from hay, dust, milk and water. It was and is still considered by medical authorities to be harmless (nonpathogenic) to man. The utilization of BG in aerosol testing in open-air tests were reaffirmed as recently as 1970 by The Surgeon General of the US Public Health Service who indicated as a result of his directed literature search and consultation with health experts, that there is no evidence of infection in man or experimental animals following exposure to BG spores, even in massive doses.

Serratia marcescens (SM) is a motile, nonsporulating, gramnegative bacillus which may produce a red pigment especially when grown at room temperature. It is commonly found in water, food and sewage and sometimes can be isolated from feces and sputum of apparently healthy people. It was used as a bacterial marker with little risk up to 1969 because of its avirulant nature. In 1969, it was recognized as having

limited pathogenic capability and should not be used for study of experimental infections in man because of the assumed role as an opportunist, producing disease if man is exposed to large doses and/or when the body defenses are weakened by age, debilitatory disease, drug abuse or antibiotics. A summary report on SM is at Appendix II.

Aspergillus fumigatus (AF) was a fungus simulant used on four occasions from 1950-1953 and abandoned when antifungal agents were removed from the BW program. It is ubiquitous in nature and can be cultured from soil, water, air, food stuffs, animals waste products and most human body orifices. AF is considered an opportunist causing aspergillosis in debilitated persons.

Rationale for Vulnerability Testing. In the beginning and continuing throughout the BW Program, there was a paucity of scientific and engineering knowledge and principles related to the vulnerability of the US and/or its personnel to BW attacks both covert and overt. Vulnerability testing was required to provide information on the agents likely to be used, means of disseminating agents, sizes of areas that could be attacked, environmental effects on agents, obstructive effects of buildings and terrain on agents, ability to detect and identify agents areas of the US and for its forces most likely to be attacked, the extent of damage possible, and data to devise physical and mathematical models to be used as substitutes for live, open air testing.

The examination of the threat of vulnerability of the US and/or its personnel to BW attack, overt or covert, was under active consideration as early as 1939. "Bacteriological Warfare Possibliities", Technical Study No. 10, 28 August 1939, Office of the Chief, Chemical Warfare Service, concluded "...that attack by airplane dissemination of infected insects and other bacteriological materials, is a possibility not to be ignored, especially when parachute troop landing can be expected." Intelligence information from WWI indicated that Axis powers had resorted to the use of BW in the form of anthrax and glanders.

Concern about the vulnerability of the US to BW attack at the highest levels in the government has been noted in previous chapters especially chapter 1. However, immediate concern was expressed by the Chairman of the Committee on BW, of the Research and Development Board of the National Military Establishment (NME) in a special report on BW activities, 5 August 1948. He concluded that: (1) Biological agents would appear to be well adapted to subversive use: (2) The US is particularly susceptible to attack by "special BW operations" (meaning subversive or covert actions involving the use of biological agents); (3) The subversive use of biological agents by a potential enemy prior to a declaration of war presents a grave danger to the US; and (4) The BW R&D program is not now authorized to meet the requirements necessary to prepare defensive measures against special BW operations. The memo recommended that the Secretary of

Defense authorize the NME to engage in the required R&D to counter the threat in the field of special BW operations and suggested that a unit be set up as an integral part of Ft. Detrick. Illustrative examples of projects to be undertaken described in the memo were testing of ventilating systems, subways, water supply systems, etc., with innocuous organisms.

House Report No. 815 entitled "Research in CBR," a Report of the Committee on Science and Astronautics, the House of Representatives, 86th Congress, First Session 1960, recommended that "more positive and imaginative attention should be given to the problems of detecting and guarding against use of CBR by saboteurs aimed at disrupting key activities in time of emergency." (Appendix III)

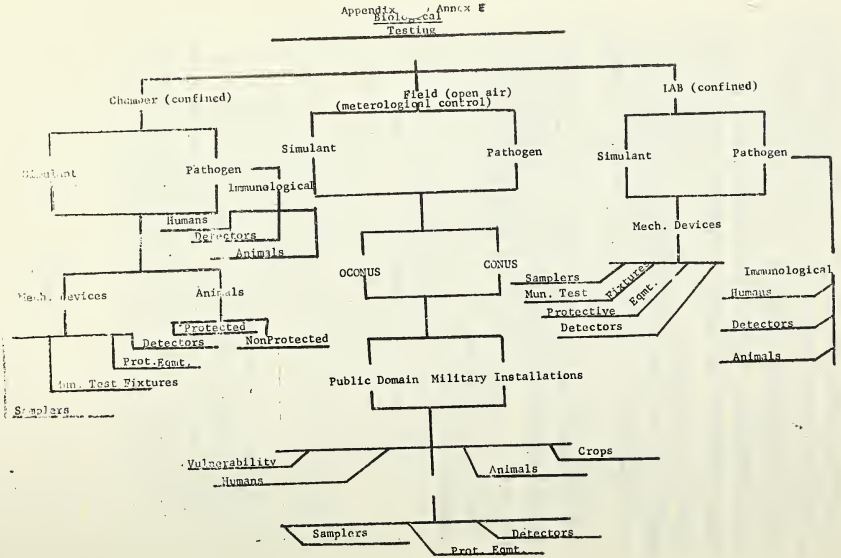
Concern regarding vulnerability of the US continued even after the Presidential ban on offensive BW in 1969. The Chairman of the President's Science Advisory Committee, BW/CW Panel, submitted a report on 16 December 1970 "Requirements for BW Defense" to the Deputy Secretary of Defense. The report stated a recognition of the need to continue many aspects of the BW defensive program to include the resolution of problems relating to US prepardness against covert attack on the civilian population.

The report of the NSC Under Secretaries Committee, 5 August 1972, entitled "Annual Review of the US CW and Biological Research Program" Appendix B, entitled "Biological and Toxin Research Program" contains a recommended 5-phase program which it states is in consonance with the PSAC report (15 December 1970 noted above). The vulnerability

Analysis phase of the NSC report states "this portion of the program will examine the US and its Armed Forces vulnerability to biological attack. It will include an active examination of ....results of vulnerability testing.... This will be a continuing program. The "Testing" phase of the recommended program states "simulated tests will be required for testing defense equipment and for vulnerability analysis." The report further states that studies indicating vulnerability of the United States and its Armed Forces must remain classified.

Thus vulnerability testing provided essential data to permit the military and civil defense authorities to assess the dangers to which the US and its allies might be exposed and to plan appropriate responses by enemy actions in the BW area.

Appendix IV summarizes BW field testing chronologically.


Biological Testing
Chamber (confined)
Field (open air) (meterological control)
IAB (confined)
Simulant
Pathogen
Simulant
Pathogen
Simulant
Pathogen
Immunological
Humans
Detectors
Animals
Mech. Devices
OCONUS
CONUS
Mech. Devices
Animals
Samplers
Mun. Test
Fixtures
Eqmt.
Protective
Detectors
Immunological
Humans
Detectors
Animals
Protected
Detectors
NonProtected
Prot. Eqmt.
Mun. Test Fixtures
Samplers
Public Domain Military Installations
Vulnerability
Humans
Crops
Animals
Samplers
Detectors
Prot. Eqmt.

APPENDIX II to ANNEX E

SERRATIA MARCESCENS INFECTION

CONTENTS

I. Definition.

S. marcescens is a motile, non-sporulating, gram negative bacillus of the family Enterobacteriace, which may produce a red pigment especially when grown at room temperature. It is commonly found in water, food and sewage and can be sometimes isolated from the feces and sputum of apparently healthy people.(1)

II. Disease associated with S. marcescens.

a. Pre antibiotic era (prior to 1946).

S. marcescens, originally named Chromobacterium prodigiosum, was first recognized in 1823 as a cause of "bleeding polanta," a red discoloration of cornmeal mush(2), and has subsequently received great historical notoriety as a masquerader of blood (i.e., blood stained communion wafers). A low degree of pathogenicity was assumed because reports of serious infection in humans were rare isolated events. In 1913(3) Woodward and Clark reported a case of "pseudo-hemoptysis" in a young man. Aside from a chronic cough and the psychological aspects of producing red (appearing bloody) sputum, he was apparently quite healthy. Thompson (4) and Aronson (5) reported the same case of meningitis. The patient apparently recovered spontaneously and there was some question as to whether the organism was a contaminant. Other reports were not available for this review suggested a pulmonary(6) and a wound (7) infection.

b. Post antibiotic era.

The post antibiotic era ushered in a period during which an increasing

number of incidences of serious infections caused by S. marcescens were reported. They began with scattered reports on series of small numbers of cases[8,9], but which have steadily increased until the present time (over 10 reports since 1970). The common threads running throughout the reports are hospitalization, intravenous and urinary tract catheterization, serious underlying disease, a debilitated state, broad spectrum antibiotics and steroid treatment[10, 11, 12, 13, 14]. All these conditions predispose patients to infection with organisms of low intrinsic virulence. The largest number of reports have emphasized the acquisition of the organisms[15, 16, 17, 18, 19], and the urinary tract as a principle infected organ. (Bibliography incomplete).

III. The use of S. marcescens as a bacterial marker.

The non-virulent aspects of S. marcescens during the pre antibiotic era and its red coloration allowing ease of identification led to its selection as a bacterial marker. In 1937, Burket and Burn[20], and in 1949, McEntegart and Porterfield[21], painted S. marcescens on gums to determine the source of bacteriemia following dental extraction. No ill effects were seen in spite of documented bacteriemia in 18 patients. Kass and Schneiderman[22], planted Serratia marcescens to demonstrate bladder colonization from the urethral meatus after catheterization. Laurenzi, Porter. Kass[23] demonstrated the bacterial clearing effect of the tracheobronchial tree after planting S. marcescens

in the oropharynx. Paine[24] demonstrated the relatively harmless effects on healthy young volunteers of aerolization of large amounts of S. marcescens (2.5 hrs exposure, 2×10^6 org. per cubic feet of air). In fact, until the early 1960's S. marcescens was routinely used to demonstrate aerolization and air sampling techniques in college bacteriology courses[25].

IV. Use of S. marcescens by the U.S. Army relative to reports of disease at that time.

The only incidence of S. marcescens aerolization by the military referred to in the published literature occurred in the San Francisco Bay area, September 1950[26].

In 1957, Wheat, et al[8] reported on 11 cases seen in a San Francisco Hospital from September 1950 - February 1951. However, the association with the above mentioned aerolization appears to be coincidental, since (1) no other hospitals reported similar findings; (2) and all the patients had urinary tract infections (2 subsequently developed septicemia, a well recognized complication of urinary catheterization). Thus, considering the evolution of disease caused by S. marcescens, it is likely that this report was the forebearer of what was to come.

Intravenous drug abuse, which is frequently associated with an increased incidence of infections, was the underlying condition associated with 19 cases of endocarditis caused by S. marcescens in the San Francisco Bay area reported

by Mills, et al in 1976[26]. Similar clustering of cases of endocarditis among addicts due to unusual organisms have been reported, (i.e., Pseudomones in Detroit, enterococci in Cleveland).

Recent reports of infections involved principally non-pigmented strains. The relationship of pigment production to the ability to infect man is unclear at the present time.

V. Summary.

The increase in infections caused by S. marcescens appears to be an illness related to medical progress and has assumed a prominent role as an opportunist, producing disease in man only in large doses (i.e., contaminated nebulizer), and/or when the body defenses are weakened by age, debilitating disease, drug abuse, or antibiotics. Its early use as a bacterial marker entailed little risk, attested to be the fact that highly reputable medical journals (i.e., 22, 23, 24), published the data, and an editorial in the Lancet[28] published as late as February 1969, emphasized the avirulent nature of the organism. Not until 1969 did recognition of limited pathogenic capability lead to the advice that the organism should not be used for the study of experimental infections in man.

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Annex E

Extract from Appendix III

RESEARCH IN CBR

A Report of

THE COMMITTEE ON SCIENCE

AND ASTRONAUTICS

The House of Representatives
The Congress of the United States

EIGHTY-SIXTH CONGRESS

FIRST SESSION

(No. 23)

House Report No. 815

Pages 15-16

As a result of its hearings and further study on the problems of research in CBR, this committee offers the following recommendations:

(1) There must be a strong and continuous intelligence effort conducted by the United States as a protective measure to keep abreast of foreign developments in the fields of CBR if this country is to have time to develop adequate passive defense and other countermeasures.

(2) Surveillance of foreign activities might also give this Nation its only inkling of imminent use of CBR against the United States, and therefore is important for this reason, too.

(3) There is an urgent need for greater public understanding of the dangers and uses of CBR if proper support is to be given to our defenses and countermeasures.

(4) In any consideration of international disarmament, a special effort must be made not to overlook the great potential of CBR and the ease of evading detection of CBR activities.

(5) There is an urgent need for a higher level of support on a continuing, longrun basis in order to develop better detection and protection measures against possible employment of CBR against this country.

(6) Civil defense plans of this country should include a more positive effort at providing shelters which are proof against CBR attack, at providing more masks and protective clothing, and in public instruction in defensive measures.

(7) More positive and imaginative attention should be given to the problems of detecting and guarding against use of CBR by saboteurs aimed at disrupting key activities in time of emergency.

(8) The committee views CBR as a weapon which is not competitive with nuclear weapons, but complementary to them, designed to do a different job.

(9) The committee cannot bring itself to describe any weapon of war as "humane," and makes no moral judgement on the possible use of CBR in warfare. It does recognize that ignoring CBR will not remove the problem of its existence or its possible employment against the United States.

(10) It is granted that some forms of CBR offer the prospect and the hope of winning battles without taking human life or destroying homes and factories. If force must be used, this is better than many of the alternatives. But it must also be recognized that even if the United States is attacked with the new "gentle" weapons, the consequences of any defeat for our Nation would be just as dangerous to our national goals and life.

(11) It is also recognized that in the present world situation with other countries pursuing vigorous programs of CBR development, the best immediate guarantee the United States can possess to insure that CBR is not used anywhere against the free world is to have a strong capability in this field, too. This will only come with a stronger program of research.

(12) At the present time, CBR research is supported at a level equivalent to only one one-thousandth of our total defense budget. In light of its potentialities, this committee recommends that serious consideration be given to the request of Defense officials that this support be at least trebled. Only an increase of such size is likely to speed research to a level of attainment compatible with the efforts of the Communist nations.

(13) If CBR is to be considered a deterrent force in the U.S. arsenal of weapons, the program of research advocated here will have to be accompanied by an adequate program of manufacture and deployment of CBR munitions.

(14) CBR warfare is not particularly expensive as compared with many other modern forms of warfare, particularly when considered as an incremental cost added to already necessary delivery techniques employed for nuclear weapons. This is a further reason why this investment must be given careful consideration.

(15) The research being done in CBR has already yielded a variety of peacetime benefits, including antidotes for poisons, new serums to prevent disease, greater understanding of how diseases are spread, new insecticides, and fundamental knowledge of life processes. (See appendix.) There is no real separation possible between potential military application of chemical and biological knowledge and peaceful applications. These peaceful applications are required in any case, and deserve added support for the national welfare.

(16) The United States is in a research and development race, particularly with the Soviet Union, whether it be for peaceful or military purposes. The study by this committee of CBR reinforces our general view of the urgency of the overall race and the necessity of full public understanding and support of science and technology everywhere in our Nation.

Appendix IV to Annex E

Biological Field Testing
(Chronological Listing)

Abbreviations

UA	Unavailable.
BG	Bacillus globigii (Bacillus subtilis var niger).
SM	Serratia marcescens.
AF	Aspergillus fumigatus.
EC	Escherichia coli.
FP	Fluorescent particle.
LP	Lycopodium Spores.
SO_2	Sulfur Dioxide.

TABLE 1

BIOLOGICAL FIELD TESTING
ANTI-PERSONNEL
BIOLOGICAL SIMULANTS
INVOLVING PUBLIC DOMAIN

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
Washington, DC	18 Aug 1949 26 Aug 1949 12-13 Dec 1949 11 Mar 1950	SM
USS Coral Sea anchored in Hamptom Rds, & USS K.D. Bailey at sea off entrance to Hampton Roads Hampton Roads, VA 1 trial at anchor, 16 trials at sea off the entrance	1-21 Apr 1950	BG SM
San Francisco, CA	Sep 1950	SM BG
Port Hueneme, CA	10 Sep - 24 Oct 1952	BG
Panama City, FL	Mar-May 1953	SM BG
Off-shore, between Port Hueneme and Point Mugu, CA, near Santa Barbara	17-27 Aug 1954	BG
Pennsylvania State Highway #16 westward for one mile from Benchmark #193	7 Jan 1955	BG
Kittakinny and Tuscarora Tunnels, Pennsylvania Turnpike	Aug 1955	BG
Offshore Hawaii	Jan-June 1963	BG

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LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
Vicinity Ft. Greeley, Alaska	Dec 1963 - Jan 1964	BG
Central Alaska	Jan - Feb 1965	BG FP
National Airport & Greyhound Terminal, Wash, DC	May 1965	BG
Oahu, Hawaii	May - Jun 1965	BG
Off California Coast (San Diego)	Feb - Mar 1966	BG
Hawaii, Hawaii	Apr - May 1966	BG
New York, NY	7-10 Jun 1966	BG
Hawaii, Hawaii	Jan - Mar 1968	BG SM
Oahu, Hawaii	Apr - May 1968	BG
Dugway Proving Ground Utah	1945 Jul-Nov 1949	BG BG
Camp Cooke, California	1955	BG FP
Edgewood Arsenal, MD	1959	BG
Key West, FL	1952	SM
Off California Coast (San Clemente)	Aug-Sep 1968	BG

TABLE 2

BIOLOGICAL FIELD TESTING
ANTI-PERSONNEL
BIOLOGICAL SIMULANTS
NOT INVOLVING PUBLIC DOMAIN

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
Marine Corps Schools Quantico, VA	24-25 May 1949	BG
Port Huemene, CA	Jul and Sep 1949	BG
US Naval Advance Base Proving Ground Port Hueneme, CA	22 Jul 1949	BG
NAB, Little Creek, VA	Dec 1950	SM BG AF
Carswell AFB, Ft Worth, TX	11-21 Feb 1951	BG SM AF
Fort Detrick, MD Limited Area	15 May 1951	SM BG
Navy Supply, Mechanicsburg, PA and Norfolk, VA	7 May - 4 Jun 1951	BG SM AF
Fort Detrick, MD	Aug - Sep 1951	SM
Fort McClellan, AL	1 - 30 Jul 1952	SM BG
Fort McClellan, AL	15-28 Sep 1952	SM BG
Camp Detrick, MD	14 Feb 1953 to 24 Feb 1953	SM BG
Dugway Proving Ground, UT	May - Jun 1953	BG SM FP AF
Eglin AFB	1 Jun - 1 Jul 1953	BG

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
Dugway Proving Ground, UT	17 Jun 1953 and 25 Jun 1953	BG SM
Camp Detrick, MD Fort Ritchie, MD	Jun 1953	SM BG
Dugway Proving Ground, UT	13 Jul 1953 to 14 Oct 1953	BG
Dugway Proving Ground, UT	13 Jul 1953 14 Jul 1953 6 Aug 1953 12 Aug 1953	BG BG BG BG
Morrisville Maneuver Area, Pelham Range, McClellan, AL	15 Sep 1953 21 Sep 1953	BG BG
Dugway Proving Ground, UT	15 Oct 1953 21 Jan 1954 27 Jan 1954 12 Feb 1954 17 Feb 1954 14 Mar 1954 7 Apr 1954	BG BG, FP BG BG BG, FP BG, FP BG, FP
Ft Belvoir, VA	1953	BG
Eglin AFB, FL and Kirtland AFB, NM	Apr - May 1954 (Eglin) and Jul 1954 (Kirtland) Apr - May 1954, Jul 1954	BG BG
Dugway Proving Ground, UT	13 May 1954 24 May 1954	BG BG
Fort Ritchie, MD	Sep 1954	BG
Dugway Proving Ground, UT	Oct 1954 15 Nov 1954 - 6 Jun 1955 1954	BG, FP BG NA
Engineer Proving Ground, Ft Belvoir, VA	1954	BG
Port Hueneme, CA	24 Jan 1955	BG

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
Dugway Proving Ground, UT	May 1955	BG, FP
	May - Jun 1955	BG
	27 Jul 1955	BG, FP
	Aug 1955	SM
Wright Patterson AFB, OHIO	Aug 1955	BG
		SM
Dugway Proving Ground UT	1 Dec 55 - 3 Feb 56	BG
Loring AFB, Maine	Jan - Feb 1956	BG
		SM
Army Chemical Center, MD	21 Mar 1956	BG
	23-24 Apr 1956	BG
Dugway Proving Ground, UT	Spring - Fall 1956	SM
Camp Cooke, CA	Summer 1956	BG, SM
Dugway Proving Ground, UT	Aug - Sep 1956	BG
	1956	BG, FP
Army Chemical Center, MD	Oct - Nov 1956	BG
Fort Detrick, MD Area B	20 May - 25 Jun 1957	SM
Dugway Proving Ground, UT	20 - 24 Jun 1957	BG, SM
	Jul - Aug 1957	BG
Explosive Ordnance Disposal Technical Center, Indianhead, MD	Sep, Oct 1957	BG
Range 75C, Eglin Air Force Base, FL	Sep, Oct, Dec 1956 and Jan, Apr, Sep, Oct 1957	SM. BG
Dugway Proving Ground, UT and Hamilton AFB, CA	7 Oct 57 and 18-21 Jan 1958	BG
McGuire AFB	15-18 Oct 1957	BG
Dugway Proving Ground, UT	1957	BG
		SM

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
Eglin AFB, FL	May - Jun 1958	BG SM
Dugway Proving Ground, UT	Aug - Sep 1958	BG, SM
	Aug 1958	SM, BG
	24 Sep 1958	BG, SM
	Jul 1959	BG
	Jul 1959 to Dec 1960	BG, SM
	Sep 1960	BG
	27 Mar 61 and 16 May 61	BG
	Jun 1961	BG
	Aug - Sep 1961	BG
Ft Eustis, VA	9-16 Feb 1959	BG
Fort Detrick, MD	12 Oct - 6 Nov 1959	BG
Ft McClellan, AL	Mar - Jun 1962	BG
	19 Mar - 13 Apr 1962	BG
	June 1962	BG
Dugway Proving Ground, UT	Aug 1962 - Feb 1963	BG
	Oct 1962 to Mar 1963	BG
Fort Detrick, MD Eglin AFB, FL	Sep 1962 May 1966	BG
Dugway Proving Ground, UT, Ft Bragg, NC Yuma Test Sta, AZ Ft Detrick, MD	Nov 1962 - Mar 1963 Jan - Apr 1963	Talc SM, BG
DPG, UT Ft Bragg, NC Yuma Test Sta, AZ	Nov 1962 - Mar 1963 Nov 1962 - Mar 1963	BG BG
Ft Detrick, MD	1962 - 1963	BG
Dugway Proving Ground, UT	16 Jan 1963 - 29 Jan 1963	BG
Yuma Test Sta, AZ	Mar - May 1963	Lipstick
Ft Bragg, NC	Mar - May 1963	Lipstick
Dugway Proving Ground, UT	Oct 1963 - Mar 1964	BG
	7 Nov - 14 Nov 1963	BG
	24 Jan - 3 Feb 1964	NA

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
"M" Field, Edgewood Arsenal, MD	19 - 26 Feb 1964	BG
DPG, UT Fort Bragg, NC	Aug - Sep 1964	Uraine Dye BG
Carroll Island, Edgewood Arsenal, MD	10 - 25 Aug 1965	BG
Fort Detrick, MD	Nov 1965	BG
Camp Pendleton, Edwards AFB, Rosamond Dry Lakebed, CA	Oct 1966 - Mar 1967	BG SM
Dugway Proving Ground, UT	Feb 1967 Jul 1968 - Mar 1969	BG Lipstick
Rosamond Dry Lake Edwards AFB, CA	26 Sep 1967 - 13 Jul 1968	SM BG
Edwards AFB, CA	15 Jul - 16 Oct 1968	SM BG
Ft Bragg, NC	Aug - Sep 1968	Lipstick
Edwards AFB, CA Pacific Missile Range Point Mugu, CA	Nov 1968 Jul 1969	BG
Eglin AFB, FL	2 Nov 1969 to 6 Nov 1969	BG

TABLE 3

FIELD TESTING
NON-BIOLOGICAL SIMULANTS/AIR DIFFUSION
INVOLVING PUBLIC DOMAIN

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
Harpers Lake, CA (Mojave Desert)	18 - 19 Aug 1949	Soap Bubbles
South Carolina, Georgia Coast	Mar - Apr 1952	FP
Minneapolis, MN St. Louis, MO	15 Jan - 24 Mar 1953	FP
Rosemont, MN	Sep - Oct 1953	FP and Lycopodium spores
San Francisco Bay, Redwood City, CA	21 and 26 Mar 1956	FP SO_2
Continental U. S. East of Rocky	30 Nov 1957 6 Feb 1958 25 Apr 1958 20 Mar 1958	FP
North Central Texas	1959 - 1960 Test No. Date A-1 13 Aug A-2 15 Aug A-3 18 Aug A-4 2 Oct A-5 5 Oct A-6 7 Oct A-7 9 Oct A-8 12 Oct A-9 10 Feb A-10 12 Feb A-11 15 Feb A-12 19 Feb A-13 22 Feb	FP FP
Vanderburg AFB, CA	Jun - Aug 1961 Feb, Mar, and Jun 1962	FP
Cape Kennedy, FL	May, Jun 1961, Jan - Mar 1962	FP
NE Oklahoma, Corpus Christi, TX, E Washington and SW Nevada	Summer 1962	FP

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
St. Louis, MO	May - Sep 1963 Apr - Oct 1964 Mar 1965	FP
Dugway Proving Ground, UT	17 - 21 May and 15 Aug 1963 4 Sep 1963	FP FP
Chippewa National Forest, MN	Jan - Aug 1964	FP
San Francisco, CA	Mar 64 - Mar 1968	FP
Wambaw Swamp Francis Marion National Forest, SC	Jun - Aug 1964	FP
Fort Wayne, IN	29 Jul 1964 - 5 Feb 1966	FP
Victoria, TX	Jul - Aug 1965 Jul - Aug 1965 9 - 29 Jul 1966	LP, FP LP, FP Glass beads & fluorescent tagged cork
Oceanside, CA	Jun - Jul 1967	FP
Searcy, AR	Sep 1967 - May 1968	FP
East Central Texas	1967	Glass beads, fluorescent tagged ground cork
Charles Lathrop Pack Demonstration Forest of the University of WA	Nov 1968	FP
Cambridge, MD	Aug - Nov 1969	FP

TABLE 3B

BIOLOGICAL FIELD TESTING
ANTI-ANIMAL
NON-BIOLOGICAL SIMULANTS
INVOLVING PUBLIC DOMAIN

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
Fort Worth, Texas Stockyards	30 Nov - 1 Dec 1964	Aerosal Deodorant
Kansas City, MO Stockyards	3-4 Dec 1964	"
South St. Paul, Minn Stockyards	11 Jan 1965	"
Sioux Falls, SD Stockyards	13 Jan 1965	"
Sioux City, Iowa Stockyards	14 Jan 1965	"
South Omaha, Neb	15 Jan 1965	"

TABLE 4

BIOLOGICAL FIELD TESTING
ANTI-PERSONNEL
PATHOGENIC AGENTS

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
Dugway Proving Ground, UT	1 Jun 1951 - 26 Aug 1951	Coxiella burnetti Psittacosis virus
	27 Mar 1952	Pasteurella pestis (avirulent Strain A-1122)
	12 May 1952	Brucella suis
(Horizontal Grid)	9 Apr 52 & 9 Jul 52	Pasteurella tularensis
	Jun & Sep 1952	Brucella suis B. melitensis
	Jul - Aug 1952	Brucella suis
	Aug - Oct 1952	Brucella suis
	21 Aug 1952	Coxiella burnetii
	Sep - Nov 1952	Coxiella burnetii
	9 Oct 1952	Pasteurella
	19 Nov 1952	Clostridium botulinum toxin
	Dec 1952	Brucella melitensis
	24 Mar & 21 Apr 1953	Pasteurella tularensis
	18 Mar -12 Jul 1955	Coxiella burnetii
	20, 28 Dec 1954 & 6 Jan 1955	Brucella suis
	Jan - Apr 1954	Bacillus anthracis
	12 & 18 Nov 1954	Pasteurella tularensis
(Horizontal Grid)	27, 29 Oct 1954 3 Nov 1954	Brucella suis
	4 Sep 54 - 21 Feb 56	Bacillus anthracis
	12 Jan 1955	Brucella suis
	6, 15 Apr & 4 May 55	Brucella suis
	Mar 55 - Feb 56	Bacillus anthracis
	Jun 54 - Jun 55	Brucella suis
Animal Exposure Chamber	Aug - Oct 1957	Bacillus anthracis
	May - Jul 1958	
	Aug 57 - Apr 1959	Pasteurella tularensis
	23 Oct & 14 Nov 1957	Pasteurella tularensis
	Apr 1958	Pasteurella tularensis
	Jul 1959	Bacillus anthracis Pasteurella tularensis Coxiella burnetii
	Apr 1960 - Feb 1962	Pasteurella tularensis
	Apr 1960 - May 1960	Pasteurella tularensis
	Sep 1960	Botulinum toxin Bacillus anthracis Coccidioides
	30 Jan 1961 - 27 Sep 1962	Coxiella burnetii
	Aug 62 - Feb 63	Pasteurella tularensis
	Nov 62 - Mar 63	Pasteurella tularensis Coccidioides

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
Dugway Proving Ground, UT (Continued)	Nov 62 - Mar 63	Coccidioides uranine Coxiella burnetii
	30 Jan 63 - 11 Apr 63	Pasteurella tularensis
	28 Mar - 11 Apr 1963	Pasteurella tularensis
	Oct 63 - Mar 64	Coccidioides
	14 Oct - 17 Nov 1965	Pasteurella tularensis
	25 Apr 66 - 6 Jun 66	Pasteurella tularensis
	9 Jul 66 - 25 Aug 66	Pasteurella tularensis
	15 Feb - 4 Apr 1967	Pasteurella tularensis Coxiella burnetii
Eglin AFB	14 Jul 1951	Hog Cholera
Farm owned by Univ of Wisconsin	Oct 1951	Newcastle Disease
Ft Detrick & DPG	Mar - May 1961	Pasteurella tularensis Brucella suis

TABLE 4A

(UNSUBSTANTIATED)
BIOLOGICAL FIELD TESTING
ANTI-PERSONNEL PATHOGENS
NOT INVOLVING PUBLIC DOMAIN

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
Dugway Proving Ground, UT	Jun - Nov 1950	Pathogens

TABLE 5

BIOLOGICAL FIELD TESTING
ANTI-CROP
PATHOGENIC AGENT
INVOLVING PUBLIC DOMAIN

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
South Carolina - Georgia Coast	Nov & Dec 1952	Dyed Lycopodium Spores Seed-dyed Cereal Rust Spores
Morris, Waseca, Le Sueur, Crookston, Duluth, & Rosemount, MN	May 1953	
Crookston, MN; Rosemount, MN; Rapid City, MN	Rosemount - 5,7 Jun 1955; Rapid City - 3 Jun 1956; Crookston 19 Jun 1956	Wheat Stem Rust
Intersection of US Highways 60 and 441, Yeehaw Junction, Florida	15, 18, 19, 20, 24, 27 Nov & 1 Dec 1956	Wheat Stem Rust
Hays, Kansas	7 May 1960	Wheat Stem Rust
Experimental Station, Beaumont, TX	Summer 1959	Rice blast
Langdon, North Dakota	12 Jun 1960	Wheat Stem Rust
Yeehaw Junction, FL	Nov, Dec 1968	Wheat Stem Rust

TABLE 5A

(UNSUBSTANTIATED)
BIOLOGICAL FIELD TESTING
ANTI-CROP
BIOLOGICAL AGENTS
INVOLVING PUBLIC DOMAIN

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
Edgewood Arsenal, MD	1949-50	TX or TX simulant
Crookston, MN	1964	TX
Avon Park AFB, FL	1954-1957 1960 1964	Cereal Stem rust spores None LX Helminthosporium oryzae
Casselton, ND	1964	TX
Crookston, MN	1956-57	
Stillwater, OK	1963-67	TX
Hayes, KS	1960, 64, 65	TX
Lincoln, NEB	1964-65	TX
Rosemount, MN	1955, 57, 64	TX
Langdon, ND	1960, 64	TX
Crowley, LA	1963, 64, 68, 69	LX and Helminthosporium oryzae
Avon Park AFB, FL	1 Apr 1965 - 31 Oct 1965	LX

TABLE 6

BIOLOGICAL FIELD TESTING
ANTI-CROP
PATHOGENIC AGENT
NOT INVOLVING PUBLIC DOMAIN

LOCATION OF TEST	DATE(s) OF TEST	SIMULANT/AGENT USED
Dugway Proving Ground, UT	18 Feb - 27 May 1952	Wheat Rust Spores
	12 Sep 52 - 26 May 53	Stem Rust of Wheat
	21 Jul - 24 Sep 53	Wheat Stem Rust
(Crop Grd #5)	12 Nov 53 - 16 Dec 53	Stem Rust Wheat
	Apr - Aug 1954	Wheat Rust
	14 Oct 54	Wheat Stem Rust
Avon Park AFB, Avon Park, Florida Bombing Range	Nov - Dec 1954	Wheat & Rye Stem Rust
ACmlC Rosemount Research Lab, Rosemount, MN	12 Jul 1955	Wheat stem rust (killed spores)
Belleglade & Ft Pierce, FL	Apr 1, May 1, Jun 1, & Jul 1, 1956 & 1957	Rice blast

Unauthorized Tests

Background. On 21 November 1976, the Long Island Newspaper Newsday reported that the Army had "conducted an experiment to test San Francisco's (SF) vulnerability to a germ warfare attack. A little more than a month later one man was dead and five other patients were infected at a local hospital by the same kind of bacterium used in the test. ... The Army conducted similar experiments for as long as 10 years, including ... a test in the New York City subway system."

On 22 December 1976, the Washington Post reported under the New York Newsday byline that the Army had released information confirming the tests conducted in Key West and Panama City, Fla., New York City and S. F. over a 16-year period. The Washington Post also stated that the Army said that similar tests were conducted in Army installations at Point Mugu and Port Hueneme, CA., Fort McClellan, AL, a Navy facility in Mechanicsburg, PA, and at the Pentagon. The Washington Post article (22 December 1976) inferred that the Serratia marscescens (SM) used in the S. F. tests caused the death in S. F. (1950) and that the incidence of pneumonia cases increased sharply in Calhoun County, AL (1952), and in Key West (1952). The Newsday article in the Washington Post (22 December 1976) article reported that SM was used at eight of the test locations, Bacillus globigii (BG), at seven of the eight sites, and a fungus, Aspergillus fumigatus (AF), at one of the eight test sites.

The Newsday article was apparently based on a 15 December 1976 Army acknowledgement that field testing with SM had been conducted in eight tests in the U.S. up to 1966 to determine vulnerability to enemy biological attacks.

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Subsequent to the two Newsday reports, articles appeared in various newspapers throughout the country. On 23 December 1976, the Atlanta Constitution reported tests were run at the following locations:

Pentagon, Washington, D.C.	(1950)
S. F., CA	(1950)
Mechanicsburg, PA	(1951)
Key West, FL	(1952)
Fort McClellan, AL	(1952)
Panama City, FL	(1953)
Point Mugu-Port Hueneme, CA	(1956)
New York City, NY	(1966)

Analysis of Allegations. The reports of the tests are essentially correct except for attributing a direct relationship of increased incidence of disease to the Army vulnerability tests in the S. F. area in 1950. In 1951, Dr. Richard P. Wheat, M. D., et al, in article "Infection Due to Chromobacteria," published in the Archives of Internal Medicine (Vol 88, 1950) reported on eleven cases seen in a San Francisco hospital from September 1950 to February 1951. The following is extracted from the "Comment" section of the referenced article:

> . . . Instrumentation of the urinary tract had been performed in every case, and the Chromobacterium probably was introduced by these procedures. An epidemiological study failed to reveal the route of infection in detail.
>
> That so many cases of urinary-tract infection by this unusual organism should have been observed was not surprising, since the obstructed and instrumented urinary passages are fertile soil for the multiplication of bacteria that are not commonly the cause of disease elsewhere. A contributing factor was the use of multiple antibiotics, which eliminated all the usual organisms that are responsible for infection of these organs and permitted the ready implantation of the highly antibiotic- and sulfonamide-resistant Chromobacterium.
>
> Similar invasion of various organs by bacteria resistant to one or more antibiotics, and not usually the cause of disease in the involved system, has become commonplace in patients treated with these agents. Such invasion has been most frequently observed in cases of superinfection of the urinary tract by members of the Pseudomonas and Proteus group. It is evident that the ever-widening use of antimicrobial agents will be associated with the discovery of infectious disease caused by a wide variety of unusual micro-organisms.

Therefore, the association with the above mentioned tests appears to be coincidental, since (1) no other hospitals reported similar findings; and (2) all the patients had urinary tract infections (two subsequently developed septicemia, a well recognized complication of urinary catheterization). All available evidence continues to indicate that SM is an opportunistic organism which infects those individuals who are debilitated or have a reduced immune response. To avoid exposing such populations to SM, the Fort Detrick Safety Director established a policy whereby the use of SM was not authorized if the simulant could enter a hospital or a sanitarium. The suspicion of attributing the cause of the one death in S. F. vulnerability tests has been refuted repeatedly and was also considered unlikely by Dr. Mills and a team from the S. F. General Hospital who had studied the relationship between SM infections and drug addiction in the S. F. area.

Because of apparent concern over a possible link between its San Francisco test in 1950 and the incidence of SM infections in the Stanford Hospital in 1952, the Army requested a group of eminent scientists to review the available information and provide recommendations on the future use of SM. The four civilian consultants from the Communicalbe Disease Center, USPHS; Department of Health, City of New York, Ohio State University; and Microbiological Institutes, National Institutes of Health, USPHS. Analysis and recommendations of the group were:

1. Experimental work in BW outside of the laboratory is impossible without the use of simulants. Simulants must be organisms having biological characteristics, other than pathogenicity, as nearly identical as possible to BW agents under study. An ideal simulant has not yet been found. Avirulent strains of

recognized pathogenic organisms should not be used in routine field trials if the necessary information can be obtained in any other possible way. Ideally a simulant should be an organism that has never been associated with a human disease and is not capable of growth in the human body. It must also be readily recognizable and recoverable by simple means.

2. Since the early days of bacteriology, SM has been the most commonly used organism for studying the dissemination of bacteria in air. Until recent years, there have been no reports of human illness associated with this organism in spite of its extensive use. In 1946 at Camp Detrick, four cases of minor illness of short duration were discovered in association with heavy exposures to SM. Reference is made to "Illness in Man Following Inhalation of Serratia Marcescens;" Paine, Tom F.; Journal of Infectious Diseases; Nov-Dec 1946; Vol. 79. A current survey among Camp Detrick personnel reveals only two cases of similarly insignificant illnesses among all those exposed while working with the organism.

3. The data in the referenced article describing the experience in San Francisco are incomplete as to the primary relation of the SM isolated from the patients and their illnesses, except in the case of one patient who died from bacterial endocarditis and SM bacteremia. With this single exception, the finding of SM in these cases was not shown to have influenced the clinical course of the patients' illnesses.

4. On the basis of our study, we conclude that SM is so rarely a cause of illness and the illness resulting is predominantly so trivial, that its use as a simulant should be continued, even over populated areas, when such studies are necessary to the advancement of the BW program.

5. The program at Camp Detrick in the search for better simulants should be then actively pursued. If a more desirable simulant is discovered, it should then replace SM.

6. In future tests over populated areas, it would be desirable to institute prior and subsequent studies in a few hospitals to determine whether the report previously referred to was purely coincidental or whether the recovery of SM from patients was related to BW field tests.

Health data for Monroe County (Key West) and Bay County (Panama City) do not support the Newsday allegations of pneumonia cases according to Dr. C. Prather, Florida's Health Officer, as given to the National Observer Weekend Edition (26 December 1976). A state-wide influenza epidemic hit Florida in 1952 and 1953 with a corresponding increase in pneumonia. According to Dr. Prather, the incidence of pneumonia in Bay County (Panama City) was relatively constant in 1951, 1952, and 1953. The Army disseminated what were believed to be innocuous biological substances, namely, SM, BG, and AF. SM, BG, and fluorescent particles were used in the S. F. test and BG mixed with charcoal in the New York subway test.

Additionally, SM has been used medically as a bacterial tracer from 1937 to 1969 with the results having been published in highly reputable medical journals as late as February 1969. The following are examples:

1. SM painted on gums to determine the source of bacteremia following dental extraction. No ill effects were seen in spite of documented bacteremia in 18 patients.

2. SM implanted to demonstrate bladder colonization from the unethral meatus after catheterization.

3. SM planted in the oropharynx to demonstrate the bacterial clearing effect of the tracheobronchial tree.

Not until 1969 did recognition of limited pathogenic capability lead to the advice that SM should not be used for the study of experimental infections in man.

In connection with open air testing, competent medical authority such as the USPHS stated no objection to the aerosolization of SM as a simulant test organism under stated test conditions.

Appendix I from Dr. David J. Sencer, Assistant Surgeon General, Center for Division Control in Atlanta GA, provides additional data regarding the incidence of pneumonia and influenza deaths near cities where the vulnerability tests were conducted. The report substantiates the lack of evidence associating the reported deaths with the organisms used in the various tests.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA 30333
TELEPHONE [illegible]

Your Reference: DASG-HCH-D

FEB 3 1977

Richard R. Taylor, M.D.
Lieutenant General
The Surgeon General
Department of the Army
Washington, D. C. 20310

Dear Dr. Taylor:

In regard to your request for information on pneumonia cases and deaths in the counties where simulated biological warfare tests were conducted, we have been able to obtain for you the following preliminary data which are attached to this letter. You will note that we have provided you pneumonia and influenza deaths by year, by county and/or city in question for the years 1943-61 and also indicating those years in which influenza outbreaks occurred. These outbreaks, you know, can increase the number of pneumonia and influenza deaths. For San Francisco we have reports of the number of cases of pneumonia and influenza by week for 1950 and 1951, which we will send under separate cover. We have contacted the four State Health Departments yesterday and requested that they determine whether cases and deaths due to pneumonia by county by month for the years in question are also available.

We do not know of any evidence that would indicate an association between the deaths reported in the press articles you included and the organisms reported to have been used in the atmospheric tests. Our surveillance of hospital-acquired infections over approximately the past 10 years does show an increase in the incidence of infections due to Serratia marcescens; however, this may reflect better country-wide surveillance, improved laboratory identifications, and the increasing susceptibility of the hospitalized patient due to increasing age, presence of chronic disease, increasing use of antibiotics, and increased use of various diagnostic and therapeutic procedures that increase the opportunities for infections to be acquired in the hospital. We have no data suggesting that Bacillus globigii is causing human disease.

Page 2 - Richard R. Taylor, M.D.

I hope this initial analysis is useful. We should know the availability of the other material by the end of this week.

Sincerely yours,

David J. Sencer, M.D.
Assistant Surgeon General
Director

Attachment

cc:
S. Paul Ehrlich, Jr., M.D.
Acting Surgeon General, PHS

PNEUMONIA AND INFLUENZA DEATHS BY YEAR FOR SELECTED CITIES AND COUNTIES *

	1943	A+ 1944	B 1945	1946	A 1947	1948	1949	A 1950	A 1951	1952	A 1953	1954	1955	1956	1957	A 1958	1959	A 1960	B 1961
[illegible]	682	497	447	418	358	402	311	268	261	297	324	266	256	268	330	283	287	305	283
[illegible]	3	2	9	2	6	7	2	5	NA**	NA**	5	6	7	4	7	8	9	11	11
[illegible]	NA	NA	68	66	59	79	26	18	29	31	19	13	14	19	23	25	27	38	17
[illegible]	3	5	8	8	1	2	2	6	NA	NA	3	3	7	8	3	7	3	8	2
[illegible]	NA	NA	34	25	16	13	15	23	21	24	22	7	22	23	29	17	22	25	19
[illegible] City, Fla.	25	30	20	8	5	11	7	4	NA	NA	6	9	3	5	7	9	10	8	2
[illegible] County, Fla.	NA	NA	11	12	0	1	2	4	15	6	6	1	3	8	2	4	6	6	3
[illegible]	12	9	12	20	11	14	4	10	NA	NA	11	13	9	5	5	10	10	7	5
Balance of Monroe County, Fla.	NA	NA	1	0	0	0	1	0	11	15	0	1	0	0	3	1	0	2	3
[illegible]	35	28	18	19	18	7	7	11	NA	NA	10	13	12	11	13	11	12	15	10
Balance of Calhoun County, Ala.	NA	NA	22	15	14	20	9	16	27	29	14	17	9	7	8	11	11	18	8

* Vital Statistics of the United States, Dept. of Commerce - Bureau of Census, 1943-1944; Federal Security Agency - Vital Statistics, 1945-1949; Dept. of Health, Education, & Welfare - Vital Statistics, 1950-1961

**This represents a reporting change for 1951 and 1952 for the entire country.

+ represents years when Influenza A or B was epidemic for the country.

Annex G

BW PROGRAM SAFETY

Background. The safety and medical aspects of RDT&E in BW were recognized formalized, implemented, emphasized and policed from the very onset of the program. The concern was primarily for the health of the operating personnel but encompassed the surrounding communities as well.

A safety organization was established in 1943, along with operation organizations reporting directly to the Commanding Officer. One of the functions was to develop, implement and police safety policies, procedures and practices for the protection of personnel and another was to conduct research, development, testing and evaluation of safety devices, procedures and practices to include immunization. In addition, a meticulous records keeping procedure was established, and maintained to assure individual immunizations, etc., were kept up-to-date. The liaison officers from USPHS and USDA were involved in several aspects of the safety program.

Accomplishments. The emphasis on safety continued throughout the lifetime of the BW Program resulting in the development of special equipment such as negative pressure isolate cabinets with specialized gloves and glove parts for handling materials; decontamination systems such as exhaust air ventilation system incorporating air incineration chambers, water and waste decontamination systems, effective filtration systems for air and fluids, and specialized personnel protective clothing and masks such as clean air supplied garments.

The specialized equipment, testing devices, techniques and practices developed and perfected by the Safety organization, some of which were wholly new and others on a scale never attempted before, have been adopted by academia, industry and private research institutions. Safety engineering

standards and practices have been embodied in a two volume document "Design Criteria for Microbiological Facilities, Fort Detrick" which to the present is referred to and followed in the design of laboratory facilities for conducting microbiological research.

Safety Record. That safety efforts were effective is attested to by the remarkably fine safety record achieved as noted in attached table and the fact that 27 vaccines, 5 toxoids and 5 skin tests were developed, perfected and effectively utilized for workers in the BW program (See Tables I and II.).

In conformation with the National Safety Council standards, the rate of infection at Fort Detrick during its lifetime was less than 10 infections per million manhours worked. This rate was better than any industrial average and 10 to 14 times better than all Civil Service and 20 to 50 times better than most industry averages during the same time frame. The three deaths represented a lower mortality rate than was found in any other survey of laboratory infections.

During the years 1950-1967, Dugway Proving Ground had only 10 infections Pine Bluff Arsenal had 34 infections from 1950-1969, and the Deseret Test Activity had only 4 from 1962-1973. These infections resulted in no fatalities or permanent disabilities.

TABLE I

Fort Detrick Laboratory acquired infections
(Includes civilian and military personnel)

Number of Infections 20 April 1943 to Termination	456
Deaths (anthrax 1951, 1958; viral encephalitis 1964)	3
Number of Infections 1943 to 1947	93
Number of Infections 1948 - 1958	277
Number of Infections 1959 - 1969	86

TABLE II

Safety Program
1943 to 1969

Agent Vaccines Developed	Toxoids	Skin Tests
1. Psittacosis virus	1. Clostridobotulinum A	1. Brucella suis
2. Bacillus anthracis	2. Clostridobotulinum B	2. Pasteurella tularensis
3. Pasteurella tularensis (attenuated)	3. Clostridobotulinum C	3. Mycobacterium tuberculosis
4. Pasteurella tularensis (irradiated)	4. Clostridobotulinum D	4. Clostridium tetani
5. Rift Valley virus	5. Clostridobotulinum E	5. Bacillus anthracis
6. Rio Bravo virus		
7. Rocky Mountain Spotted Fever Rickettsia		
8. Blastomycea dermatiditis		
9. Pneumococcus pneumoniai		
10. Eastern Equine Encephalomyelitis virus		
11. Brucella suis		
12. Paateurella pestis		
13. Japanese B Encephalitis virus		
14. Salmonella typhii		
15. Venezuelan Equine Encephalomyelitis virus		
16. Q Fever Rickettsia		
17. Q Fever & Rocky Mountain Spotted Fever (combined)		
18. Germiston virus		
19. Vibrio comma		
20. Coccidioides immitis		
21. Influenza virus		
22. Typhus Rickettsia		
23. Pasteurella tularensis (425)		
24. Yellow Fever virus		
25. Mycobacterium tuberculosis		
26. Malleomyes mallei		
27. Bolivian Hermorragic Fever Virus		

Annex H

Medical/Safety Considerations for Conduct of Open-Air Tests with Pathogens

Background:

Medical/safety aspects of open-air tests with pathogenic microorganisms conducted by the DOD were guided by the recommendations and observations of independent advisory committees. Three committees were assembled to advise the Army on test conduct. These were: the Ad Hoc Committee on BW Testing (Scheele Committee) at Dugway Proving Ground (DPG)-1953, the Inter-Agency Survey Committee on BW Testing at DPG (Price Committee)-1959, and the Deseret Test Center Medical Advisory Committee (Davis Committee)-1962. A summary of committee composition, purposes, recommendations and findings follows.

Ad Hoc Committee on BW Testing at Dugway Proving Ground (Scheele Committee). The "Scheele Committee" was convened at the request of Robert T. Stevens, Secretary of the Army, in 1953 for the purpose of advising the Department of the Army on the advisability and safety of testing prototype hardware containing animal and plant pathogens at Dugway Proving Ground. The Committee was chaired by Dr. Leonard Scheele, Surgeon General of the US Public Health Service. Members of the Committee were eminent authorities in their fields of biological specialization and were drawn from various universities and federal and state (Utah) agencies. Incorporated is a list of the Committee membership. The Committee assembled for two series of meetings: One series was held at Ft. Detrick and DPG during July of 1953 to consider agents which could or could not be safely tested at DPG; a second series of meetings at DPG was held during October of 1953, at the request of MG Egbert Bullene, Chief Chemical Officer, to consider the specific subject of the safety of conducting field trials on the Salt Flats at DPG using Bacillus anthracis.

Although review of the minutes and comments of Scheele Committee actions provides some insight into a deep concern for, and deliberation on, medical and safety considerations with respect to testing by the technical staff and/or consultants at Ft. Detrick prior to establishment of the committee, no definitive correspondence or memoranda related to the subject could be retrieved from the files.

(July 1953 meetings.) During this series of meetings, various agents were considered safe for testing within limits prescribed by the committee. Basically, those agents which were present in the United States in animal reservoirs and which were relatively widespread were deemed safe for testing at Dugway. "Human infections acquired in nature are of public health

interest but do not constitute major problems . . . ." "To reduce even such a small hazard as might develop, continuous surveillance of the rodent and ectoparasite populations should be continued . . . ." These statements were the prime precepts which delineated the Dugway test orientation and which laid the foundation for pursuit of the expanded Ecology and Epidemiology (E&E) program in the Dugway and surrounding areas.

The Committee considered other agents, as well, which were deemed to be, at that time, unsafe for testing because of lack of evidence for endemicity in western wildlife.

The Committee emphasized the importance of continuing and expanding meteorological investigations on and adjacent to DPG before conduct of tests of persistent agents, such as B. anthracis. In this regard, they recommended that numerous small and large scale tests be done with viable biological simulants (specifically with B. globigii (BG) and inert particulates (FP) to determine cloud travel and deposition. Persistence studies of organisms in both aerosols and soil should also be completed. They recommended a continuing and increased effort on disease surveillance in both wildlife and domestic animals in the area for those agents under consideration for open-air testing. They further recommended that "appropriate state officials" be continually informed of tests to be conducted with pathogenic agents in order that their cooperation may be obtained in maintaining human, animal and crop epidemiological intelligence in areas adjacent to Dugway. Finally, to keep the Surgeon General informed of testing activities on a continuing basis, the committee recommended permanent on-site Public Health personnel be assigned to both Ft. Detrick and DPG. All of these recommendations were immediately and fully implemented.

(October 1953 meetings.) A review of work done at DPG on agent spread and persistence from Salt Flat release of biological simulants (BG) and FP, and work at Ft. Detrick "on the lethal end point of N/anthrax)" indicated that small stepwise releases may be made "provided adequate precautions for safety and for handling of emergency situations" were available in advance. The Committee recommended that precautions should include "assurance of an adequate supply of specific chemotherapeutic agents for prophylactic treatment, availability of personnel for administration of such materials, and plans for appropriate cooperation with health and agricultural officials at state and federal levels." All of these recommendations were fully implemented. The Committee established levels of agent release beginning with small and proceeding to larger releases.

Tests could be conducted under meteorological conditions which, in the opinion of the test staff, would be unlikely to provide for travel of clouds in dangerous concentrations to areas known to be inhabited or occupied by humans or livestock. On the basis of this meeting, two successful series of B. anthracis tests were conducted over an 18 month period in stepwise fashion under the parameters established by the Committee. No untoward effects of these tests were ever reported. Extended surveillance of wildlife in the areas surrounding the test site was maintained for many years as a component of the E&E effort. No epizootic or evidence of elevated serological antibody levels in the wildlife were detectable.

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MEMBERS OF SECRETARY OF DEFENSE
AD HOC COMMITTEE FOR DUGWAY PROVING GROUND
OR SCHEELE COMMITTEE - 1953

Leonard A. Scheele, M.D., Chairman
Surgeon General
Public Health Service
Department of Health, Education, and Welfare
Washington 25, D.C.

Members:
Assistant to the Secretary of Defense
(Health and Medical)
Washington 25, D.C.

Chief, Bureau of Animal Industry
US Department of Agriculture
Washington 25, D.C.

Professor of Bacteriology
College of Agriculture
University of Wisconsin
Madison 6, Wisconsin

State Director of Public Health
Utah State Department of Health
Salt Lake City, Utah

Health & Special Weapons Defense Office
Federal Civil Defense Administration
Washington 25, D.C.

Operations Research Office
The Johns Hopkins Univeristy
6410 Connecticut Avenue
Chevy Chase, Maryland

President, Armed Forces Epidemiological Board
Professor of Microbiology
College of Medicine
New York University
477 - 1st Avenue
New York 16, New York

Chief, Biological Warfare Branch
Research and Development Division
Office of the Chief Chemical Officer
Washington 25, D.C.

ADVISORS TO THE COMMITTEE

Chief, Office of Health Emergency Planning
Public Health Service
Department of Health, Education and Welfare
Washington 25, D.C.

Director, Microbiological Institute
National Institutes of Health
Public Health Service
Department of Health, Education and Welfare
Bethesda, Maryland

Interagency Survey Committee (Price Committee): This Committee was organized in 1959 by David E. Price, Chief, Bureau of State Services, U.S. Public Health Service, at the request of MG Marshall Stubbs, U.S. Army Chief Chemical Officer. Meetings again were held at both Ft. Detrick and DPG. As with the Scheele Committee, the purpose of this Committee was to make recommendations on pathogenic agents which could or could not be considered in open-air tests at DPG. Membership of this Committee was again drawn from universities and various federal and state agencies (Utah and Nevada). All were eminent authorities in their fields of biological specialization. A list of the membership of this Committee is incorporated.

The Price Committee reaffirmed the basic precepts defined by the Scheele Committee, lauded the extensive detailed epidemiological, wildlife dynamics, and ecological material resulting from the expanded E&E program and review in detail the open-air biological test activities which had been completed during the 1953-1959 time frame. Essentially the same list of agents approved by the Scheele Committee was approved.

Where agents had not been previously tested at Dugway, the Committee recommended that ecological, laboratory safety and soil persistence studies be initiated at least one year prior to consideration for use in open-air tests. Detailed studies were recommended for initiation to permit estimation of concentrations of organism simulants and patterns of aerosol travel between the biological sampling grids and highway U.S. 40 (35 miles to the north). These studies were later completed with no evidence of agent having reached U.S. 40. The Committee repeatedly commended the progress of work in the ecology and epidemiology area and strongly recommended support for continuation of these studies. Likewise, it was pleased with the working

agreement with Utah State officials and recommended a similar agreement with officials from the State of Nevada.

Consideration was given by the Committee to the subject of tests with "infected" (sic) mosquitoes and "uninfected" (sic) arthropods but recommended against same because of a concern for the potential for establishment of permanent foci for infection and arthropod colonies.

Finally, the Committee recommended that it be retained in a permanent status, subject to call by the U.S. Army Chief Chemical Officer. The Committee was not subsequently reconvened because the U.S. Public Health Service Liaison Officers, resident at both Ft. Detrick and Dugway (mentioned under the section on the Scheele Committee), served as the intermediaries in relations with USPHS medical authorities and consultants.

All Price Committee recommendations were fully implemented.

INTERAGENCY SURVEY COMMITTEE - 1959

David E. Price, M.D., Chairman
Chief, Bureau of State Services
U.S. Public Health Service
Department of Health, Education and Welfare
Washington, D.C.

Members:
Chairman, Utah State Board of Health
Utah State Department of Health
Salt Lake City, Utah

Associate Director
National Institute of Health
U.S. Public Health Service
Bethesda, Maryland

Chairman, Department of Epidemiology
School of Public Health
University of Michigan
Ann Arbor, Michigan

Chief Staff Officer, Laboratory Services
Animal Disease Eradication Service
Agriculture Research Office
Department of Agriculture
Washington, D.C.

Acting State Health Officer
Nevada State Health Department
Carson City, Nevada

Professor of Research Medicine
Hospital of the University of Pennsylvania
Philadelphia, Pennsylvania

Department of Bacteriology
College of Agriculture
The University of Wisconsin
Madison, Wisconsin

National Institute of Allergy and Infectious Diseases
Rocky Mountain Labcratory
Hamilton, Montana

Program Coordinator, Research Division
U.S. Army Chemical Corps Research and Development Command
Washington, D.C.

CONSULTANTS TO INTERAGENCY SURVEY COMMITTEE

Chief, Virus and Rickettsia Section
Communicable Disease Center
U.S. Public Health Service
Montgomery, Alabama

Chief, Epidemiology Branch
Communicable Disease Center
U.S. Public Health Service
Atlanta, Georgia

The Johns Hopkins Hospital
Baltimore, Maryland

Agriculture Research Office
Department of Agriculture
Washington, D.C.

Deputy Commander
U.S. Army Medical Research and
Development Command
Washington, D.C.

Deseret Test Center Medical Advisory Committee (Davis Committee):

This Committee was organized under the auspices of the Secretary of the Army. The Committee was chaired by Dr. Dorland G. Davis, Director of the National Institute of Allergy & Infectious Disease. Incorporated is a list of the other members of the Committee. All members of this Committee were eminent public health authorities. They were assembled to advise the Secretary of the Army and the Commanding General, Deseret Test Center, on ecology, epidemiology and safety of conducting field tests with pathogenic microorganisms at remote extra-continental test sites. Their guidance was in consonance with precepts established by the predecessor Committees (Scheele and Price). Several experts had been members of those Committees, as well. Specifically, they made recommendations on the use of specific agents at specific test sites. They met in six series of meetings between 1962 and 1969. These meetings, some of which were held at test sites, were generally held at Dugway and Deseret Test Center, Ft. Douglas, Utah. All of the Committee members visited various test sites to observe, firsthand, that their recommendations were implemented. Their observations and recommendations included: (a) ecology and epidemiology considerations, which served as the basis for initiation of extensive E&E studies in all test areas for which agent tests were being planned; (b) meteorological considerations, to minimize the possibility of exposure of human, domestic animals and wildlife populations to agent; and (c) safety considerations for participating military and civilian personnel, to minimize hazards associated with possible exposure to agent. The majority of their effort was devoted to E&E studies because of their importance in evaluating immediate and residual effects in the specific remote site environment. They recommended both pre-test

baseline studies and post-test residual studies. In every case, they found the test teams in a high state of readiness prior to test conduct. No impact on the environment was ever detected nor were any other untoward effects.

MEMBERS OF MEDICAL ADVISORY COMMITTEE

Dr. Dorland J. Davis, Chairman
Director, National Institute of Allergy and Infectious Diseases
National Institute of Health
Bethesda, Maryland 20014

Members:

Chief, Section of Wildlife Disease and Parasite Studies
Patuxent Wildlife Research Center
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Assistant Chief, Ecological Investigations Program
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Chief, Epidemiology Branch
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Emergency Animal Diseases
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Annex I

Environmental and Ecology Programs

Background. Emphasis on ecology and the impact of effluents on the environment came into national focus within the last decade. However, this problem was highlighted in the BW program as far back as 1951. Based upon guidance from the Chief Chemical Officer in 1951, a program was initiated to study and analyze the plants and animals of Dugway Proving Ground, Utah, and the adjacent areas. A broad spectrum of detailed studies was designed to provide baseline data on plant and wildlife distributions, population dynamics, ecology, etc. The same requirement was also imposed on the Deseret Test Center when it was established in 1962.

Dugway Proving Ground. Under the guidance and recommendations of the Scheele and Price Committees (described in the foregoing), Dugway Proving Ground has been intimately involved in the conduct and management of a variety of ecological surveys, surveillances, analyses, and evaluations for 25 years (1952). The basic directive for these specific studies was to collect baseline data required to assure that testing activities would not create an immediate and residual hazard to wildlife, livestock, domestic animals and humans.

Based upon guidance from the Chief Chemical Officer in 1951, a program was initiated to study and analyze the plants and animals of Dugway Proving Ground and the adjacent areas. A broad spectrum of detailed studies was designed to provide baseline data on plant and wildlife distributions, population dynamics, ecology, etc. In November 1952, a contract was entered into with the University of Utah to initiate the program.

The investigative areas were:

1. Identification of the plants and animals in the vicinity and the development of adequate reference collections for the ready identification of species being studied;

2. Study of the potential for transmission of the candidate agents contemplated for test at Dugway by vectors naturally resident on the wildlife of the Proving Ground and surrounding areas;

3. Study of ecological relationships of possible vectors, hosts, and predators in relation to the physical environment and to other members of the biota, including foods, ranges, distribution, density, reproduction and life histories;

4. Study of the daily and seasonal activities or migrations of animals and the long time trends in the fluctuations of their population numbers as they influence the possible spread or control of vectors; and

5. Establishment of sample areas for study of econological fluctuations.

This scheme was diligently pursued by the contractor and the following facilities were established at Dugway:

1. A field operations laboratory to support field teams for the trapping, processing, tagging, identifying, packaging, storing and recording of morbid and live field samples for further study and analysis;

2. A faunal colony and ecology laboratory used for the rearing of wild animals and insect vectors necessary in experimental infection work;

3. An animal quarantine and holding facility to receive and hold wild animal specimens procured from the field; and

4. Laboratories and associated animal rooms for work with pathogenic material.

In 1953, the Environmental and Ecology (E&E) program was expanded in

scope to encompass the recommendations made by the Scheele Committee. Federal agencies such as the USPHS cooperated in this program. Pursuant to the request of the Army, A USPHS Commissioned Officer was assigned to Dugway, as the Director of E&E Division, to serve on the commanders staff. In this capacity he served as the contracting officer's representative and project coordinator. Every effort was made to follow Committee recommendations. Six years later the Price Committee strongly supported the existing ecological and epidemiological effort at Dugway.

In April 1955, a symposium on the "Ecology of Disease-Transmission in Native Animals" was held at Dugway, sponsored by the University of Utah. Advisors and participants were invited from educational institutions and from various agencies such as the U.S. Public Health Service and other governmental agencies. Presentations and discussions were published. In 1956, the annual International Northwestern Conference on Disease in Nature Communicable to Man (INCDINC) was sponsored by the University of Utah with presentations by E&E program personnel.

Periodically, reports were issued to fulfill the contract requirement. These reports culminated in "Ecological Check Lists" edited by A. M. Woodbury in 1965. This and other reports, dealing with surveys for pathogens and their hosts, present a wealth of information on the biota of the Great Salt Lake Desert and are the most extensive ever attempted in the Bonneville Basin. Production of numerous special reports continued. Some, such as Vest, 1962, "Biotic Communities of the Great Salt Lake Desert," became landmark contributions in the study of the environment and were well received by the scientific community. Other reports reviewed the status of information on such pathogens as tularemia, plague, Venezuelan Equine Encephalitis, etc. Starting in 1959, a series of 12 annual reports were issued with the title, "A Study of the Ecology and Epizoology of the

Native Fauna of the Great Salt Lake Desert."

In 1965, methodology was established to test for chemical toxicological effects on the biota and by 1971 acetylcholinesterase levels in wildlife and livestock were being examined routinely as indicators for exposure to organophosphorus chemicals as part of the chemical safety program. Meanwhile, surveillance continued on disease levels, population interactions and related factors of disease and epidemiological safety interest.

In 1970, the contract with the University of Utah was terminated, and studies were continued for three years by Ecodynamics, Inc., of Salt Lake City at approximately the same level of effort. These studies are now being conducted in-house on a much diminished scale. Requirements have been reduced in consonance with the elimination of biological warfare by the United States in 1969.

Since 1966, arthropod-borne viruses have been studies in detail. The 1971 VEE epidemic in horses in the southern United States prompted a 1972 expansion in surveillance of domestic and wild mammals as well as mosquitoes for detection of possible incursion of the VEE virus into Utah.

The Dugway E&E program investigations have resulted in original isolation of Utah in the causative organisms of Plague, Q-Fever and arboviruses for California Encephalitis, Hart Park, trivittatus, Main Drain, Jamestown Canyon, St. Louis Encephalitis, and Lokern.

Throughout the program, data concerning disease incidence, native populations and parasites, etc., have been correlated to examine trends between five zones of comparison; these zones range from close to Dugway to distant control areas of Utah and points in Nevada and Idaho. In the 25 years of study, no change has been observed in animal population distributions or dynamics attributable to the testing program nor has any

evidence been developed indicative of epidemiological involvement of resident wildlife resultant from the extensive biological test program completed in years past. Contractor and domestic reports support this conclusion. Cyclic changes can be explained as natural phenomena.

Deseret Test Center. Acting on the recommendations of the Deseret Test Center Medical Advisory Committee, Deseret Test Center, from its establishment in 1962 to its merger with Dugway Proving Ground in 1968, sponsored a contractual E&E effort with the Smithsonian Institute and the University of Oklahoma. These programs provided required E&E surveys in those areas outside the continental United States which had been designated for possible open-air BW testing.

The purpose of these studies was to determine potential reservoirs of specific infectious agents, if any, and possible routes of dissemination.

Studies were conducted during 1963 through 1969 on selected islands in the Central Pacific Ocean from latitudes 35° N to 20° S and longitudes 145° E to 145° W (approximately from the Hawaiian Islands west to Guam and south to Samoa). Other investigations were conducted in Alaska and the Bering Sea (i.e. Pribilof Islands), and off the Pacific Coast.

Specific objectives of this ecological program were: to identify and determine the distribution of birds and mammals and their ectoparasite; to conduct biological studies on their breeding and feeding habits and migratory routes; and to ascertain the breeding and host preferences of mosquitoes and biting flies.

Pelagic birds were studied more intensely in the Pacific, while in Alaska mammals were emphasized because of differences in relative abundance in the respective areas. As at Dugway, no immediate or residual environment effects were observed during or subsequent to completion of test activities

on the test sites.

Pine Bluff Arsenal: Prior to the formal establishment of the production laboratories in October 1953, a research contract was negotiated with the University of Arkansas to assure that the planned biological mission would pose no ecological or environmental hazards.

Contractural provisions included studies of both plant and animal life (study activities) but primarily addressed surveys, analysis and evaluations of community animal life in relation to potential transmission of candidate agents to local animal populations. Collection of baseline data for the various surveillance categories was accomplished (for on-going studies, tests and experiments). Support facilities including a field operations laboratory for use in all phases of wildlife entrapment, and a faunal colony for experimental infection work, were extensively used in a broad spectrum study effort. Periodic reports prepared in accordance with contract requirements, summarized and evaluated results of the various ecological surveys, studies and surveillances indicated no immediate or residual environmental effects.

As the biological operations mission progressed, an in-house capability for performing required ecological studies was gradually established with concurrent reductions in the scope of the contractural effort. The contract studies were halted in 1957. In-house studies to verify environmental safety were continued until termination of the mission in 1969.

Annex J

Transportation of Biological and Etiologic Materials (U)

Introduction. The history of military shipping experience relative to biological and etiologic agents and materials cannot accurately be reconstructed from inception due to non-availability of supporting documentation. In addition to comparing with the earliest of regulations issued by the U.S. Post Office, U.S. Public Health Service and commercial airlines, however, military shipments were subjected to more restricted packaging standards to maximize transportation safety. During the intervening years, standards issued by both the military and non-military departments became progressively more restrictive with emphasis upon packaging reliability rather than design criteria. As a result, military shipments have continually been performed under optimum safety conditions, and without accident.

Background. The earliest packaging regulations for etiologic agents were those of the U.S. Post Office in 1951 which applied to "specimens of diseased tissues, blood, serum and cultures of pathogenic microorganisms." Military operating procedures for shipping biological materials were first known to have been published by Fort Detrick in 1950-1951, and by the Department of the Army in Technical Bulletin 237 dated 6 June 1952; these source documents have not been located. It is important to note, however, that the earlier non-military regulations and standards primarily addressed packaging design criteria rather than reliability factors in event of an in-transit accident or incident. Accordingly, in 1954, Fort Detrick initiated a review of procedures and regulations issued specifically for transport of infectious materials in the biological warfare program.

This review reported the results of repeated performance-type tests (rough handling) using prototype packages. The favorable results obtained from these tests--no package leakage--supported the elimination of two currently employed safety precautions: (1) nonstop military aircraft flights, and (2) use of a military escort vehicle and an accompanying decontamination truck during land transport.

Due to discovery of a leakage of experimental living poliomyelitis virus in a commercial shipment on 24 May 1956 (at Washington National Airport), the U.S. Public Health Service on 15 March 1957 issued a Federal Regulation specifying packaging standards for shipment of infectious microorganisms exclusive of Postal Mail. This regulation is code of Federal Regulations Title 42, Public Health, identified as 42 CFR 72.25, Interstate Quarantine, Shipment of Certain Things, Etiologic Agents, which specified a maximum volume of 1 U.S. gallon of etiologic agent, Subsequently, as noted in the Federal Register of 13 May 1958, the Civil Aeronatuics Board (CAB) adopted the packaging provisions of 42 CFR 72.25, with certain amendments, effective 25 June 1958. On 19 September 1958, the commercial airlines followed the Civil Aeronautics Board by accepting 3 gallons of etiologic agent in any of the aircraft with the requirement for decontaminating material between the separating containers; however, both the quantity and decontaminant requirement were deleted some time prior to 1966 for they do not appear in the current official air transport restricted articles tariff No. 6-D. The first military directive on the subject published in January 1959, was Chemical Corps Safety Directive 385-9, "Shipping Criteria for Etiologic Agents and Material." This regulation summarized existing regulations, formalized the packaging specifications previously developed and accepted under 42 CFR 72.25,

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and except for diagnostic specimens (laboratory samples), made technical escort mandatory for all Army shipments of etiological agents, although not required by 42 CFR 72.25.

The first severe testing of etiologic agent packaging occurred in May 1961 and resulted from inquiries by the Federal Aviation Agency and commercial airlines into the validity of packaging reliability standards described in Chemical Corps Safety Directive 385-9. A variety of drop tests including high altitude drops ranging to 4,000 feet at the Army's Dugway Proving Ground, Utah, and other actual/simulated drop tests utilizing packages prescribed in the Chemical Corps Safety Directive were conducted with extremely favorable results--only one container sustained breakage and no leakage occurred through the secondary container. Revised packaging standards resulting from these tests were subsequently standardized at Fort Detrick and in 1962 recorded in Technical Memorandum 12. In January 1964, U. S. Army Materiel Command issued AMCR 384-101, "Safe Shipping Criteria for Etiologic Agents and Biological Materials." Subsequently, on 7 June 1965, Department of Agriculture (USDA) and approved by HEW with formal agreements between those Departments and the Department of Defense (DOD). The regulation approved the packages described in Technical 12 and authorized use of the same principles to package amounts of 1 gallon or less. In addition it removed the requirement for a technical escort for shipment of etiological agent with 500 ml. or less in the primary container, but continued the requirement for escort if the total quantity in any one vehicle, aircraft, or other conveyance exceeded 3 gallons--a requirement in effect since 14 February 1963 when authorized by the next higher Army command. The military requirement of a decontaminant (calcium hypochlorite) between the primary and secondary containers

was removed 12 November 1969 in U.S. Army Materiel Command Supplement 1 to AR 55-8. Analysis indicated this decontaminant caused deterioration of the tin container and could cause explosion under certain conditions during disposal of opened packages. This supplement also eliminated the use of particulate absorbent material, such as vermiculate, which when contaminated could be easily spread outside a broken package. Use by the military of larger gallonage containers received attention as early as 1959 when a 13 gallon seed tank adapted for use during production was modified for packaging agent in quantities up to 16 gallons. Other type containers such as a 15-gallon stainless steel keg, within a protective configuration, were developed and subjected to performance testing--50 foot air drops to hard surfaces. Such containers were always shipped under military technical escort in military trucks and planes (or Logair) due to the 1-gallon perpackage limitation in the commercial airlines restricted articles tariff. Logair was a scheduled domestic cargo aircraft service provided by commercial air carriers under contract to the U.S. Air Force and controlled by that service through Air Force Logistics Command (AFLAC) - except for technical escort personnel, no passengers were permitted on these flights. Commercial trucks were not used for transport of Army shipments of etiologic agents. Authority for more than 1-gallon shipments was obtained from the Public Health Service, after individual review, in accordance with a 1954 agreement concerning the shipment of potential biological warfare agents. Such shipments were approved after thorough evaluation of the containers, mode of shipment and provisions for decontamination and containment in the event of an accident, satisfying the USPHS that the overall hazard was less than that of commercial shipments in full compliance with 42CFR 72.25.

The development of more sophisticated biological munitions and their large area coverage potential, prompted development of improved packaging to insure safe transport by land or air. On 17 November 1964, the Chemical-Biological Joint Technical Coordinating Group (JTCG-CB) established a tri-service Ad Hoc etiologic agent shipping and handling safety committee to resolve attendant problems. Extensive research and study into developing"aircraft crash-equivalent standards" was accomplished including the design and designation of adequate containers for shipment of etiologic agent by air or land without technical escort. These and other containers that met prescribed velocity impact standards were later approved by The Surgeon General and the Public Health Service.

An agreement between the Department of Health, Education and Welfare and the Department of Defense for shipment of etiological agents was formalized on 13 December 1965. This agreement, in addition to the other Federal requirements, assured that etiologic agents/potential biological warfare agents were shipped only in accordance with standards approved by the U.S. Public Health Service and the Administrator of the Agricultural Research Service. Except for the possible use of packaging used to transport radioactive materials, only military packaging of biological/etiological material was designed and tested to meet extraordinary standards used by the military services for transportable containers of etiologic agents. The combination of these regulations and packaging standards was directly responsible for the successful accomplishment of military shipments without incident. No known leakage of infectious or toxic biological material, or instance of a personnel infection occurred during a military shipment.

Annex K

Human Volunteer Testing

Authorization and Establishment. Since World War I and the introduction of mustard gas into military inventories, the use of chemical and biological agents in open warfare has been addressed as a moral, social and tactical issue at military conferences as well as a matter for open public concern. Although the use of biological agents in the military armamentarium was not a universally accepted proposal, the requirement to investigate the effects of such a weapon if applied against the United States received attention at the highest levels of the executive branch of the Federal government, the civilian scientific community and the military establishment. In the post-World War II years addressing this requirement remained the responsibility of the U.S. Army Chemical Corps with the collaboration of the U.S. Army Surgeon General. A report of the Armed Forces Medical Policy Council in 1952 noted that while tests with simulants had demonstrated the vulnerability of the United States to biological attack, no scientific data were available to assess human vulnerability to biological agents.

This concern led to intensive consultation between the Chief Chemical Officer and the Army Surgeon General. Simultaneously, the Secretary of Defense, Secretary of the Army, Army Chief of Staff and the Chemical and Medical elements of the Army addressed the subject of research in defense against biological warfare utilizing human volunteers. The responsibility to provide a defense against biological warfare was assigned to Army Medical Services under the purview of the Army Surgeon General. Although the origin of the term "Whitecoat" is not documented here, its use to describe proposed research involving

volunteers is found in correspondence dating back to October 1954. "Operation Whitecoat" was the code name for the plan to use human volunteers in field experiments concerning the effects of certain biological pathogens upon humans. Thorough legal investigation and ethical review yielded a group of conditions under which volunteers could be used in research.

a. Voluntary consent is required. Written consent must be witnessed, and signed by the individual concerned.

b. No experimentation which could predictably lead to death or permanent disabling injury will be investigated with the use of human volunteers.

c. Proper medical supervision and treatment capability will be immediately available to the subjects.

d. Experimentation must be expected to yield fruitful results for the good of society, not available by other means.

e. Experimentation should avoid all unnecessary physical and mental suffering.

f. The degree of risk taken should never exceed the importance of the experiment or the expectable benefits from it.

g. The volunteer may remove himself from the experiment at any stage if he feels that he has reached the limits of his physical or mental endurance.

The above elements were incorporated in the policies and procedures for the use of human volunteers in biological warfare research published by the Army Chief of Staff (CS 385-30, June 1952) with approval of the Secretary of the Army. Further consultation between the Chief Chemical Officer and the Army Surgeon General led to the development of a plan for a project which would involve human volunteers in the first attempt to obtain dose-response data on Q fever. After extensive legal review and coordination with civilian advisory groups of both the Chief Chemical Officer and the Army Surgeon General

authority for this project was granted by the Acting Secretary of the Army on 14 January 1955. This authorization added a new dimension to the biological (BW) research then being conducted by the Chemical Corps at Camp Detrick, Maryland. For the first time, effective research leading to the development fo a defense against the use of microbiological agents could be scientifically conducted and evaluated without relying solely upon data extrapolated from animal studies.

This project, known as the CD-22 program, terminated its initial research effort in 1956 after yielding the first scientific data of its kind, gathered by U.S. military investigators from experiments conducted on human volunteer subjects. Areas of interest concerning the project were: the vulnerability of man to biological agents; prevention and treatment of BW casualties; and identification of biological agents. Information such as the minimum infectious dose, effectiveness of prophylactic and therapeutic measure, serologic responses to infection and the effects of various doses of inoculum, eventually provided answers to the questions contained within the research objectives. The entire program was monitored by the Commission on Epidemiological Survey (CES) of the Armed Forces Epidemiological Board (AFEB) which provided technical consultation, reviewed protocols, and attended some tests.

The authorization to use volunteers, success of the two-year research project CD-22, the definition of responsibilities concerning research into BW defense and the legal requirements essential to Operation WHITECOAT culminated in the organization of the United States Army Medical Unit (USAMU) and its activation at Camp Detrick, Frederick, Maryland on 20 June 1956. USAMU was assigned the research responsibilities of the Army Medical Department's requirement to provide a defense against BW.

Between 1956 and 1961 the ground work for an effective, on-going recruiting program aimed at continuing the supply of volunteer personnel for Project Whitecoat.

Unit Expansion and Progress. The first significant action to have a direct bearing on USAMU was a revised Agreement on Responsibilities for the Conduct of Research and Development for Defense Against Biological Warfare, signed by the Army Surgeon General and the Chief Chemical Officer on 21 February 1956. This document in conjunction with the policies of the Secretary of the Army, governed the research responsibilities of the Commander, USAMU until 1963; when revised agreements were signed. The revised agreements did not change the status of BW medical defense research but added chemical warfare (CW) defense to the Army Medical Departments' tasked responsibilities. CW defense work was never assigned to USAMU or its successor, USAMRIID.

During the CD-22 project, personnel concerned with research at Fort Detrick were assigned to WRAMC. Even though personnel were assigned to USAMU after its establishment, WRAMC remained as the next higher headquarters until 1958, when USAMU was assigned to the United States Army Medical Research and Development Command (USAMRDC). In 1963, USAMU was internally reorganized to reflect the unit divisional structure which remains essentially the same today.

In August 1957, Ward 200, WRAMC, was established at USAMU to provide a medical treatment facility for all military personnel and to satisfy the requirement for an inpatient facility for conducting research studies in Project Whitecoat volunteers. By December 1957, 110 Project Whitecoat volunteers were available for participation in research programs. The CES of the AFEB continued to monitor the overall effort and reported directly to the Army Surgeon General. A research project, designed to identify the infectious dosages of F. tularensis organisms, began in FY 58 and was recorded

as the first research project involving human volunteers (WHITECOAT) performed at USAMU.

Venezuelan Equine Encephalitis (VEE), the second major project was conducted by USAMU in conjunction with the Allied Sciences Division, Biological Warfare Laboratories. Animals infected intraperitoneally showed no symptoms of disease except a diphasic fever curve which was detected 24-72 hours subsequent to onset in 75% of the animals tested. Although attenuation of the Trinidad strain was achieved in tissue culture, potentially hazardous reactions occurred, precluding definitive prophylaxis achievement. VEE research continued until 1962, when responsible investigators published a research paper on the comparative pathology of the disease as experimentally introduced into various animals. This project did not initially involve the use of WHITECOAT designated volunteers. However, several professional members of the USAMU staff actively participated as volunteers in the studies. During 1964, the immunization requirements were reasonably established for VEE and tularemia. The research findings pertaining to VEE and tularemia were followed with the preparation of industrial sized lots of immunizing vaccines against these diseases. Since that time, several publications have been prepared demonstrating significant findings such as the effects of aerosol age on the infectivity of airborne P. tularensis, effects of respiratory acquired P. tularensis on blood chemistry, and the effects of live attenuated VEE vaccine on immune status. The use of this vaccine with at risk laboratory personnel proved to be completely successful in preventing laboratory acquired VEE infections of symptomatic nature.

In 1969, USAMU was redesignated the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) and although the mission was generally the same, the motivating purpose was altered to reflect current

DA policies and strategic plans. The continuing search for chemoprophylactics vaccines and improved methods for their utilization was no longer structured to meet the requirements for BW defense, but was directed toward the control of communicable diseases in man. In November 1969, President Nixon announced several major decisions concerning the use of biological weaponry, research and stockpiles. BW defense (the mission of USAMRIID immunization and protective measures) research is still authorized. This decision came approximately at the time of the USAMRIID redesignation. USAMRIID research objectives and ultimate goals are oriented and planned with the reasonable expectations, therefore, that they will benefit the civilian community as well as fulfill a military objective.

Project WHITECOAT. The authorization to allow human volunteers to participate actively as research test subjects provided the basis for a meeting between Army and Seventh Day Adventist Church Officials. Preliminary plans were made to establish the Seventh Day Adventist (SDA) Church membership as a potential resource for Project Whitecoat volunteers. This meeting in October 1954 initiated the project that has afforded some 2200 Seventh Day Adventists the opportunity to participate in continuing research at USAMRIID, and an additional 800 to function as laboratory technicians, ward attendants, and at several other significant positions. An official statement of attitude was rendered by the SDA Church indicating offical approval of the project as planned. The SDA General Conference as well as the Army Surgeon General regarded the services rendered by the volunteers in such a light that a commendatory article, published in the official church newspaper on 3 November 1955, openly indorsed the program by both parties. The article colorfully described the contribution of each "WHITECOAT" with particular reference to service to the country and individual standards of fortitude. This article,

as much as any single action, influenced the theme of the conscientious objector volunteer mission as it relates to USAMRIID. The SDA Project Whitecoat volunteers have provided the Army Medical Department with an extremely valuable and irreplaceable resource and have performed, without question, "Beyond the Call of Duty."

Project Whitecoat volunteers were selected from personnel classified as noncombatants (formerly identified by a 1-A-O draft status) during their training at Fort Sam Houston. Twice annually, the Commander and Executive Officer, USAMRIID, along with the Director, National Service Organization for the SDA Church, interviewed potential Project Whitecoat volunteers at Fort Sam Houston to select from those interested to volunteer a group of men to be assigned to the unit. Personnel were oriented as a group in order that a common understanding of the general provisions of the program was insured. Potential participants were then interviewed individually to determine the compatibility of their needs of conscience and the requirements of Project Whitecoat. If an individual was selected, his reassignment orders were annotated as "earmarked for W/C Project TSC" and personnel reports were similarly modified. Coordination between the Commander, USAMRIID, and the Commander, Medical Training Center (MTC) advised the latter of the impending visit and requested permission for group presentation and personal interviews.

The above procedure proved effective as long as selective service classification (1-A-O) was prominent data in military records and the special provisions of conscientious objector status remained in effect. Coincident with the termination of the draft was the absence of the requirement to provide identification of conscientious objectors, since the theory attendant to a volunteer military force presumed unrestricted assignment policies. The position of the SDA Church concerning the volunteer Army is consistent with past statements of attitude: A noncombatant status must be guaranteed their personnel prior to

entry into military service. To date, a three-year enlistment program as a "volunteer" has been approved by the Department of the Army. This program is now being implemented by the Selective Service System and includes provisions for classifying all interested candidates as 1-A-0s. No Project Whitecoat recruiting has been effected since the discontinuance of the draft.

During the early stages of Project Whitecoat (circa 1959) volunteers participated in several projects, and for the purpose of command and control the volunteers were assigned to the units enlisted detachment. Two hundred spaces were authorized by the Army Surgeon General to perpetuate Project Whitecoat. This authorization does appear on the TDA. In that all Project Whitecoat personnel are required to complete 91A-AIT Training, the speces appear as three line items on the TDA: E-5, E-4, E-3 91As. The number of volunteers required was reduced to 172 during 1964. Volunteer projects generally required about two months/year of of Whitecoat's time. During non-project intervals the volunteers performed mission work as laboratory technicians, ward attendants, building systems monitors, and administrative assistants in such a manner that the Institute relied upon their resources for continuity and perpetuation of functions.

The Department of the Army officially set forth the specific regulations for the conduct of research studies in subject volunteers with the publication of AR 70-25 in 1962: Use of Volunteers as Subject of Research. Withdrawal from any particular project and, if the individual so desires, from the entire program, is guaranteed upon request. Desired projects are reviewed thoroughly by the Commander and his staff and forwarded to the Commander, USAMRDC, for final approval as appropriate. The required involvement of high-level personnel insures the proper conduct of experiments administered to human research test subjects.

Of all agencies concerned about the welfare of Project Whitecoat volunteers, it would be reasonable to assume that the Seventh Day Adventist Church would head the list, since the overwhelming majority of Project Whitecoat volunteers are members of the SDA Church. Since the initial attitude statement rendered by the Secretary, General Conference of Seventh Day Adventists, the position of the SDA Church has remained in favor of Project Whitecoat and the voluntary participation of Adventist inductees. Several papers and items of official correspondence have originated from various levels in the SDA hierarchy unequivocally supporting the research conducted at USAMRIID. In light of the Adventist doctrine that prescribes the strict manner in which the human body should be maintained, the absence of derogatory correspondence from the SDA Church indicates that few complaints have been forwarded to church officials. Occurrences such as those reported in some periodicals would certainly have had a deleterious effect on the strength of Whitecoat volunteers assigned to USAMRIID if any credence were given those reports.

Sample Project Synopsis. The procedures used to initiate and control the experiments involving human volunteers are organized and disseminated by the Secretary, Medical Division and ultimately become the Standing Operating Procedures which the Commander, USAMRIID will administer throughout the course of an experiment. The objective, scope, anticipated risk, and special circumstances surrounding a project are prepared by the originating division and Medical Division secretary and are collectively referred to as the protocol of the project. A master bleeding schedule is included as a record of hematological data accumulated during the experiment since variations in blood chemistry are important in final evaluations. The protocol is reviewed and analyzed at a conference attended by the Commander, Scientific Advisor, and Research Division Chiefs to refine procedure and determine the potential, foreseeable benefits expected from the research. Once a protocol is accepted by the conference

members and signed by the Commander, it is forwarded to higher headquarters for final approval. A comprehensive distribution list insures maximum utilization of research data and prompt implementation of the findings by the responsible divisions. After the approved protocol is distributed, individual volunteers are selected, notified and interviewed. The multipurpose interview provides the volunteers with pertinent and required protocol information, obtains his consent, completes the administration necessary for admission, and consolidates health historical records for review. A final selection process based upon scrutiny of individual medical histories results in the identification of primary and alternate test subjects. This information is provided the Adjutant. Once the health records are screened by the interviewers, they are returned to the Ward Secretary for filing. Master laboratory slips are prepared in duplicate for primary and alternate test subjects and forwarded to the Clinical Laboratory, Pathology Division for record administration.

On the day of admission, admission sheets are forwarded to Walter Reed Army Medical Center, Registrar Division. Telephonic notification of each primary and alternate test subject is provided, as the WRAMC Registrar in exchange for the Registrar numbers pertaining to the test subjects. Registrar numbers are then forwarded to the Ward Secretary. As the admission sheets are returned by WRAMC, they are incorporated into the patient Clinical Record folder along with the admission card, consent statement, and other pertinent project data.

As the project is completed, narrative summaries are prepared, signed and returned, along with the project charts, to the Medical Division Secretary who transmits a copy of the cover sheet to the Medical Records Library, Registrar Division, WRAMC. Project charts, when completed, are filed in a records area. Master folders containing all project information,

are prepared and reflect the names of participating volunteers, a copy of the protocol, publications referenced, summaries of findings by all investigators, narrative summaries pertaining to each individual and copies of information included in the USAMRIID Annual Report. All project information is ultimately summarized by the Chief, Medical Division. The Secretary, Medical Division extracts descriptive project information from the cover sheets and transcribes it into the permanent, continuing list of USAMRIID research projects involving human volunteers.

Summaries and Source Documents. A list of all studies involving human volunteers conducted by the US Army Medical Research Institute of Infectious Diseases (USAMRIID) and its antecedents, USAMU and WRAMU is found at Table 1. The individual medical records of all volunteer subjects who participated in these studies are on file at USAMRIID as are the records of the individual projects.

An attempt has been made to identify all extra-mural contracts associate with the USAMRIID program since its inception, Table 2. The participation of volunteers is indicated as known. Regulations governing routine retirement and destruction of extra-mural contract records preclude a definitive statement on this aspect.

All publications in the open scientific literature relating to human volunteer studies conducted by USAMRIID through 1972 have been listed, Table 3. Since the inception of this type of research efforts have been made to insure that information of value to the general scientific community be published in appropriate journals.

Vaccines studies developed or under study have been included in a separate list, Table 4.

Source materials relating to each of the summaries described above are on file at USAMRIID, Fort Detrick, Maryland.

ADDENDUM

Human Volunteer Recruiting Since Termination of the White Coat Program

Since the end of the draft in 1973, no White Coat Volunteers have been recruited. Under the original provisions of the volunteer Army recruiting regulations conscientious objectors could not enlist in the US Army, thus making it impossible for Seventh Day Adventist/conscientious objectors to participate in the White Coat Program.

In 1975 the provisions of AR 601-210 were changed to permit persons to enlist as Medical Research Volunteer Subject (MRVS). This program implemented by US Army Recruiting command produced six enlistees in 1975. During 1976 this program and direct recruitment among 91B Medical Advanced Individual Training Students at Fort Sam Houston, Texas attracted 76 persons for the MRVS program. Two additional volunteers have elected this program during January and February 1977.

ANNEX K

TABLE 1

U. S. ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES

RESEARCH PROJECTS INVOLVING VOLUNTEERS 1954-1976

87-857 O - 77 - 13

YEAR AND PROJ. NO.	TITLE	NUMBER OF VOLUNTEERS
1954-1956	Vulnerability of Man to Biologic Agents/Project CD-22/Laboratory and Field Assessment of Infectivity of Q Fever (Coxiella burnetti); Efficacy of Vaccine; Efficacy of Antibiotic Therapy	91
1956-1957	Analysis of 42 Cases of Laboratory-Acquired Tularemia. Objectives were (1) To evaluate clinical and laboratory manifestations of the disease and to attempt to establish criteria for earlier diagnosis. (2) To assess the efficacy of phenolized and/or acetone-extracted tularemia vaccine in the prevention or modification of the disease. (3) To determine the therapeutic efficacy of tetracycline.	42*

*This is a study of patients conducted during the course of providing medical care. The subjects were not volunteers but had acquired their illness as a consequence of occupational exposure. The vaccines had been given for accupational health protection before the patients came under medical care.

FISCAL YEAR AND PROJ. NO.	TITLE	NO. OF VOLUNTEERS (NON-SDA)	HOSPITAL DAYS	CONVL LEAVE
1958				
58-1	Evaluation of a Living Vaccine for Tularemia (LVS)	21		
58-2	Evaluation of Rift Valley Fever Vaccine	3	17	0
1959	None			
1960				
60-1	Evaluation of Attenuated VEE Virus Vaccine (TC-50)	(16)		
60-2	Evaluation of Attenuated VEE Virus Vaccine (TC-80)	(13)		
1961				
61-1	Assessment of Respiratory Immunization with Tularemia Vaccine (LVS)	17 (7)		
61-2	Evaluation of WEE and VEE Titers in Men Immunized with Attenuated VEE Virus Vaccine (TC-80) with Subsequent IM Challenge of 5 with Virulent VEE	(20)		
61-3	Evaluation of Serological Responses to Attenuated VEE Virus Vaccine (TC-80) and WEE and EEE Vaccines	(5)		
61-4	Evaluation of Attenuated VEE Virus Vaccine (TC-80) as Therapy for Various Malignancies and Lymphomas	(12)		
61-5	Evaluation of Attenuated VEE Virus Vaccine (TC-80)	5 (13)		

YEAR AND PROJ. NO.	TITLE	NUMBER OF VOLUNTEERS (NON-SDA)	HOSP DAYS	CONVL LEAVE
1961 (Continued)				
61-6 (was 61-A)	Evaluation of Attenuated VEE Virus Vaccine (TC-80)	8	13	0
61-7 (was 61-1	Respiratory Virulence of Aged Aerosols of Pasteurella tularensis, SCHU-S4, for Man (30-min) (61-TE-1462)	7	15	0
61-8	Evaluation of Attenuated VEE Virus Vaccine (TC-80)	6 (5)		
1962				
62-1A	Evaluation of Attenuated VEE Virus Vaccine (TC-80)	(6)		
62-1	Respiratory Virulence of Aged Aerosols of Pasteurella tularensis, SCHU-S4, for Man (60-min) (61-TE-1519)	8	20	0
62-2	Respiratory Virulence of Aged Aerosols of Pasteurella tularensis, SCHU-S4, for Man (180-min) (61-TE-1519)	8	14	0
62-3	Assessment of Respiratory Immunization with Living Tularemia Vaccine (LVS) Against Challenge with Pasteurella tularensis, SCHU-S4	20	17	4
62-4	Evaluation of Attenuated VEE Virus Vaccine (TC-81)	(7)		
62-5	Evaluation of Attenuated VEE Virus Vaccine (TC-81)	(13)		
62-7	Respiratory Virulence of Aged Aerosols of Pasteurella tularensis, SCHU-S4, for Man (120-min) (62-TE-1564)	8	15	0
62-8	Evaluation of Reimmunization with Attenuated VEE Virus Vaccine (TC-81)	(4)		
62-9 (was 9B)	Estimation of Human Immunizing Dose of Attenuated VEE Virus Vaccine (TC-81, 10^{-4}, 10^{-5}, 10^{-6})	6		

YEAR AND PROJ. NO.	TITLE	NUMBER OF VOLUNTEERS (NON-SDA)	HOSP DAYS	CONVL LEAVE
1962 (Continued)				
62-10	Evaluation of Interference of Response to Attenuated VEE Virus Vaccine (TC-81) by Yellow Fever Vaccine (17-D)	36		
1963				
63-1	Respiratory Virulence of Aged Aerosols of Pasteurella tularensis, SCHU-S4, for Man (180-min) (62-TE-1629)	8	14	0
63-1A	Evaluation of Attenuated VEE Vaccine (TC-93), ND-4	(13)		
63-2	Evaluation of Attenuated Tularemia Vaccine (LVS), NDBR-101, Lot 2	17		
63-2A	Evaluation of Attenuated Tularemia Vaccine (LVS), NDBR-101, Lots 1-4, 6	33 (6)		
63-3	Evaluation of Metabolic Changes in Immunized and Nonimmunized Man Exposed to an Infectious Dose of Pasteurella tularensis, SCHU-S4 (62-TC-1684)	20	17	0
63-4	Respiratory Virulence of Aged Aerosols of Pasteurella tularensis, SCHU-S4, for Man (120-min) (62-TE-1713)	8	18	5
63-5	Evaluation of Attenuated Tularemia Vaccine (LVS), NDBR-101, Lot 1	(8)		
63-6	Evaluation of 1-year Storage Stability of Tularemia Vaccine (LVS), NDBR-101, Lots 2 and 4	20	21	0
63-7	Evaluation of Attenuated VEE Virus Vaccine NDBR-102, Lot 4	2 (7)		
63-8	Determination of Human ID_{50} of Attenuated VEE Virus Vaccine (TC-93) ND-4 from National Drug Co.	42		

YEAR AND PROJ NO.	TITLE	NUMBER OF VOLUNTEERS (NON-SDA)	HOSP DAYS	CONVL LEAVE
1963 (Continued)				
63-9	Evaluation of Attenuated Tularemia Vaccine (LVS), NDBR 101-2	(11)		
63-10	Evaluation of Susceptibility of Volunteers Previously Infected with Tularemia (Respiratory) to Reinfection by Aerosolized Pasteurella tularensis	23	23	12
63-11	Evaluation of Attenuated Tularemia Vaccin (LVS), NDBR-101, Lot 3	(9)		
1964				
64-1	Evaluation of Metabolic Changes in Normal Humans with Hyperthermia Induced to Mimic the First Day of Fever in Acute Tularemia	8	23	13
64-2	Evaluation of Attenuated Tularemia Vaccine (LVS), NDBR-101, Lot 4	(5)		
64-2A	Evaluation of Attenuated VEE Virus Vaccine (TC-83), Lot 3-2	1 (6)		
64-3	Classified Project	(4)		
64-4	Classified Project	(4)		
64-5	Classified Project	(4)		
64-6	Evaluation of Intermittent and Continuous Tetracycline Prophylaxis in Respiratory Tularemia, SCHU-S4	22	56	14
64-7	Evaluation of Attenuated Tularemia Vaccine (LVS), NDBR-101, Lot 6	(11)		
64-8	Evaluation of Metabolic Changes in Normal Humans with Fever Induced by Bacterial Endotoxin	8	30	13
64-9	Evaluation of Personnel Exposed to a Patient with Bolivian Hemorrhagic Fever	7 (12)		

YEAR AND PROJ. NO.	TITLE	NUMBER OF VOLUNTEERS (NON-SDA)	HOSP DAYS	CONVL LEAVE
1964 (Continued)				
64-10	Evaluation of Metabolic Changes in Humans during Induced Q Fever (63-TE-1823)	8	42	19
64-11	Evaluation of Metabolic Changes in Humans during Antibiotic Therapy	8	27	13
64-12	Evaluation of Intermittent Therapy and a 28-Day Prophylactic Course of Tetracycline in Respiratory Tularemia	24	41	12
64-13	Evaluation of Attenuated Tularemia Vaccine (LVS), NDBR-101, Lot 1	(7)		
64-14	Evaluation of Metabolic Changes in Nonimmunized Man Exposed to an Infectious Dose of Pasteurella tularensis while on an Animal Protein (as opposed to a vegetable protein) Diet	7	34	16
64-15	Evaluation of Two Courses of Tetracycline Therapy and a 14-Day Course of Tetracycline Prophylaxis in Respiratory Tularemia	12	42	13
64-16	Evaluation of Metabolic Changes in Humans during Induced Sandfly Fever	8	34	16
64-17	Respiratory Virulence of Aged Aerosols of Pasteurella tularensis, SCHU-S4, for Man (180-min) (64-TE-1907)	8	16	3
64-18	Evaluation of Attenuated Tularemia Vaccine (LVS), NDBR-101, Lot 2	(3)		
1965				
65-1	Respiratory Virulence of Aged Aerosols of Pasteurella tularensis, SCHU-S4, for Man (180-min) (64-TE-1907)	8	17	5
65-2	Evaluation of Clinical and Serological Responses of Volunteers to Phase I Q Fever Vaccine	6		
65-3	Evaluation of Clinical and Serological Responses of Volunteers to Phase I Q Fever Vaccine			

YEAR AND PROJ. NO.	TITLE	NUMBER OF VOLUNTEERS (NON-SDA)	HOSP DAYS	CONVL LEAVE
1965 (Continued)				
65-4	Evaluation of Attenuated Tularemia Vaccine (LVS), NDBR-101, Lot 3	(7)		
65-5	Evaluation of Tetracycline Therapy and Prophylaxis in Respiratory Tularemia	22	36	14
65-6	Evaluation of Individuals Following Accidental Respiratory Exposure to SEB	(15)		
65-7	Evaluation of Attenuated Tularemia Vaccine (LVS), NDBR-101, Lot 4	(12)		
65-8	Evaluation of Attenuated Tularemia Vaccine (LVS), NDBR-101, Lots 2 and 4	20		
65-9	Evaluation of Attenuated VEE Virus Vaccine (TC-83/3-2L3)	(19)		
65-10	Evaluation of Metabolic Changes in Humans during Graded Reduction of Dietary Intake or during Low Dose Cortisol Administration	5	33	15
65-11	Evaluation of Tetracycline Therapy in Respiratory Tularemia Due to SCHU-S5 Strain	8	34	15
65-12	Evaluation of Clinical and Serological Responses of Volunteers to Phase I and Phase II Q Fever Vaccine	16		
65-13	Evaluation of 3-year Storage Stability of Tularemia Vaccine (LVS), NDBR-101, Lots 2 and 4	14	27	14
65-13A	Evaluation of Metabolic Changes in Immunized Subjects Exposed to Infectious Doses of Pasteurella tularensis	8	34	15
65-14	Viremia determinations in Humans Vaccinated with the Recommended Immunizing Dose of VEE Virus Vaccine, Live, Attenuated (TC-83/3-2)	3		
65-15	Classified Project	(4)		

YEAR AND PROJ. NO.	TITLE	NUMBER OF VOLUNTEERS (NON-SDA)	HOSP DAYS	CONVL LEAVE
1965 (Continued)				
65-16	Evaluation and Comparison of Efficacy of Phase I and Phase II Henzerling Strain Q Fever Vaccines Against Challenge with the AD Strain (Phase II) Q Fever (65-TE-2033)	18	28	1
65-17	Classified Project	(9)		
65-18	Classified Project	10		
1966				
66-1	Evaluation of Tetracycline Prophylaxis and Therapy of Respiratory Tularemia in Volunteers	16	35	1
66-2	Classified Project	10	3	
66-3	Classified Project	3 (1)	2	
66-4	Classified Project	2	2	
66-5	Classified Project	2	2	
66-6	Classified Project	2	3	
66-7	Classified Project	3	4	
66-8	Classified Project	4	5	
66-9	Classified Project	4	5	
66-10	Classified Project	4	5	
66-11	Classified Project	3	4	
66-11A	Classified Project	4	4	
66-12	Classified Project	4	4	

YEAR AND PROJ. NO.	TITLE	NUMBER OF VOLUNTEERS (NON-SDA)	HOSP DAYS	CONVL LEAVE
1966 (Continued)				
66-13	Evaluation of Effects of Respiratory Tularemia on Task Performance of Volunteers (BEID-2) and Tetracycline Therapy of Respiratory Tularemia in Volunteers	18	29	15
66-14	Investigation of Clinical Effects of Attenuated VEE Virus Vaccine in Volunteers (TC-83/3-2L3)	20	9	
66-14A	Investigation of Clinical Effects of Attenuated VEE Virus Vaccine in Volunteers (TC-83/3-2L3)	20	13	5
66-15	Determination of the Effect of Diet Upon Normal Periodicity of Whole Blood Amino Acids in Humans	6	8	
66-16	Classified Project	10	5	
66-17	Classified Project	8	4	
66-18	Classified Project	10	4	
1967				
67-1	Evaluation by Task Performance of Respiratory Tularemia in Man (BEID-3)	10	23	15
67-2	Study of Whole Blood Amino Acids in Normal Adult Male Subjects			
	2A	6	6	4
	2B	24		
	2C	6	22	11
	2D	10	10	6

YEAR AND PROJ. NO.	TITLE	NUMBER OF VOLUNTEERS (NON-SDA)	HOSP DAYS	CONVL LEAVE
1967 (Continued)				
67-3	Preliminary Evaluation of Plague Vaccine, Live, Attenuated (Strain EV-76-WR, Freeze-Dried, Lot 7)			
	(1A) 5×10^3	6	13	13
	(1B) 5×10^4	8	10	7
	(1C) 5×10^5	6	9	7
	(1D) 5×10^6	6	9	3
	(1E) 5×10^7	6	9	11
	(2A) 5×10^6	10	8	9
	(2B) 5×10^7 Reimmunization of 5×10^5 and 5×10^6	10	8	9
67-4	Evaluation of Metabolic and Biochemical Responses to Immunization with 17-D Strain Yellow Fever	10	15	7
67-5	Evaluation of Metabolic and Biochemical Responses to Immunication with 17-D Strain Yellow Fever	12	15	10
67-6	Acceptability Study of Eastern Equine Encephalitis (EEE) Vaccine, Tissue Culture Origin, Lot 1-1966	(6,		
1968				
68-1	Evaluation of Metabolic and Biochemical Responses to Immunization with 17-D Strain Yellow Fever	12		
68-2	Evaluation of Metabolic, Biochemical and Serological Responses to EEE Vaccine Inactivated, Tissue Culture Origin, Lot 1-1966	20 GroupI 17 GroupII 15		
68-3	Evaluation of Behavioral, Metabolic and Serological Responses to Infection with Sandfly Fever Virus, Sicilian Strain (Task Performance BEID-4 and 5)	20 GroupI 17 GroupII 18		
68-4	Evaluation of 5-year Storage Stability of Tularemia Vaccine, Live, Attenuated, NDBR-101, Lot 4. Part I: Immunization. Part II: Aerosol Challenge	20	21	15
68-5	Evaluation of Response to Immunization with 17-D Strain Yellow Fever	14	16	6
68-6	Evaluation of Circadian Variation in Tyrosine Metabolism in the Human	13	12	10

YEAR AND PROJ. NO.	TITLE	NUMBER OF VOLUNTEERS (NON-SDA)	HOSP DAYS	CONVL LEAVE
1968 (Continued)				
68-7	Comparison of Blood Levels and Urinary Excretion of Chloromycetin® and a Generic Preparation of Chloramphenicol	22	5	3
68-8	Evaluation of Clinical and Biochemical Responses to Attenuated VEE Vaccine (TC-83/3-2L6)	20	20	13
68-9	Evaluation of Response of Volunteers to Adenovirus Vaccine, Live, Oral, Type 7, Lot 16CV-0100 (L-AV-7)	24	28	11
1969				
69-1	Evaluation of Clinical and Biochemical Responses to Attenuated VEE Virus Vaccine (TC-83/3-2L9)	24	19	12
69-2	Acceptability Study of WEE Vaccine, Inactivated, Tissue Culture Origin, Lot 1-1967	(6)		
69-3	Evaluation of WEE Vaccine, Inactivated, Tissue Culture Origin, Lot 1-1967	19	13	8
69-4	Evaluation of WEE Vaccine, Inactivated, Tissue Culture Origin, Lot 1-1967	6		
69-5	Evaluation of VEE Immune Globulin (Human) in Volunteers	30		
69-6	Evaluation of Combined EEE (Lot 1-1966) and WEE (Lot 1-1967) Vaccines, Inactivated, Tissue Culture Origin	20	12	9
69-7	Evaluation of Factors Affecting Serum and Plasma to be Used in Quantitative Electrophoretic Studies of Lipoproteins and Glycoproteins	16		
69-8	Evaluation of Human Response to Simultaneous Administration of Live VEE Vaccine (NDBR-102) and Combined, Inactivated EEE (Lot 1-1966) and WEE (Lot 1-1967) Vaccines	20	12	7
69-9	Acceptability Study of Rift Valley Fever Vaccine, Formalin-Inactivated, Tissue Culture Origin, NDBR-103, Lot 6	(3)		

YEAR AND PROJ. NO.	TITLE	NUMBER OF VOLUNTEERS (NON-SDA)	HOSP DAYS	CONVL LEAVE
1969 (Continued)				
69-10	Evaluation of Human Response to Rift Valley Fever Vaccine, Formalin-Inactivated, Tissue Culture Origin, NDBR-103, Lot 6	20	9	8
1970				
70-1	Evaluation of Influence of Sandfly Fever on Work Performance (BEID-6), Muscular Function and Selected Laboratory Measurements	10	18	12
70-2	Selected Clinical Laboratory Measurements in Humans Infected with Sandfly Fever Virus	8	12	9
70-3	Evaluation of Lipid-Vitamin Changes During Sandfly Fever Infection	5	28	18
70-4	Acceptability Study of Chikungunya Vaccine, Inactivated; Dried, Tissue Culture Origin, Lot E-20	(6)		
70-5	Evaluation of Chikungunya Vaccine, Inactivated, Dried, Tissue Culture Origin, Lot E-20	20	11	10
70-6	Evaluation of the Serological Response in Volunteers to the Administration of Combined Eastern and Western Equine Encephalitis Vaccine	16		
70-7	Evaluation of the Serological Responses of Volunteers to the Administration of Plague Vaccine U.S.P. (E Medium)	29		
70-8	Multiple Task Performances in Humans Infected with Sandfly Fever Virus and Administered Symptomatic Treatment BEID-7	14	19	13
1971				
71-1	Evaluation of Lipid Metabolism during Sandfly Fever Infection	5	29	16

YEAR AND PROJ. NO.	TITLE	NUMBER OF VOLUNTEERS (NON-SDA)	HC DAYS	CONVL LEAVE
1971 (Continued)				
71-2	Evaluation of Volunteers of Adenovirus Vaccine, Live, Oral, Type 21, Lot 16CiX-01201	15	34	14
71-3	Evaluation of Human Metabolic Responses to the 17-D Strain of Yellow Fever Vaccine	14	14	7
71-4	Acceptability Study of Eastern Equine Encephalitis Vaccine, Inactivated, Dried, NDBR 104, Lot 1, Run 1	(4)	-	-
71-5	Evaluation of Eastern Equine Encephalitis Vaccine, Inactivated, Tissue Culture Origin, NDBR 104, Lot 1, Run 1	16	-	-
1972				
72-1	Infectivity of Human Plasma Presumed to Contain Sandfly Fever Virus	1	10	9
72-2	Chemical Analysis of Blood and Urine Collected Under Standard Conditions	21	7	3
72-3	Median Infective Titer of Sandfly Fever Virus in a Pool of Human Plasma	20	9½	9¼
72-4	Associated Administration to Volunteers of Venezuelan Equine Encephalitis Vaccine, Live, Attenuated and Yellow Fever Vaccine, 17-D Strain	32	-	-
72-5	Responses of Host Carbohydrate Metabolism During Sandfly Fever	10	13½	13½
1973				
73-1	Prophylaxis of Sandfly Fever	18	15½	16½
1974				
NONE				
1975				
75-1	Acceptability Study of Western Equine Encephalomyelitis Virus Vaccine, Inactivated, Dried, MNLBR 106, Lot 1	(6)	-	-

YEAR AND PROJ. NO.	TITLE	NUMBER OF VOLUNTEERS (NON-SDA)	HOSP DAYS	CONVL LEAVE
1975 (Continued)				
75-2	Evaluation in Volunteers of the Active-Rosette-Forming Lymphocyte Test as an Assay for Previous Immunization to Tularemia	(9)	-	-
75-3	Persistence of Venezuelan Equine Encephalitis Antibodies Following Vaccination with the Live, Attenuated, TC-83/3-2 VEE Vaccine	(5) Former SDAs	-	-
75-4	Tuberculin Skin Test Antigen in Man and its Effect on the Active-Rosett-Forming Lymphocyte Test	(9)		
1976				
76-1	Proposed Clinical Evaluation of Rocky Mountain Spotted Fever Vaccine, Formalin-Inactivated SS Strain, Chick Embryo Cell Origin, Lot 1	12		
76-2	Acceptability Study of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated, Dried, MNLBR 109, Lot No. C-84-1	(6)		
76-3	Rejuvenation and Preservation of P. Vivax (Chesson Strain) and Assessment of Blood Schizontocidal Activity of Mefloquine HCl (WR 142,490)	(1)	22	20
76-4	Immunization of At Risk USAMRDC (Fort Detrick) Laboratory Workers with Monovalent Influenza A/Swine (A/New Jersey/8/76) Virus Vaccine	169	-	-
76-5	Reactogenicity and Antigenicity of Influenza Virus Vaccines: Bivalent A/Victoria/75 and A/New Jersey/76 and Monovalent B/Hong Kong/72	174	-	-
76-6	Reactogenicity of Western Equine Encephalomyelitis Vaccine, Inactivated, Dried Lot 2-1974	6	-	-

ANNEX K

TABLE 2

EXTRA-MURAL MEDICAL RESEARCH CONTRACTS

U.S. Army Medical Research Institute

Of Infectious Diseases

Ft. Detrick, MD

DA-18064-404-CML 474	*Ohio State Univ. (V)	Early diagnosis of infectious diseases	Jan 55- Dec 58
DA-49-007-MD751 (V)	Univ of Maryland	Studies of Rift Valley fever, related viruses and tularemia	Jul 56 - Dec 65
DA-49-193-MD-2867 (V)		Pathogenesis, detection, prevention and treatment of infectious diseases of military importance	Jan 66 - Nov 75
DA-49-193-MD-2125	National Drug Co.	Establish and perform a research program on a series of biologicals	Jul 60 - Jun 70
DADA17-70-C-0107		Development of special biological products	Jul 70 - Current
DA-49-193-MD-2398	Johns Hopkins U.	Investigation of immunological aspects of group B arboviruses	Feb 63 - May 74
DA-49-193-MD-2428	Chas Pfizer & Co.	Preparation and evaluation of staphylococcal enterotoxoids	May 63 - Apr 67
DA-49-193-MD-2528	Tufts University	Biochemical studies on bacteria and on latent agents	Nov 63 - Oct 67
DA-49-193-MD-2533	MIT	Studies of biologically active agents	Jan 64 - Jan 67
DADA17-68-C-8060	Northeastern		Jan 68 - Feb 72
DA-49-193-MD-2534	MIT	Effect of diet on the relative levels of protein synthesis in various tissues	Feb 64 - Jan 66

*While specific contract documentation could not be found, it appears from review of associated correspondence that a contract did exist at least as early as 1955 with Ohio State University. Additional details at Appendix 1.

87-857 O - 77 - 14

DA-49-193-MD-2553	Brandeis Univ	Viral and bacterial induced alterations of cellular and enzymic components during the early phases of infection	Feb 64 - Jan 67
DA-49-193-MD-2560	MIT	Infection and nutrition: mechanisms of interaction	Jun 64 - Jun 70
DA-49-193-MD-2567	U. Louisville (V)	Behavioral effects of infectious diseases	Mar 64 - Jun 72
DA-49-193-MD-2580	IIT Research Inst.	Research in aerosol immunization	Jun 64 - Jul 67
DA-49-193-MD-2829	Cordis Corp	Virus detection by fluorescence polarization	Oct 65 - Sep 67
DA-49-193-MD-2823	U. Cincinnati	Host parasite interactions in experimental systems	Oct 65 - Sep 68
DA-49-193-MD-2882	U. of Tennessee	Metabolic changes in animals following specific bacterial infection	Feb 66 - Mar 71
DA-49-193-MD-2589	Wistar Inst.	Influence of deuterium oxide on biological systems	Jun 65 - May 66 ?
DA-49-193-MD-2597	Harvard School of Medicine	Separation and characterization of antigens of Rickettsia tsutsugamushi	Aug 64 - Aug 66 ?
DA-49-193-MD-2598	Georgetown Univ	The metabolic effects of fever and infection	Jul 64 - Jul 67
DA-49-193-MD-2599	Johns Hopkins Univ	Studies of cellular defense against infection	Jul 64 - Jun 67
DA-49-193-MD-2604	Hood College	The structure of bacterial cell walls as affected by antibiotics	Jun 64 - May 65
DA-49-193-MD-2630	IIT Research Inst.	Susceptibility to infection in irradiated animals	Jul 64 - Oct 67

DA-49-193-MD-2670	Loma Linda Univ	Virus-host relationships in gnotobiotes	Sep 64 - Aug 66
DA-49-193-MD-2674	Wadsworth Vet. Hosp Los Angeles, Calif	Rapid diagnosis of bacteremia	Oct 64 - Sep 66
DA-49-193-MD-2679	Collaborative Res. Inc	Studies of inhibition of viral multiplication	Jan 65 - Sep 69
DA-49-193-MD-2694	Rutgers Univ	Biochemical changes in avian tissues during the bioenergetics of infection and the incubation period of disease	Jan 65 - Current
DA-49-193-MD-2724	U. of Tennessee	Studies on intracellular bacterial parasites	Apr 65 - Mar 69
DADA-17-67-C-7073	Univ of Michigan	Management of animal cell cultures for fermentor production of virus vaccines	Jan 67 - Aug 69
DADA17-67-C-7102	Univ. California	Mode of action of staphylococcal enterotoxin B	May 67 - Nov 67
DADA17-68-C-8073	Univ. Vermont		Jan 68 - Jul 72
DADA17-67-C-7145	IIT Research Inst	Research in immunization with soluble Viral antigens	Aug 67 - Jul 69
DADA17-68-C-8079	Chas. Pfizer Inc	Large scale production and evaluation of staphylococcal enterotoxoid B	Feb 68 - Feb 70
DADA17-68-C-8125	Univ. Florida	Pathology of experimental enterotoxemis	Sep 68 - May 71
DADA17-67-C-7109	EG&E Inc	Rapid identification of microorganisms using light- scattering techniques	Apr 67 - Apr 68
DADA17-68-C-8131	Science Spectrum		Apr 68 - Oct 71

DADA17-68-C-8080	Ohio State Univ	Early diagnosis of infcctious diseases	Sep 68 - Jul 72
DADA17-72-C-2151	W. Va. Univ Med Ctr		Jul 72 - Mar 75
DADA17-73-C-3098	Yale Univ.	Sequential immunization of spider monkeys with three group B arboviruses: Yellow fever, Langat, and Dengue-2	May 73 - May 75
Project Order 4604	Veterans Admin. Hosp., Pittsburgh	Role of cyclic nucleotides in the regulation of lymphocyte transformation	Jun 74 - May 76
DADA17-72-C-2161	Medical College of VA	Investigation of attenuated strains of group A arboviruses	Jul 72 - Dec 75
DAMD17-74-C-4079	Baylor College of Medicinc	Muscle composition in infcction	Jun 74 - Dec 74
DAMD17-74-C-4095	Johns Hopkins U	Adjuvant effects on immune responses to biological agents	Jul 74 - Current
DADA17-73-C-3090	Washington State U	Studies of the antigenic composition of Coxiella burnetii	Apr 73 - Current
DAMD17-74-C-4007	Wycth Laboratories	An investigation of E. coli enterotoxins	Aug 73 - Current
DAMD17-74-C-4012	Pan American Health Organization	Program for preparation of immune globulin against Bolivian hemorrhagic fever	Jul 73 - Jun 74
DAMD17-74-C-4112	Northwestern Univ. Medical School	Viral vaccine immunogenicity to host cell-mediated and humoral immune responses	Jun 74 - Current
DAMD17-74-C-4025	Univ of Notre Dame	Development of a colony of germ free hamsters as a biomedical response	Oct 73 - Jul 74

DAMD17-74-C-4047	Stanford Res. Inst.	Field ionization mass spectrometric rapid diagnosis in infectious diseases	Dec 73 - Current
DAMD-17-74-C-4057	Johns Hopkins Univ.	Radiometric methods for rapid diagnosis of viral infection	Jun 74 - Dec 74
DAMD17-75-C-5041	Johns Hopkins Univ.		Feb 75- Current

TABLE 3

REPRINTS

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TABLE 7

VACCINES UNDER STUDY AT

U.S. ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
FORT DETRICK, FREDERICK, MARYLAND 21701

VACCINE	RESEARCH YEARS	STATUS OF VACCINE
Anthrax	1959-1968	Development completed
Venezuelan equine encephalomyelitis	1960-1974	Development completed
Tularemia	1960-1969	Development completed
Plague	1965-1974	Development completed
Q fever	1960-1974	Development completed
Rocky Mountain spotted fever	1972-1974	Final development
Chikungunya	1969-1974	Final development
Rift Valley fever	1963-1974	Final development
Western equine encephalitis	1968-1974	Intermediate development
Eastern equine encephalitis	1967-1974	Intermediate development
Staphylococcal enterotoxin B	1964-1974	Intermediate toxoid
California encephalitis	1969-1974	Early development
St. Louis encephalitis	1969-1974	Early development
O'Nong-Nyong	1969-1974	Early development
Mayaro	1970-1974	Early development
Sindbis	1971-1974	Early development
Langat	1971-1974	Early development

Appendix I to Annex K

CHRONOLOGICAL SUMMARY OF THE U.S. ARMY CHEMICAL CORPS -

OHIO STATE CONTRACT VOLUNTEER STUDIES

1. Significant opposition existed to the extrapolation of data from animals to man and it was deemed necessary to obtain data by direct challenge of man. Therefore, by 31 July 1952, the Chemical Corps had issued the directive CMLRE-B-2.729.3, subject: "Use of Human Subjects in Hazardous Tests."

2. The first formal action regarding microbial challenge of volunteers was 26 March 1953.

3. A plan, apparently prepared as of 9 October 1953, for the respiratory challenge of man with Francisella (Pasteurella) tularensis was forwarded to the Secretary of the Army on 21 January 1954 and approved by him 30 March 1954.

4. Contract negotiations were then initiated and culminated on 21 January 1955 in a signed contract (DA-18-064-CML-2655) with the Ohio State Research Foundation and Dr. Samuel Saslaw as the responsible physician.

5. On 31 January 1955, Dr. A. G. Wedum was appointed Project Officer by the Ass't Secretary of the Army.

6. Based on evidence from respiratory challenges of monkeys and guinea pigs, the planned respiratory exposure of volunteers was reassessed and it was elected to perform aerosol challenges only if the results from intradermal inoculation were not prohibitive. A revised plan and contract entitled "Plan for Assessment of an Agent" was sent to the Secretary of the Army on 1 April 1955 and approved by him 24 June 1955.

7. Intradermal testing was completed in January 1957.

8. To accomplish the respiratory phase of the contract, it was necessary, based on joint agreement between TSCO and the Chief Chemical Officer, dated 21 February 1956, to appoint a new contract officer; on 27 September 1957, COL Wm. D. Tigertt was designated Project Officer in relief of Dr. Wedum.

9. The results of the intracutaneous and respiratory challenges were reported in the open literature in 1961 and 1962. Six publications resulted and a copy of each is attached (References 1-6).

Reprinted from the Archives of Internal Medicine
May 1961, Vol. 107, pp. 689-701

Tularemia Vaccine Study

I. Intracutaneous Challenge

SAMUEL SASLAW, M.D., Ph.D.
HENRY T. EIGELSBACH, Ph.D.
HENRY E. WILSON, M.D.
JOHN A. PRIOR, M.D.
AND
SALLY CARHART, M.S.
COLUMBUS, OHIO

The frequency with which Pasteurella tularensis infects hunters of rabbits and laboratory workers studying this microorganism makes vaccination of these persons desirable. However, the protective value of available nonviable vaccines is not certain. Studies on this point have been conducted by Foshay et al.[1] and Kadull et al.[2]

The ideal method of evaluating a vaccine intended for protection of humans is to challenge volunteers, both vaccinated and nonvaccinated, with a reproducible known infective dose of the disease-producing agent. A study in a small vaccinated group challenged by a known infective dose can provide more specific information in a shorter time than by assembling a much larger number in a study in which vaccinated persons are "exposed" accidentally in varying degree or not at all.

Pasteurella tularensis offers certain advantages in such a critical study employing human challenge with viable microorganisms. A broad base of preliminary experience is provided by accumulated data and literature on experimental animal and accidental human infections. The specific detailed studies in monkeys performed in these laboratories preliminary to the human studies described below are the subject of a separate report.[3] The highly infectious nature of P. tularensis and the excellent therapeutic effect of streptomycin in terminating infection is ideal for study of experimental infection in volunteers.

The purpose of this study was to compare the response of nonvaccinated and vaccinated men challenged with a carefully controlled known small number of P. tularensis organisms, administered intracutaneously.

Materials and Methods

Volunteers were inmates of the Ohio State Penitentiary, 21 to 35 years of age. Those accepted for the project were required to pass a rigid

Submitted for publication May 28, 1960.
From the Department of Medicine, College of Medicine, Ohio State University, Columbus. This study was supported under contract with the U.S. Army Cmlc, Fort Detrick, Frederick, Md.

Reprinted from the Archives of Internal Medicine
May 1961. Vol. 107. pp. 702-711

Tularemia Vaccine Study

II. Respiratory Challenge

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Previous studies from these laboratories demonstrated that man can readily be infected by intracutaneous inoculation with approximately 10 Pasteurella tularensis organisms (SCHU S4 strain).[1] Prior vaccination with killed Foshay vaccine did not prevent local lesions, but did reduce the incidence of systemic manifestations of infection. Review of accidental laboratory infection indicates that the respiratory route may serve as a portal of entry.[2] Experimental respiratory infections can easily be induced in both vaccinated and nonvaccinated monkeys, and response to therapy is good.[2] This present report describes the response to respiratory challenge with P. tularensis of nonvaccinated volunteers and of volunteers who received either killed vaccine or a viable attenuated vaccine.

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From the Department of Medicine, College of Medicine, Ohio State University, Columbus, Ohio. This study was supported under Contract with the U.S. Army CmlC, Fort Detrick, Frederick, Md.

Materials and Methods

Volunteers were inmates of the Ohio State Penitentiary, 21 to 35 years of age. Criteria for selection and conditions of volunteering have been described.[3]

Vaccination with Foshay killed tularemia vaccine was conducted as previously described.[3] The viable vaccine was administered by the multiple puncture technique (150) through a drop of rehydrated lyophilized vaccine in a 5 to 10 mm. area on the outer aspect of the ether-cleansed upper arm. The vaccine contained 1×10^9 viable organisms per milliliter and was prepared by one of us (H. T. E.) from the more immunogenic of 2 variants isolated at Fort Detrick in 1956 from a Soviet preparation.[4]

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STUDIES WITH TULAREMIA VACCINES IN VOLUNTEERS*

III. SEROLOGIC ASPECTS FOLLOWING INTRACUTANEOUS OR RESPIRATORY CHALLENGE IN BOTH VACCINATED AND NONVACCINATED VOLUNTEERS

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Previous reports from this laboratory have described the clinical aspects of tularemia infection in both vaccinated and nonvaccinated volunteers following intracutaneous[4] and respiratory[5] challenge. These studies offered an excellent opportunity to compare the serial antibody responses following vaccination with killed or viable attenuated vaccine as well as the serologic picture in nonvaccinated and vaccinated volunteers challenged by either the cutaneous or respiratory route. It is the purpose of this report to describe the serologic aspects of experimental tularemia in man.

Materials and Methods. Fushay killed (phenolized) vaccine and the viable attenuated vaccine were administered as previously described (Saslaw *et al.*[4,5]). Challenge with *P. tularensis* (Schu S4 strain) by both the cutaneous[4] and respiratory[5] route in both nonvaccinated and vaccinated volunteers has also been described.

SERUM. Blood was collected in sterile tubes from volunteers at weekly intervals following vaccination and at biweekly intervals after challenge. Serum obtained from these specimens was stored at −20° C.

BACTERIAL AGGLUTINATION TEST. To each 0.5 ml. of serum dilutions, 0.5 ml. of formalin-killed bacterial suspension (approximately 3×10^9 organisms) was added, and the tests incubated overnight in a 37° C. water bath before reading. Titers were recorded as the highest dilution showing at least 2+ agglutination.

HEMAGGLUTINATION TEST. These tests were performed as described by Alexander, Wright and Baldwin[1] and Wright and Feinberg[2]. In brief, washed human type "O" red blood cells were sensitized by incubation with *P. tularensis* polysaccharide†, washed and then 0.5 ml. added to 0.5 ml. of serum dilutions

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†Kindly supplied by Dr. P. S. Nicholes, Utah University.

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STUDIES WITH TULAREMIA VACCINES IN VOLUNTEERS*

IV. BRUCELLA AGGLUTININS IN VACCINATED AND NONVACCINATED VOLUNTEERS CHALLENGED WITH PASTEURELLA TULARENSIS

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Previous studies from this laboratory have been concerned with the clinical[9,10] and serologic[11] aspects of experimental tularemia in vaccinated and nonvaccinated volunteers following intracutaneous or respiratory challenge. These studies provided a unique opportunity to investigate the occurrence of brucella agglutinins in tularemia under controlled conditions. Various workers (Eisele[1], Feinberg and Wright[2], Foshay[3], Francis[5], Francis and Evans[6], Poston and Smith[8], Stanfield, Taylor and Morgan[13]) have shown that patients with naturally acquired tularemia can exhibit agglutinins for brucella species, but there is not general agreement as to the frequency with which this serologic cross reaction occurs and its importance from the diagnostic standpoint. The present report is concerned with brucella agglutinin formation in 98 vaccinated and nonvaccinated subjects challenged by the intracutaneous or respiratory route with virulent *P. tularensis*. Ancillary studies in rabbits immunized with killed *P. tularensis* also will be presented.

Materials and Methods. Volunteers received either Foshay killed (phenolized) vaccine or viable attenuated vaccine by methods described previously[9,10]. Procedures used for intracutaneous and respiratory challenge have also been discussed in our earlier reports[9,10]. Brucella tube agglutination tests were carried out by standard methods (Spink *et al.*[12]). Tube antigen was obtained from the Bureau of Animal Industry, Beltsville, Maryland.

Formalin-killed suspension of *P. tularensis*, Strains 38, Schu S-4, 425, 503 and the viable vaccine strain† were used to immunize 3, 3, 3, 2 and 4 rabbits, respectively. All strains were grown on GCBA medium (BBL) for 72 hours, harvested in physiologic saline containing 0.5% formalin, and allowed to remain at 4° C. for 24 hours. After appropriate sterility tests had been completed, the suspensions were washed 3 times with sterile saline and resuspended in a concentration which, when diluted 1:10, was equivalent in opacity to MacFarland tube No. 2. Each rabbit was injected intravenously with 0.5, 1.0, 1.0 and 1.0 ml. on 4 consecutive days, respectively. Blood samples were obtained from the marginal ear vein before immunization and at weekly intervals thereafter. At 7 and 11 weeks after the first immunization, each rabbit received an intravenous booster injection of 0.5 ml. of the same suspension used originally. Curves of antibody production and decline were established in each rabbit by three serologic tests: *P. tularensis* bacterial agglutination and polysaccharide hemagglutination, and *Brucella abortus* bacterial agglutination. Procedures used in per-

*This study was supported under Contract with the U.S. Army Cmlc, Fort Detrick, Frederick, Maryland.

†Kindly supplied by Dr. Henry T. Eigelsbach.

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Reference 5

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STUDIES WITH TULAREMIA VACCINES IN VOLUNTEERS.* V. IMMUNODIFFUSION STUDIES WITH *PASTEURELLA TULARENSIS* ANTIGEN-HUMAN ANTIBODY SYSTEMS

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Previous reports[4-9] from this laboratory described the clinical and serologic aspects of tularemia in vaccinated and nonvaccinated volunteers following intracutaneous or respiratory challenge with *Pasteurella tularensis*. It was impossible to predict, from bacterial agglutination or hemagglutination tests, whether or not an individual would become ill after challenge. The possibility was considered that qualitative characterization of pre-challenge sera with immunodiffusion tests might relate a particular antibody component to immunity. The present report describes application of the Ouchterlony[3] double diffusion technique in experimental tularemia in volunteers. Preliminary studies of *P. tularensis* antigen-rabbit antibody systems are described separately (Carlisle, Hinchliffe and Saslaw[1]).

Materials and Methods. Volunteers received either Foshay killed (phenolized) or viable attenuated vaccine by methods described previously (Saslaw *et al.*[6,7]). Challenge with *P. tularensis* (SCHU S4 strain) by both the cutaneous[6] and respiratory[7] route in both vaccinated and nonvaccinated volunteers has also been described. Immunodiffusion test antigens were prepared by sonic vibration (Carlisle, Hinchliffe and Saslaw[1]) of suspensions of *P. tularensis*, strains 38, SCHU S4, and the viable vaccine strain (LVS).† Since preliminary studies (Carlisle, Hinchliffe and Saslaw[1]) showed no significant qualitative or quantitative differences in these antigens, strain 38 was used except where indicated. Details of preparation of sonic-vibrated antigens and performance of agar diffusion tests have been described (Carlisle, Hinchliffe and Saslaw[1]).

Results. PRECIPITIN LINE RESPONSE AFTER VACCINATION. After Foshay vaccination, precipitins were detected in sera of only 11 of 40 (27.5%) volunteers. As shown in Table 1, precipitins appeared far less frequently and later (mean, 15 days) than significantly elevated titer rises in either bacterial agglutination (mean, 9 days) or hemagglutination (mean, 6 days) tests.

Some degree of correlation was observed between precipitin line response and *peak* bacterial agglutination titers (Table 2). For example, no precipitins were detected in 10 sera

*This study was supported under Contract with the U.S. Army CmlC, Fort Detrick, Frederick, Maryland.

†Cultures kindly supplied by Dr. Henry T. Eigelsbach.

Reference 6

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Studies with Tularemia Vaccines in Volunteers.* VI. Assessment of Role of Properdin in Resistance. (27592)

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Recently there has been resurgence of interest in nonspecific resistance to infection (1). The role of properdin in resistance to infectious disease is not clear(2). Previous studies from this laboratory(3-7) have been concerned with clinical and serologic aspects of experimental tularemia in vaccinated and non-vaccinated volunteers after intracutaneous or respiratory challenge. Both Foshay killed (phenolized) and viable attenuated vaccine stimulated production of antibodies, but there was no correlation between inci-

*Supported under contract with U. S. Army CmlC, Fort Detrick, Md.

ANNEX L

Demilitarization

Policy Directives. Beginning in March 1969, at the President's direction, the National Security Council conducted a major review of United States policy concerning biological warfare. Government agencies participating in the review were: Department of State, Department of Defense, Arms Control and Disarmament Agency and the Office of Science and Technology. Comments were also received from the scientific community and evaluated by the President's Scientific Advisory Committee.

Pending the outcome of this study, Department of Army directed immediate cessation of all production of toxins and biological agents and filling of dissemination devices with these agents on 15 August 1969.[1/] On 25 November 1969, the President issued an announcement of US policy regarding biological warfare which included the following:

(1) The US shall renounce the use of lethal biological agents and weapons and other methods of biological warfare.

(2) The US will confine its biological research to defensive measures such as immunization and safety measures.

(3) The Department of Defense will prepare recommendations for the disposal of existing stocks of bacteriological weapons.

On 14 February 1970, a White House announcement extended the policy to military programs involving toxins whether produced by biological

means or chemical synthesis and directed the destruction of toxin weapons and stocks which were not required for defensive research program.

Planning and Project Approval. General guidelines for preparation of demilitarization plans were provided to Ft. Detrick by Headquarters US Army Munitions Command on 12 November 1969. The guidelines involved:

(1) Absolute adherence to safety and control procedures with no tradeoff for time or cost.

(2) Verification of the efficacy of the detoxification procedures.

(3) Strict accountability procedures for demilitarized items.

(4) Preparation of a risk analysis defining degree of risk for each step and for the total operation.

(5) Preparation of detailed step-by-step operation procedures, production plans, security plans, reporting procedures, inspection, and managerial control programs for the entire operation.

(6) Maximum protection provided to operating personnel and absolute assurance that agent released from any possible accident during the demilitarization will be totally contained.

(7) All aspects of the operation to be justifiable from a personnel safety, security and community safeguard standpoint, with sufficient hard data to be incontrovertible in the event the procedures, facilities and concepts of operation are challenged in an objective evaluation of the program.

Demilitarization plans were prepared for all BW stockpiles of antipersonnel and anticrop agents at four locations: Pine Bluff Arsenal, AR, (antipersonnel materiel); and Rocky Mountain Arsenal, CO,

Beale Air Force Base, CA, and Ft. Detrick, MD (anticrop materiel). Test quantities of BW agents and munitions were also destroyed at Ft. Detrick and at Dugway Proving Ground according to procedures approved by the Army Materiel Command. Enough material was retained to support approved defensive R&D programs.

The four major demilitarization plans were evaluated first by an Ad Hoc Committee of Army experts including representatives of the Armed Services Explosives Safety Board and the Air Force Armament Laboratory. The plans and accompanying environmental impact statements (EIS) were reviewed by officials of the US Department of Health, Education and Welfare, US Department of Interior, US Department of Agriculture, Environmental Protection Agency and appropriate state and local officials. The EIS were filed with the President's Council on Environmental Quality

Demilitarization of Antipersonnel Materiel. Between 10 May 1971 and 1 May 1972, the stockpile of antipersonnel BW agents and munitions was destroyed at the Directorate of Biological Operations (DBO) located at Pine Bluff Arsenal.

The disposal operation was preceded by a complete, replicated inventory and a series of special experimental and engineering studies necessary to establish or verify plant procedures. A separate verification office was established to provide overall accountability of each item or material as it proceeded through the destruction process. Independent observers were appointed from HEW and USDA to follow the

entire program to advise on matters relating to their areas of responsibility. The Center for Disease Control (CDC) was employed to independently test all samples submitted (of destroyed agent material residues from DBO) to certify as to the non-pathogenicity of these samples. Extensive press coverage was provided through a constant series of briefings, news releases, closed cricuit TV, and tours of non-contaminated areas throughout the operation. Detailed SOPs were prepared and approved by the Army Ad Hoc Committee; and prior to starting any operation, all personnel were thoroughly trained in the job to be done.

Demilitarization operations began on 10 May 1971. The procedures used for destruction varies with the item. Munitions containing either botulinum toxin or shellfish poison were smelted in a deactivation furnace at 2000°F. Agent materials such as dry Bacillus anthracis spores were removed from munitions, mixed with 2 percent caustic solution and heated for three hours at 280°F. The components of these munitions were also smelted at 2000°F. Larger munitions, were emptied and their agent fill were slurried in caustic solution and sterilized at 280°F for three hours. Bulk agents were handled in a similar manner.

Residues from the agent destruction operations were neutralized, innoculated with a non-pathogenic culture derived from soil, river water, and sewage and allowed to biodegrade to reduce BOD. After biodegradation, the solutions were sterilized again at 280°F for three hours, verified sterile by independent observers, pasteurized at 210 to 250°F and discharged to a package sewage unit for a second biodegradation.

Discharge from this unit was collected in an evaporation bed for drying and eventual disking into the soil.

Cans, containers, munition components and packaging were destroyed by various means including cutting and crushing, incineration and smelting at 2000°F. All metallic residues were collected, accounted for, verified free of agent after sterilization and placed in a sanitary land fill at Pine Bluff Arsenal. Unused hardware, munitions, components and packaging materials were destroyed and disposed of by the same procedures.

Following the complete disposal and certification of the BW stockpile, all facilities in the biological complex were thoroughly cleaned and decontaminated using procedures, controls and certification necessary to provide incontrovertible data that non-immunized personnel could utilize any and all parts of the complex for any purpose. All agent contaminated areas were washed; equipment and apparatus were disassembled; ductwork and piping galleries were opened and the entire area was subjected to gaseous formaldehyde for 16 hours. Process systems throughout the plant and laboratory areas were sterilized by steam at 250°F for three hours. Biological test tabs of heat resistant spores, distributed throughout the system prior to the start of decontamination, were examined afterwards for viable spores as a positive check on the completeness of decontamination.

On 1 May 1972, the DBO facility was turned over to the Food and Drug Administration, Department of Health, Education and Welfare as the National Center for Toxicological Research. All biological material

had been completely destroyed and the production facilities decontaminated without a single biological agent infection exposure of the staff at a total cost of $10,830,600.

Demilitarization of Anti-Crop Materiel. At the time of the President's ban on BW, two anticrop biological agents existed in the stockpile: urediospores of agent TX, the casual agent of wheat stem rust, and spores of agent LX, the causal agent of rice blast. The TX stockpile was stored at Beale Air Force Base, and at Rocky Mountain Arsenal. LX was stored only at Ft. Detrick. The planning, approval and execution of the disposal operations for all three sites as well as the processes employed were practically identical.

Beale Air Force Base Operations. Destruction of TX at Beale Air Force Base, California, was planned and accomplished by the Special Projects Division of Rocky Mountain Arsenal assisted by Ft. Detrick personnel. Project planning, operational procedures and review by the Ad Hoc Committee and the staffing and approval of the final plan and EIS were comparable to those involved in the Pine Bluff Arsenal demilitarization program.

Disposal operations at BAFB required modification of an existing building on land leased by the Army to ensure total containment of the agent during operations. Process equipment was designed, installed and thoroughly tested.

Preceding the operation was an extensive series of laboratory and engineering studies to verify techniques for destroying the agent and decontaminating the facility. As in the case with Pine Bluff Arsenal operation, a control and verification system was developed to record the entire operation including movement of material, laboratory assays and disposal operations to assure credibility of the program. Independent observers, with free access to all disposal activities and records at BAFB were appointed from the US Department of Agriculture and the State of California.

The demilitarization operation was a six step process:

(1) Verification of the viability of the TX stock by incubation of random samples to determine percent germination.

(2) Inactivation of the material by exposure to carboxide gas (10% ethylene oxide - 90% CO_2) once a day for five successive days.

(3) Certification of inactivation to the minimum level of 99.964% by incubating random samples.

(4) Incineration of the inactivated spores in a 4 stage hearth incinerator at 1600° - 2000°F followed by fumigation of the residual ash with paraformaldehyde.

(5) Verification of destruction by microscopic examination of the ash for the presence of spores and by chemical analysis.

(6) Disposal of the ash in an approved area by disking into the soil to a depth of six inches and planting the area with a cover crop of millet.

Following the TX disposal operation, all equipment, trash, air filters, empty drums and ash residue were decontaminated by fumigation with paraformaldehyde. Effectiveness of facility decontamination was verified with BG strip indicators. The land and buildings were returned to the Air Force. Some equipment items were disposed of by the BAFB Property Officer and non-reuseable materials were placed in a BAFB sanitary landfill. Remaining equipment, trash and empty drums were shipped to Rocky Mountain Arsenal for disposal.

The demil operation at BAFB was completed on 10 March 1972 at a cost of $498,153.

Rocky Mountain Arsenal Operation. Rocky Mountain Arsenal was nearly identical to the BAFB demilitarization project. The RMA Special Projects Division, aided by Ft. Detrick personnel, was responsible for planning and conducting the operation. Detailed plans and procedures were reviewed by the Army Ad Hoc Committee, and the final plan and EIS were staffed through the same Federal agencies and the State of Colorado. Preliminary technical studies used to support BAFB operations also supported the RMA project. Safety and security precautions, independent observation from the Department of Agriculture and State of Colorado, and verification procedures were essentially identical to the BAFB project.

The RMA demilitarization facility was housed in an existing two story brick and tile building modified to provide total containment of TX spores. The RMA TX stock was about 25 times the size of the BAFB stock;

therefore the process equipment was larger although practically identical in design, and the operation was longer and more costly. The demilitarization process was identical at that used at BAFB.

TX demilitarization at RMA began on 2 August 1971 with an assay of agent viability. Operations were suspended shortly thereafter for equipment and building alterations. Operations were resumed on 18 January 1972 and disking of residual ash into the soil at RMA was completed on 11 January 1973. The facility and equipment were decontaminated and certified by 4 November 1972. Equipment was turned over to the RMA property officer or discarded. Drums, filters and trash were incinerated at 1000°F then buried in an RMA landfill. The total TX disposal operation at RMA was completed by 15 February 1973 at a total cost of $2.41 million.

Ft. Detrick Operations. Planning, approval and execution of the LX demilitarization project at Ft. Detrick was accomplished similarly to the TX operation under the direction of the Ft. Detrick staff. Detailed plans, based on approved SOPs, were prepared and reviewed by the Army Ad Hoc Committee. The final plan and the EIS were reviewed by Federal, State and local officials as in previous cases. Independent observation and certification of the operation was provided by US Department of Agriculture and State of Maryland officials.

The demilitarization was accomplished in existing total containment facilities at Ft. Detrick, so the operation enjoyed the exceptional effluent treatment measures and safety and security controls employed for BW agent research and development. Incineration equipment was procured and installed and some modifications of the building were required to provide personnel change facilities.

The LX demilitarization program was based on extensive laboratory and pilot testing and engineering analysis to establish design and operating parameters, to verify analysis and control procedures, and to check plant decontamination and agent containment methods. Prior to initiating demilitarization operations, the LX stock was carefully recorded and analyzed as in the other BW demilitarization operations.

The destruction operation was a six-step process similar to the TX demilitarization:

(1) LX lots were sampled and assayed to establish viability.

(2) Containers of LX spores were inactivated with carboxide gas (10%) ethylene oxide and 90% carbon chloride) in a pressurized gas chamber at 18 psig for twenty hours followed by a second exposure for 24 hours. Initial attempts to deactivate with a single 20 hour treatment did not produce the desired destruction level of 99.943% at the 99.5% confidence level. In fact, four lots required additional treatment for as long as 71 hours.

(3) Inactivation was certified by sampling and assay to measure the residual viability.

(4) Inactive spores were incinerated in a dual chamber, gas fired furnace operating at 1200-1500°F.

(5) The resulting ash was crushed, sampled and analyzed microscopically and chemically to verify the absence of spores.

(6) Certified ash was then disced into the soil at an approved disposal site at Fort Detrick and the area was seeded with a cover crop of orchard grass.

The residual storage drums were incinerated in the furnace for 10 minutes, removed and sterilized at 250°F for 2 hours, crushed and buried in an approved landfill. All combustible material was incinerated at 1000°F. The biological safety cabinets were chemically decontaminated and the entire building was decontaminated with paraformaldehyde and certified using biological test strips. The building was vacated on 31 March 1973.

The total LX stock was destroyed between 17 January and 18 May 1972 at a cost of $990,000. Ash disposal was completed on 16 March 1973 signifying the end of the program.

Mr. MILLER. Dr. Augerson will now present a short statement concerning use of humans in testing.

Senator KENNEDY. General Augerson.

General AUGERSON. I am Assistant Surgeon General for Research and Development. I replaced General Dirks who testified before you in late 1975. We welcome the opportunity to assist your subcommittee.

My prepared remarks address two principal areas of interest.

First, I would like to summarize the efforts made since the hearing in the fall of 1975, to guarantee the protection of human research subjects within the Army, and to improve the process by which these guarantees are assured.

Second, I want to review briefly human experimentation in the biological warfare program since World War II.

The Army wholeheartedly supports the aims and emerging conclusions of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research.

Senator KENNEDY. You will support the expansion of the jurisdiction to include——

General AUGERSON. DOD.

Senator KENNEDY [continuing]. The witness nodded his head affirmatively, let the record show.

Mr. MILLER. We may have to answer on the basis that we individually and personally support it. The position of the Defense Department has not yet been finalized.

[The biographical sketch of General Augerson follows:]

BIOGRAPHICAL SKETCH OF WITNESS: William Sinclair Augerson was born in 1927 in Denton, Texas. Education at Bowdoin College was interrupted by sea duty service in the Navy 1945 and 1946. He graduated cum laude in 1949. Subsequently he attended Cornell University from which he received an M.D. degree in 1955. He held a commission as Second Lieutenant Signal Corps, USAR, from 1951 to 1955.

He entered the Army Medical Corps in 1955 and has served in a variety of hospital, research and field medical assignments since that time. Field assignments have included 4th Infantry Division, 101st Airborne Division, 82d Airborne Division, and Americal Division, Vietnam where he was Division Surgeon and 23rd Medical Battalion Commander. Research assignments have included: Aeromedical Laboratory, Wright Patterson Air Force Base; Space Task Group, National Aeronautics and Space Administration (Project Mercury); Walter Reed Army Institute of Research; and the Office of the Director Defense Research and Engineering. He has been Assistant Surgeon General for Research and Development and Commander of the US Army Medical Research and Development Command since August 1976. Hospital assignments have included Brooke General Hospital, US Army Hospital, Ft. Wolters, Walter Reed General Hospital, and 2nd General Hospital, Germany where he was Chief of Professional Services and Commander.

He is a diplomate of the American Board of Internal Medicine, is a senior flight surgeon and has served as an experimental subject. His awards and decorations include the Silver Star, Legion of Merit and a citation from the American Medical Association for his work in space medicine.

Senator KENNEDY. Your statement will be included in the record as though read.

General AUGERSON. We have observed and sometimes participated in their deliberations and have established working communication with the Commission's supporting staff, providing them with documents relating to human use regulation in the Army, and responding specifically to their inquiry. We have read their thoughtful reports with interest, especially the one concerning prisoners.

Concern for the welfare of human subjects of research as a moral requisite remains today what it was in the early part of the 19th century when William Beaumont studied Alexis St. Martin, the French Canadian scout with a gastric fistula resulting from a wound, or Walter Reed and the Yellow Fever Commission by their study of experimentally induced human infection discovered and elaboratаed upon the cause of Yellow Fever.

Beaumont arranged for lifetime care and pension of his subject through direct appeal to the Army Surgeon General. Reed anguished over his subjects for the entire 6-year span that the human experiments were done. You might be interested in what he wrote in 1902 concerning the problems during which critical experiments were being conducted in Havana. I quote:

> Of course, it will be thoroughly appreciated that in experimentation on human beings, aside from the grave sense of responsibility, at times well-nigh insupportable, which the conscientious observer must always feel, even with the full consent of the subjects to be experimented upon, there must be added another factor, viz., the difficulty of finding willing and suitable nonimmune individuals for experimentation just at the proper and urgent moment.

A high degree of concern governed procedures for recruiting and obtaining informed participation of volunteers; there were no prescribed requirements for independent verification of process in order to assure respect for human rights, because physicians in quest of new knowledge to cure disease were overwhelmingly credible as patient advocates. But this inherent credibility was dealt a significant blow by the activities leading to the Nuremberg trials.

As new issues developed, there has been specific codification of procedures, and with the passage of time, an elaborate system of regulations, directives, review processes and approval chains evolved to regulate the use of human volunteers in research.

Generally, the Department of Defense has, but on its own initiative, devised specific regulations which followed emerging guidelines for policy, and used existing mechanisms to enforce its regulations.

There has been a very great effort in the past year to assure protection of human subjects in Army research. This effort has had the vigorous attention of the Secretary of the Army and the Chief of Staff.

Some of the changes made since the fall of 1975 are:

(a) The Secretary of the Army revoked all existing protocols for human subjects in chemical and antidote research. He required review, compliance with appropriate memoranda, regulations and the Food and Drug Administration memorandum of understanding. He further required notification in writing before any human research was resumed.

(b) The Chief of Staff established an Army volunteer program study group (AVPSG) to study the problem of volunteers and develop a plan to insure the rights of volunteers. The Surgeon General was given supervisory responsibility of the group.

Five Army regulations, circulars, pamphlets pertaining to this subject have been revised and published, three more are in press, four more have completed staffing; and a few others are under revision. There has been command emphasis within the Army on seeing that commanders attend personally to matters of human subjects. There have been a number of searching internal reviews.

(c) In the Army Medical Research and Development Command, all prisoner volunteer research was terminated by my predecessor. My command published a detailed regulation in September 1976 on human subjects. One human subjects research review board, which reviews all human research protocols for the Army, has been busy processing some 200 submissions in 1976 and rejecting 30—about 15 percent—which indicates it exerts specific control. This past year we have not approved any testing with simulants.

In fact, we disapproved a chemical simulant test because of inadequate pharmacological data.

The involvement of the Food and Drug Administration in drug development—subsequent quality assurance of the procured material—is thorough and extensive. The Army has some 40 active "new drug exemptions" for investigational new drugs, IND's, including one for a nerve agent antidote described in earlier testimony.

We have been active and seen that the Food and Drug Administration was fully informed. They have been vigorous, questioning and helpful. I have met personally with them twice this year.

The LSD followup study has moved slower than we wished, due to the problems of organizing a control group, as well as the persistant problem of constrained clinical resources. We will complete the matched study of 50 controls, 50 LSD subjects in midsummer. When that study is complete, we should be able to move faster on the remaining subjects.

(d) We are currently operating under a April 23, 1976 memorandum of understanding between the U.S. Army Material Development and Readiness Command and the Army Surgeon General. This memorandum is more explicit on human volunteers than earlier versions.

The Human Use Committee at Edgewood Arsenal was reconstituted to include civilian and other nonlaboratory personnel. The committee, by its questions, has made useful improvements in the safety procedures for the test of a new demilitarization suit.

My staff and I have been significantly more involved in technical review, communication, decisionmaking in the Biomedical Laboratory at Edgewood Arsenal. This communication has been assisted by the new medical director and new senior medical staff at the laboratory. This further diminishes the possibility of the use of subjects in an unauthorized manner.

I hope that this resume gives the clear picture of changes the Army has made since 1975 and shows the Army acted to improve the protection of human subjects.

Since chemical research was reviewed last year, it seems appropriate to discuss the role of human subjects in the biological warfare program. You have available a history of the program as we in the Army were able to reconstruct it.

The national BW program began over one-third of a century ago, the simulant test which was re-reported this winter, was a quarter of a century ago.

The Korean war brought about an expanded program which eventually raised questions requiring human tests.

As noted in the history, the Army Chemical Corps was assigned the responsibility for the entire national program during this period, including defensive aspects, maintaining liaison with the Army Surgeon General.

Progress in Chemical Corps research and development from 1946–52 and repeated reviews at high governmental levels led to definition of two basic questions:

(a) Are troops in the field vulnerable to BW weapons systems?

(b) Are defensive measures effective?

The Armed Forces Medical Policy Council in 1952 noted that:

(a) Simulant tests had shown the vulnerability of our territory to biological attack.

(b) There was a lack of scientific data to assess human vulnerability to biological agents.

(c) Answers could be obtained only by tests in human subjects.

Extensive consultation on the need for human experimentation ensued between the Chief Chemical Officer, the Army Surgeon General, and other reviews by the Secretary of Defense, Secretary of the Army, and the Army Chief of Staff.

The first policy guide was a Chemical Corps Directive CMLREBZ .729.B, "Use of Human Subjects in Hazardous Tests," dated July 31, 1952, a document which I have not seen. This was superseded by a Secretary of Defense policy statement of February 26, 1953. This now declassified top secret document, subject: "Use of Human Volunteers in Experimental Research," is on pages 196–198 of your report of hearings on biomedical research in 1975.

The familiar requirements for free informed consent, compelling need for the experiment, reasonable scientific indication of a useful result, no deliberate incurring of death or disabling injury, minimal numbers of subjects, proper preparation for care, responsible capable investigation, free withdrawal and prohibition of use of POW's were clearly established.

On June 30, 1953, an Army Chief of Staff Memorandum (CS:385) to the Chief Chemical Officer and the Army Surgeon General addressed policies and procedures for chemical, biological, and radiological (CBR) experiments involving human volunteers. This document approved by then Secretary of the Army Stevens reiterated Secretary of Defense policy and stated that all such proposals required review and comment by the Army Surgeon General and final approval by the Secretary of the Army.

I will outline the human programs, including some involving prisoners. Extending throughout the program, however, there was use of other volunteer subjects, often investigators and members of the

scientific staff and medical soldiers, a tradition which goes back at least as far as the Army Yellow Fever Commission.

Planning for the exposure of volunteers to micro-organisms began in the summer of 1953 by medical officers from another service—U.S. Air Force—assigned to the Medical Investigative Division, Safety Division of the Chemical Corps Biological Laboratory at Fort Detrick. By October 1953, it had been determined that challenge (respiratory) of man with tularemia (Pasturella tularensis) was needed. The Secretary of the Army approved the research plan in late March 1954.

Attempts to secure a contractor were protracted, and involved eight universities and the Navy Bureau of Medicine and Surgery. As far as the record indicates, only one organization refused to expose individuals, resource constraints eliminated others.

Obtaining enough volunteers was an obstacle for most. The initial plan envisioned use of university students.

A contract was signed with Ohio State University Research Foundation in January 1955, and provided for the use of civil prison volunteers as subjects. We have not been able to obtain a copy of the contract or consent forms. The research was reported in the medical literature and the use of prison volunteers described.

Exposure of subjects began in March 1956 and ended in 1958.

In 1954, the Chief Chemical Officer requested the assistance of the Army Surgeon General to develop a study of "The Vulnerability of Military Personnel to BW Attack." The assistance of the Armed Forces Epidemiological Board (AFEB) in developing and reviewing this project designated CD–22 was sought and a special Commission on Epidemiology Survey (CES) formed for this purpose in 1954.

The Secretary of the Army approved the research plan in January 1955. Human studies were carried out during 1955 and 1956, including open-air testing at Dugway. Volunteers were recruited with assistance of the Seventh Day Adventist Church from conscientious objector military personnel—the beginning of the "Whitecoat" program. The agent involved in these tests was the Q fever organism.

On February 21, 1956, a joint Army Chemical Corps-Army Medical Service agreement delineated specific responsibilities for the conduct of research and development on certain defensive aspects of biological warfare. The Army Surgeon General accepted responsibility to conduct a defensive research program—both in-house and by contract—including:

(a) Development and assessment of appropriate therapeutic and prophylactic measures.

(b) Development and application of rapid epidemiological, clinical and laboratory identification techniques.

(c) Conduct of appropriate studies in experimental animals.

(d) Exposure of volunteers to potential biological warfare agents in accordance with Chief of Staff of the Army Memorandum CS 3-385.

(e) Collection, collation and dissemination of appropriate medical information from the program.

The agreement further stated that the Army Surgeon General would accomplish the above through a specific medical unit. This led to the establishment of a medical department activity at Fort Detrick,

separate from the Chemical Corps, which has evolved to become the U.S. Army Medical Research Institute of Infectious Diseases.

The human program was monitored by the Commission of Epidemiological Survey of the Armed Forces Epidemiology Board—a distinguished civilian advisory group, who provided technical consultation, review protocols and attended some tests.

Additional requirements developed which resulted in the establishment of contracts with the University of Maryland, Chiefly, but not solely, using prison volunteers—Maryland House of Corrections, Jessup—in investigations on tularemia, Q fever, Rift Valley Fever, and certain intestinal disease producing agents. The work began in July 1956 and ended in 1975.

With the formation of the medical unit at Fort Detrick in 1956, the soldier volunteer program was transferred from Walter Reed as a field activity. As mentioned earlier, conscientious objectors, whose objections were to the bearing of arms, were offered an opportunity for a program where they received enlisted medical training and were subsequently assigned to the medical unit at Detrick for medical duties and service as volunteer subjects. More generally known as the "Whitecoat" program, this activity has been frequently reviewed and reported on in the press.

With the termination of the draft in 1973, "Whitecoat" recruiting terminated. In 1975, under the provisions of AR 601–210, the recruiting of medical research volunteer subjects began. Not restricted to conscientious objectors in 1976, 76 enlisted medical personnel elected to enter this program.

These volunteers do not sign up for "everything" in advance. They volunteer—or decline to volunteer—on an individual narrow protocol by protocol basis. The studies in which they participate are directed toward infectious disease research to meet Army requirements, including diseases not of BW concern such as malaria.

In summary, the use of human volunteers in the biological welfare program of the United States, conducted by the Army was guided by policies designed to protect the rights of volunteers which equaled or exceeded those in the civilian community at the time.

The requirements arose from valid national needs, were approved by responsible officials, and conducted by competent scientists with cautious concern for the well-being of the subjects. We know of no death or permanent injury in any volunteer in this program.

Despite the concerns for security, civil scientists were in a position to observe and guide the work. The majority of the research has been published in scientific journals—with peer review editorial policies—and has made a useful contribution to the understanding prevention and treatment of infectious disease.

If desired, copies of documents referred to will be provided to the subcommittee staff.

Senator Kennedy. I want to ask you a question concerning the bottom of page 3 of your statement.

What we are really interested in now is compliance by DOD. We have had a record in the past where they have had agreements and memoranda, rules and regulations, and little compliance.

I think it would be interesting if you could tell us about what you have been doing in the area of compliance.

Would you just elaborate on this?

I think this is at the heart of the issue.

Mr. Miller. I think one point I will make while General Augerson is thinking about this is that we have established a new procedure.

This is having to do with the agents themselves as opposed to the test subjects in which we have a positive verification, first of all the materials are needed for research, and that what we store are minimal and verified by the Surgeon General himself as to the necessity, and then this is further confirmed by the Inspector General of the Army.

Maybe General Augerson would like to answer the part having to do with test subjects.

General Augerson. In compliance, one of the important things in any military system is, of course, the emphasis that the command structure gives.

The Secretary of Army and the Chief of Staff in the last year and a half have made this clear, have made it clear to everyone, in my opinion, that this is an important area, protection of human subjects, and they expect scrupulous adherence to the rules.

It has been brought to the attention of the Army through the command channel. The Secretary of the Army brought, in the fall of 1975, a great deal of existing work using human subjects to a halt, until it was reviewed to be sure it did indeed comply with appropriate, regulations, memoranda, and Food and Drug Administration understandings.

I believe your committee is aware of some of the procedural steps in the way of changed regulations and review groups.

We have made a distinct point on my part and those about me working closely with the Food and Drug Administration.

Their efforts have been quite helpful. I have met with them personally several times myself.

Senator Kennedy. Are you in charge of all the enforcement of all regulations——

General Augerson. No; enforcement mechanism in the Army other than the enforcement of commanders, is formally the Inspector General system. There have been a number of reviews by the Inspector General.

Senator Kennedy. What can you tell us about those?

General Augerson. One pertaining to the review of the use of human subjects, in that particular review the Inspector General found some lapses in compliance with the details of the regulations that were supposed to apply.

Senator Kennedy. In the areas of internal reviews which the Inspector General is charged with enforcing, have you personally examined these internal reviews?

General Augerson. Yes, sir; and the one I referred to particularly.

Senator Kennedy. Have you spot-checked or do you just review them yourself, read them? Do you have the resources to doublecheck these?

General Augerson. No, I do not doublecheck on the Inspector General.

Senator Kennedy. He is supposed to doublecheck on you?

General Augerson. That is right. We provide him some technical assistance when he puts teams out that are working in a technical area.

Senator Kennedy. Would it be useful for us to have an opportunity to examine those from the Inspector General, those reviews? I would think it would be.

Mr. Miller. We can provide those, Senator Kennedy.

Senator Kennedy. Fine.

[The information referred to may be found in the files of the subcommittee.]

Senator Kennedy. The point I am getting at is that we have seen no rules, we have seen statements and comments in the past. The real question is the enforcement of it. I think we are very impressed with you personally and your interest and obvious awareness on this issue, and we are very much interested that this gets all the way down to the programs. We want to continue our interest and oversight in that area.

We have been after the Central Intelligence Agency to provide information to us on what was being done in the biological warfare materials. This material is declassified, and just arrived a few minutes ago. There are a few instances where they have indicated that biological warfare materials were used against enemy leaders. In this case they mentioned an instance involving a Nazi leader during a period of the war to prevent his appearance at a major economic conference during the war. They used food poisoning, which was rather successful.

We have not had an opportunity to examine this material, which has just arrived here, and I do not know whether any of you are prepared to make any comments on it.

Mr. Miller. We are not familiar with that.

Senator Kennedy. We will get a chance to examine it in detail. We will make it a part of the record. It does appear that there have been some instances, with just a preliminary examination, that we have or at least the Central Intelligence Agency has used biological warfare in times of conflict in the past. The instances I mentioned here.

[The information referred to follows:]

SUMMARY REPORT ON CIA INVESTIGATION OF MKNAOMI

Project Discovery.

The initial identification of the relationship between the CIA and the Army Biological Laboratory at Fort Detrick as a possible questionable activity requiring further investigation occurred in late April of this year. It resulted from information provided by a CIA officer not directly associated with the project in response to the repetitive appeals of the DCI that all past activities which might now be considered questionable be brought to the attention of Agency management. As a result of the information provided by him and by two other officers aware of the project, it became clear that further investigation of the matter was in order. The three identified the project at Fort Detrick as having involved the development of BW and possibly CW agents and associated dissemination systems that were suitable for clandestine use against human targets. They moreover identified lethal agents as among those involved in the project.

Concern about these assertions was heightened because the ADDS&T had noted in a recent review of the 1963 IG Survey of the Technical Services Division (TSD) that approximately $90,000 in that current fiscal year was spent at Fort Detrick "for the maintenance of a biological warfare capability" This statement appeared so important that a quick check was made to determine its significance. In response to questions about the activity, the cognizant officer in TSD -- now the Office of Technical Service (OTS) -- reported that a small effort had been carried on at Fort Detrick, but that it related to the development of incapacitants and BW/CW detection and did not carry the serious implications of the IG's report. It had in any event been terminated some years ago. The ADDS&T was satisfied with this response. When new and more disturbing information about the nature of the Fort Detrick activity emerged, however, the words of the IG Survey tended to give it credibility. Thus, late in April 1975 a search was begun for any records or other information available on the project. Difficulties were immediately encountered because the project cryptonym could not be identified. The search for records of fund transfers to Fort Detrick did ultimately produce information in that regard, however, and checks by the Office of Security on one of the individuals identified as having been involved in Fort Detrick activities did provide information on the basic agreement between the Army and the CIA relating to the project. The project cryptonym was then remembered by an OTS officer responsible for the activity in its later phases. This enabled OTS to recall the proper files from Records Center; two MKNAOMI files were retrieved. Some additional information was also produced from the Office of Logistics files. This collection of material largely confirmed the nature of the project as reported by the informants and identified a number of people involved in the activity. Additional cause for concern resulted from the association of several of these people with specific assassination plans as revealed in the IG's report on that activity.

A major concern after the discovery of the records involved the disposition of a stockpile of BW agents and toxins maintained by Fort Detrick for possible Agency use. It was not known whether or not these materials had been destroyed along with the Army's CW stockpiles in response to Presidential Directives of November 1969 and February 1970. An unsigned memo raising the question of the disposition of Agency materials maintained by Fort Detrick posed the option of having it stored in a commercial laboratory. It was the impression of those in OTS who were familiar with the project that the material had in fact been destroyed but no records confirming it could be found. In an attempt to find such confirmation, laboratory storage facilities in OTS were searched and in the course of that search about 11 grams of shellfish toxin and 8 mg of cobra venom -- but none of the other materials -- were discovered.

Subsequent to the decision in late April that a full investigation of the Fort Detrick project was needed, all information uncovered was passed to the DCI, to staff members of the Rockefeller Commission and to the White House staff handling intelligence community investigation matters. In June, Senator Church was informed by Rod Hills of the White House that a sensitive activity was under investigation.

Sources of Information.

This summary report on the activity is based upon an investigation utilizing: (1) the files and documents uncovered as a result of the initial search which are limited and contain only a small number of Agency-originated documents; (2) the material found in OTS storage which includes the shellfish toxin and several pieces of delivery hardware; (3) interviews voluntarily given by current Agency employees who had some knowledge of the project and by a number of retired employees indicated by the records as having been more deeply involved at stages of particular interest; (4) information contained in the IG's Report on assassination planning and (5) information developed by a DoD investigation initiated as a result of conversations with the White House about the matter; this information has been incorporated in this report only where it illuminates specific aspects of the story uncovered from Agency sources, however.

Special Operations Division of Fort Detrick.

The Agency association with Fort Detrick involved the Special Operations Division (SOD) of that facility. This Division was apparently responsible for developing special applications for BW agents and toxins. Its principal customer appears to have been the US Army Special Forces. Its concern was with the development of both suitable agents and delivery mechanisms for special use in paramilitary situations. These applications clearly include one-on-one situations in which clandestine delivery was an objective. Both

standard BW agents and biologically derived toxins were investigated by the Division. Discussions with former Fort Detrick employees indicate that SOD was first established as a distinct, highly secure activity within Fort Detrick in about 1948, though no records going back that far have been found. The Division was abolished in 1970 or 1971 as the Fort Detrick operation was terminated.

CIA Relationships with SOD.

The CIA relationship with SOD was formally established in May 1952 through a memorandum of agreement with the Army Chief Chemical Officer for the performance of certain research and development in the laboratory facilities of the Special Operations Division of the Army Biological Laboratory at Fort Detrick. The animus for establishing this relationship seems to have been a belief in OTS that the special capabilities of the Fort Detrick group and its access to biological materials of all sorts provided the Agency with expertise and capabilities which were appropriate to its function and not otherwise available. Discussions indicate that the perception of the requirement for such capabilities was tied to earlier OSS experience. This experience included the development of two different types of agent suicide pills to be used in extremis and a successful operation using BW materials against a Nazi leader. In the latter case, Staph. enterotoxin (food poisoning) was administered to Hjalmar Schacht so as to prevent his appearance at a major economic conference during the war. This agent was included in the materials maintained for the Agency by SOD. Initial funding was at the $200,000 a year level which grew to a high point in FY 1958 of $350,000 and then dwindled to $75,000 a year in the late 1960's. Though there appear to be some gaps in available funding records, total Agency funding in the period from FY 1953 through FY 1970 is estimated to have been somewhat more than $3 million. These funds were apparently used to generally augment the level of effort undertaken by SOD. Agency requirements for specific R&D were not levied in any programmatic way, but rather the Agency identified particular work being done by SOD as part of its program supporting the Army Special Forces as being of interest and then levied requirements for the customizing of such developments for Agency use. Through the course of years, Agency objectives in the project became better defined. Thus a project approval memo of 1967 identifies the four functional categories of project activity:

a. Maintenance of a stockpile of incapacitating and lethal agents in readiness for operational use;

b. Maintenance, assessment and evaluation of a designated balance of biological and chemical disseminating systems for operational readiness;

c. Adaptation and testing of a non-discernible micro-bioinoculator (a dart device suitable for the clandestine and imperceptible inoculation with BW/CW agents) to determine compatibility with various materials and to assure that the microbioinoculator cannot be identified structurally or easily detected upon a detailed autopsy; and

d. Provide technical support and consultation on request to meet ad hoc requirements related to offensive and defensive BW/CW.

In the later years the activities dwindled to the point of simply maintaining a stockpile of agents and delivery systems for possible Agency use.

Project Management within CIA.

Based on all the information available, it appears that from its outset the project was characterized by a compartmentation that was extreme even by CIA standards. Only two or three Agency officers at any given time were cleared for access to Fort Detrick activities. This work was managed first within the Biology Branch and later in the Chemistry Branch of TSD. Because of the sensitivity of the activity, queries by operations officers as to the availability of materials and delivery systems of the type being developed at Fort Detrick were automatically turned away by TSD unless initial approval for contact had been given by the Deputy Director for Plans. Even when this was the case, the Chief of TSD often referred the operations officer directly to one of the cleared officers dealing with Fort Detrick and was never informed as to the nature of the discussions. This method of procedure has been confirmed both through interviews and by the IG report on assassination planning. Almost no written records were kept. Though some CIA-originated documents have been found in the project files, it is clear that only a very limited documentation of activities took place. No records on such things as material control, receipt, delivery, destruction, etc., can be found. No documents relating to any possible operational use of the material have been found. The files as they exist are quite different from those normally maintained in the course of a typical CIA R&D project. As noted above, funding to the project was provided simply on the basis of augmenting the level of effort established by Army funding. There appears to have been no relation of funding to specific tasking, nor can any strict accounting of funds on the basis of effort expended in the Agency's behalf be found. Project officers with whom discussions were held stated that the funding was simply provided to maintain the availability to the Agency of the capabilities of SOD. Finally, there is little evidence of much specific program definition on the part of the Agency. Though occasional specific requests for material

or for investigations relating to the solution of a hypothetically posed operational problem can be found, the Agency through the years appears generally to have ridden on a program generated internally by SOD largely on the basis of Special Forces requirements. There are one or two exceptions which will be discussed below.

Activities of Peculiar CIA Interest.

Though discussions with people associated with the project reflect an overriding interest in incapacitants, particularly in later years, available records make it clear that CIA interests included maintaining a stockpile of lethal materials and delivery systems. The evidence indicates that the Agency relied upon the use of specific BW agents and toxins being investigated as a normal part of the Army's BW program. However, directions were given to investigate such matters as agent stability over varying periods of time, the suitability of specific agents for preparation in dry form, the development of dart coatings, and the preparation of materials in a form suitable for dusting of clothes, pillows, etc.

A major early requirement of the Agency was to find a replacement for the standard cyanide L-Pill issued to agents in hazardous situations and U-2 pilots for suicide purposes in the event of capture. Work on this problem was done at Fort Detrick and ultimately centered on the coating of a number of 80 drill bit (the smallest made) with shellfish toxin. In the course of this work some shellfish toxin was stored in the TSD laboratory for the purpose of conducting stability tests. Though the tests of lethality were actually made at Fort Detrick, the toxin was stored in TSD where records could be maintained with assurance that samples of the same toxin were regularly tested. In conjunction with this project, a considerable amount of work was done in developing concealment schemes for the drill or pin to be used in the event suicide was necessary. The culmination of this effort occurred with Powers' flight in May 1960 during which he carried such a device concealed in a silver dollar. In this case the grooves of the drill bit were filled with shellfish toxin. The discovery of the device by the Soviets ended the program, as a compromise of such devices seemed to have destroyed their future utility. The Powers flight was the only time such devices were provided for operational use.

Primary Agency interest seemed to relate to the development of disseminating equipment to be used with a standard set of agents kept on the shelf. A number of such dissemination devices appear to be peculiarly suited for the type of clandestine use one might associate with Agency operations. Some of these were included among hardware stored for the Agency at Edgewood Arsenal subsequent to the closure of SOD: attache cases rigged to disseminate an agent into the air, a cigarette lighter rigged to disseminate an agent when lighted, a fountain pen dart launcher, an engine head bolt designed to release an agent when heated, a fluorescent light starter to activate the light and then release an agent, etc. Available records do not indicate whether or not all

these were developed specifically for the CIA, though the DoD investigation has identified the head bolt device as falling into such a category. The e association of this equipment with specific Agency requirements because of nature is apt to be misleading, however. At a meeting in June 1952, at the very outset of the Agency's association with SOD when CIA representatives stated they as yet had no specific requirements, a list of SOD priorities fc work on dissemination devices was provided. This dissemination list include such things as cigarettes, chewing gum, cigarette lighters, wrist watches, fountain pens, rings, etc. Presumably work on these devices was already unc way in response to Army Special Forces requirements. Nevertheless, the Ager clearly showed an interest in such devices and levied requirements for the special preparation of some.

One development peculiarly associated with the CIA was the "microbio-inoculator" which was an extremely small dart device which could be fired through clothing to penetrate the skin so as to inoculate the target with an agent without his perception of being hit. An added fillip to this development was the requirement that no indications of the use of such a device be discernible in the course of autopsy. A large amount of Agency attention was given to the problem of incapacitating guard dogs. Much of the equipment delivered to the Agency and some of the testing undertaken by it involved a dart delivery system carrying dog incapacitants, and an antidote used subsequently to restore the dog to normal activity. Though most of the dart launchers used in these developments were developed for the Army, the Agency did request the development of a small hand-held dart launcher for its peculiar needs.

A lot of work was done on human incapacitation. OTS apparently received continuing requests for safe, effective and rapidly acting, incapacitating devices. Many of these related to requirements for incapacitating Viet Cong leaders before they could render themselves incapable of talking and terrorists before they could take retaliatory action. Much work was done in trying to use the dart system for such purposes, but real success was never actually achieved. Since a larger amount of an incapacitating agent is required to safely inactivate a human than a lethal agent required to kill him, no scheme was developed for introducing sufficient amounts through the use of darts. Attempts were made to solve this problem by increasing the area of the darts available for coating and for making a dart which would dissolve in tissue which could thereby introduce more material into the system. Work on this project was underway when the association with SOD ended and Edgewood Arsenal endeavered to complete the project using unexpended Fort Detrick funds. Success was not achieved, however. One reason for the preoccupation of those involved in the project with the incapacitant problem may well have been the substantially greater difficulty of solving it when compared to developing lethal mechanisms.

Substantial work was also done for the Agency in the development of spoilants for agricultural products, biological materials for the contaminati of petroleum stores, and agents for use in the destruction of electronics, optical systems, structural materials, etc. At times in the history of the project, requirements for such materials as these were apparently very high on the Agency's list.

Shellfish Toxin.

By the late 1950's, a stockpile of some 15-to-20 different BW agents and toxins was maintained on a regular basis by SOD for possible Agency use. The supply included such agents as food poisons, infectious viruses, lethal botulinum toxin, paralytic shellfish toxin, snake (krait) venom, Microsporum gypseum which produces severe skin disease, etc. Varying amounts of these materials ranging from 100 grams to 100 milligrams were maintained.

As noted above, with the Presidential Order requiring the destruction of Army BW and toxin stockpiles, the question was raised as to the disposition o Agency materials. Though specific accounting for each agent on the list is n on hand, DoD indicates that, with the likely exception of the shellfish toxin all of these materials were in fact destroyed by SOD personnel.

The 11 grams of shellfish toxin -- along with 8 milligrams of cobra veno -- was found by the Chief of the OTS Chemistry Branch, in Vault B10 in the basement of [which houses OTS. This vault is a lightly used laboratory area and historically associated with the Biology and Chemistry Branches of OTS. It has been regularly used for the storage of dangerous materials of various types. In past years, the combination to the vault had been available only to the Chief and Deputy Chief of the Chemistry Branch and their secretary. More recently, the combination had been given to other memb of the Chemistry Branch as well since nuclear battery tests had been run in the laboratory. With the discovery of the material on 20 May 1975, however, the combination was changed and is now available only to the Chief of the Chemistry Branch, his secretary, and OTS security officers. On 13 June the vault was put under 24-hour guard.

The freezer in which the toxin was found is located under one of the wor benches in the laboratory. The Fort Detrick material was the only thing in the freezer and was in two one-gallon cans along with several smaller containers. There were no labels on the gallon cans, but on top of each was a folded piece of paper with pertinent information about the contents. This information provided the types and amounts of material and the date on which it was put into storage. The shellfish toxin was, according to this information, put into the freezer in February 1970, and the cobra venom, in February 1961. The shellfish toxin was packaged in several different forms including two individual doses in tablet form.

The discovery of the material was a result of repeated attempts with OTS to determine what disposition had been made of Agency BW materials hel by Fort Detrick. In making one more check on this, a former Chief of the Chemistry Branch, who retired in September 1972, was called and asked if h knew what the disposition had been. The retired officer stated that he th that perhaps some of the shellfish toxin might not have been destroyed and in storage in OTS. In following up on this lead, the material was found i freezer.

Though it is hard to understand how, inquiry shows that such material could in fact have been stored for so long a time without anyone's being aw of it. The laboratory is no longer used for the type of work for which it was originally built and had become a disordered storage facility. There h been no requirements for use of the freezer in the intervening years and it indeed possible that no occasion arose to investigate the contents of the freezer. There have been no reported functioning difficulties with the fre during this entire period.

After finding the shellfish toxin in the vault, a complete inventory w taken. A large number of dangerous chemicals or drugs of various types was found. These materials relate to a number of past programs of TSD, includi the drug project, the development of harassment materials for crowd control or meeting disruption, crop contamination programs, etc. Small amounts of five other lethal preparations were found. Two of these are known to have been obtained by the Agency for testing at Fort Detrick. Nothing is known about the reasons for storing the others. In addition to these lethal mater a number of L-Pills were found. Also discovered was some of the hardware developed as part of the MKNAOMI project: 30/06 micromissile cartridges con taining dog incapacitant, 10 hand-held launchers loaded with darts coated wi dog incapacitant, 10 capsules containing an oral dose of dog incapacitant, a 4 pistols, two of which were commercial, syringe-firing devices used for wil animal capture and two were weapons modified to fire darts.

The current Chief of the Chemistry Branch had no recollection at the tim of its discovery of the shellfish toxins having been obtained from Fort Detri and stored in the laboratory. On 30 June, discussions were held with the officer (now retired) who was Branch Chief at the indicated time of the transfer of the material to OTS. He stated that the toxin had in fact been called back from Fort Detrick and stored in the laboratory on the basis of hi own decision which resulted from conversations with the current Branch Chief who was then the MKNAOMI Project Officer. It was their belief that the cost and difficulty of isolating the shellfish toxin were so great that it simply made no sense to have it destroyed, particularly when there would be no future source of the toxin. Furthermore, they felt that storing it was not in violation of the new policy because of provisions allowing for the preservatic of research amounts of such materials. The current Branch Chief believes this explanation is correct but still does not recall the actual act of receiving the material from Fort Detrick. Both agree that no one, including the Chief

of TSD, was told of this decision or the fact that the material had been delivered by Fort Detrick. As the earlier Branch Chief recalls, this took place prior to his being told by the Chief of TSD to personally inform Fort Detrick that destruction of the material on the inventory list should take place. Neither could recall precisely how the material was delivered to OTS, but the DoD investigation indicates that it was delivered by someone from Fort Detrick.

Both are certain that the shellfish toxin in storage in OTS is the same toxin as that listed on the inventory included in the disposal memorandum. This view is supported by the DoD investigation. There is, however, a discrepancy between the amount in storage as calculated from the labels and the amount shown on the inventory. Since the material in storage is in several different forms and complete reliance is placed upon labeling rather than measurement, however, no real discrepancy may actually exist.

Discussions with Richard Helms and Tom Karamessines, DCI and DDP respectively, at the time the disposal question arose, have established that both were aware of the disposition question and that clear instructions were given that the Agency stockpile should be destroyed by the Army and that, in accordance with Presidential Directives, the CIA should get completely out of the BW business. Helms' memory is sharpened on this matter by his presence at the meeting at which the Presidential decision was made.

The explanation derived from these interviews as to how the shellfish toxin came to be in Agency storage is fully consistent with other available information. The earlier Branch Chief stated that the material was always handled with extreme care. Undoubtedly, it was simply transferred from one freezer to another and in his view was continually under adequate control. He is certain that nothing was done with it subsequent to its delivery and prior to his departure from the Agency in 1972. The current Branch Chief has given assurance that it was untouched subsequent to that until its discovery in May of this year.

After the discovery of the material, OTS was told to investigate ways in which they could safely dispose of it with full documentation. Edgewood Arsenal was contacted and arrangements were made to deliver the material to Edgewood for disposal on 11 June 1975. The disposal was to be witnessed by a representative from the IG's office. On the day prior to the scheduled delivery, these arrangements were cancelled, however, because the DDS&T wished to consider further ways of insuring that the destruction of the material could not be later misinterpreted. Upon informing Edgewood Arsenal of this decision, OTS was told that while Edgewood would dispose of chemical material for the CIA, it would not do so in the case of biological materials since that was not consistent with the mission of the arsenal. No further efforts toward the disposal of the material have taken place, and it remains under guard in the OTS vault.

Operational Uses of MKNAOMI Material.

There is no record associating the project with actual operations. Discussions with those involved in the project indicate that hand-launchers with darts loaded with dog incapacitant were delivered for use in S.E. Asia. In fact, one such operation has been uncovered. It involved the penetration of the North Vietnamese Embassy in a S.E. Asian capital so as to emplace audio devices. The compound was guarded by watch dogs which made entry difficult even when it was empty. Darts were delivered for the operation but were not used. The guard dogs -- in gross violation of proper guard dog behavior -- ate meat treated with dog incapacitant which was offered by the entry team. The discussions also indicate that some of the material or crop spoilants may have been employed. While no direct connections to assassination planning have been found, there are some disturbing similarities between the agents being investigated at Fort Detrick and some of the reported schemes |

MEMORANDUM FOR: Director of Central Intelligence

SUBJECT : Contingency Plan for Stockpile of Biological Warfare Agents

1. On 25 November 1969, President Nixon ordered the Department of Defense to recommend plans for the disposal of existing stocks of bacteriological weapons. (On 14 February 1970, he included all toxin weapons.)

2. On 13 January 1970, the Special Operations Division of Fort Detrick, Maryland prepared a requested agent inventory, less toxins, and submitted it to the Scientific Director, Fort Detrick. This inventory was a required input to assist the Commanding Officer, Ft. Detrick to prepare a comprehensive plan for demilitarization on site of all biological agents/munitions which are stockpiled in support of operational plans.

3. Under an established agreement with the Department of the Army, the CIA has a limited quantity of biological agents and toxins stored and maintained by the SO Division at Ft. Detrick. This stockpile did not appear on the inventory list. The agents and toxins are:

Agents:

1. Bacillus anthracis (anthrax) - 100 grams
2. Pasteurella tularensis (tularemia) - 20 grams
3. Venezuelan Equine Encephalomyelitis virus (encephalitis) - 20 grams
4. Coccidioides immitis (valley fever) - 20 grams
5. Brucella suis (brucellosis) - 2 to 3 grams
6. Brucella melitensis (brucellosis) - 2 to 3 grams
7. Mycobacterium tuberculosis (tuberculosis) - 5 grams

8. Salmonella typhimurium (food poisoning) – 10 grams

9. Salmonella typhimurium (chlorine resistant) (food poisoning) – 3 grams

10. Variola Virus (smallpox) – 50 grams

Toxins:

1. Staphylococcal Enterotoxin (food poisoning) – 10 grams

2. Clostridium botulinum Type A (lethal food poisoning) – 5 grams

3. Paralytic Shellfish Poison – 5.193 grams

4. Bungarus Candidis Venom (Krait) (lethal snake venom) – 2 grams

5. Microcystis aeruginosa toxin (intestinal flu) – 25 mg

6. Toxiferine (paralytic effect) – 100 mg

This stockpile capability plus some research effort in delivery systems is funded at $75,000 per annum.

4. In the event the decision is made by the Department of Defense to dispose of existing stocks of bacteriological weapons, it is possible that the CIA's stockpile, even though in R&D quantities and unlisted, will be destroyed.

5. If the Director wishes to continue this special capability, it is recommended that if the above DOD decision is made, the existing agency stockpile at SO Division, Ft. Detrick be transferred to the Huntingdon Research Center, Becton-Dickinson Company, Baltimore, Maryland. Arrangements have been made for this contingency and assurances have been given by the potential contractor to store and maintain the agency's stockpile at a cost no greater than $75,000 per annum.

Thomas H. Karamessines
Deputy Director for Plans

TO [illegible]: Contingency Plan for Stockpile of [illegible] Nuclear Weapons [illegible]

THRU: [illegible] (14 February 1970)

Distribution:
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Senator KENNEDY. We will work with you, Mr. Miller, and have the staff perhaps review some of those reports from the Inspector General, just to try to get a continuing review as to how these protocols and regulations are actually being administered.

I think it would be very helpful. We value your cooperation and help. It is quite clear to me, both from your testimony and the testimony of your panel, your own deep interest and concern about this issue and desire to see that those procedures are followed.

Mr. MILLER. Absolutely.

Senator KENNEDY. I think that is very helpful and very valuable.

Senator SCHWEIKER. Do you have any data available now on the characteristics of the bacteria used that could identify and test strain of SM that was used in the San Francisco Bay test back in the fifties? In other words, information on chemical or biological properties such as resistance and susceptibility to various antibiotics, for example? Is this sort of a "profile" available? If so how might the characteristics of the test strain compare to the characteristics of the SM that was found in the hospital? Was any comparison made, according to the records?

General AUGERSON. I do not think that most hospital laboratories of that period had the ability to identify or recognize the many strains of serratia. I have heard the numerical designation of which strain it was that was used, but I do not remember it, do you, Colonel Carruth?

Colonel CARRUTH. No.

General AUGERSON. I know nothing of its antibiotic properties.

Senator SCHWEIKER. Would Dr. Wheat's article cover that?

General AUGERSON. Dr. Wheat's article does not speak to strains. It does have some data in there indicating antibiotic resistance. I believe there was some differences in the resistance among the several cases.

Colonel CARRUTH. It is difficult to answer that because the record does not indicate the specific strain that was used in the San Francisco test. However, we will search the records and see if we can determine exactly which strain might be used.

Senator SCHWEIKER. One of the things that concerns me a little bit—I have been focusing on the public domain sector and I think frankly that is where my primary concern is—but, by the same token, if somebody miscalculates and makes a mistake on a military base, you could have problems there. I think the fact that your Fort Detrick safety officer was concerned, and took what I thought was a very proper step, indicates that even testing within a military installation or military base may cause problems. What kind of controls are built in for testing within the base, in terms of the occupants of the base and the varying degrees of susceptibility of people there, particularly those confined in bed or weakened by some pre-existing illness?

Second, how do we control what the air currents or wind currents might be, to make certain that the test is confined to a certain area?

There is one allegation, which apparently seems to have some basis, that out at the Dugway Proving Grounds a lot of sheep were killed mysteriously, and also that a highway was blocked off and tires were washed down because of very serious, unexpected change in the weather or wind direction.

Obviously something went wrong in terms of wind drift or weather calculations.

My question is: What controls do we have, even when the testing is done on a military base, not in the public domain? Do you have safeguards so that something like a change in wind direction does not affect the test?

Would you care to comment on the sheep deaths? I am sure you are very familiar with that story. Is it a false allegation, or was there in fact a sheep incident?

Colonel CARRUTH. It is a fact, Senator, that the sheep did die. The evidence and the laboratory analysis of that data on cause of death is somewhat inconclusive.

You mentioned how do we control simulants after release. One of the things that must be remembered about *Serratia marcescens*, and that is again the organism that is primary concern, is that it does not survive very long in the open atmosphere. It is killed very rapidly by ultraviolet light, when it is released, and is also sensitive to changes in temperature and humidity.

In Dr. Wheat's article one of the things that is noticeable in it is that the period of time over which those infections occurred was something over a 3-month or 4-month period. Some of them occurred in February, and our tests were conducted in September.

I believe that the competent medical knowledge as well as biological knowledge does not believe that *Serratia marcescens* could survive for that length of time.

Senator SCHWEIKER. In connection with another incident I referred to, is it true as it has also been alleged that a portion of a large highway was closed to traffic and the tires on vehicles were actually washed down because of concern about possible contamination from a test?

Colonel CARRUTH. I did not turn that up in my compilation of the report.

Senator SCHWEIKER. What is your answer?

Colonel CARRUTH. I did not review any data that would indicate that.

Senator SCHWEIKER. You do not know? OK. Thank you.

Senator KENNEDY. We will go into executive session. I again want to express our appreciation for the cooperation we have received.

I must say there have been very deep concerns for the test which have been done with simultants in open areas as well as those begun in military bases or military locations with pathogens, which, I think, raise very substantial questions and problems.

The cooperation with the Department of Defense, working in connection with the human subjects panel, in terms of fashioning guidelines to protect individuals in any of these areas where these organisms will be used is extremely important.

I think it was also useful for us to get some perspective as to what the nature of the challenge is in terms of our national security issues. We did not get into those in detail. But I think we were able to put this into some perspective. We are very grateful for the cooperation we received from the Department of Defense in this matter.

We will go into executive session now.

Senator Schweiker. Before we do that, Mr. Chairman, I, too, want to say I think the Army has been very responsive here with their report. I think it is a good step forward. While I have been critical of the past, I recognize that the folks administering the program today had no responsibility for it. Also, the fact that we are considering a new bill means we are setting higher standards in all fields of health-related activity and testing involving human subjects.

I think that has to be viewed as the context in which I have been critical today.

Thank you.

Senator Kennedy. We will recess and go into executive session in the other room.

[Whereupon, at 11:18 a.m., the subcommittee recessed to reconvene subject to the call of the Chair.]

BIOLOGICAL TESTING INVOLVING HUMAN SUBJECTS BY THE DEPARTMENT OF DEFENSE, 1977

MONDAY, MAY 23, 1977

U. S. Senate,
Subcommittee on Health and Scientific Research
of the Committee on Human Resources,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9.40 a.m., in room 4232, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman of the subcommittee) presiding.

Present: Senators Kennedy and Schweiker.

Opening Statement of Senator Kennedy

Senator Kennedy. The committee will come to order.

On March 8 the Department of Defense presented to the subcommittee a report of the history of biological research and testing by the U.S. Army. Representatives of the Department testified that during the 1950's and 1960's the Army had conducted a number of simulated biological warfare tests in the public domain and without the knowledge or consent of the people exposed to these tests. They also acknowledged that, while the simulants used in the tests were believed to be safe at that time, it is known that at least some of them are not safe and were not safe then.

While we understand that these simulated tests were initiated and carried out in the atmosphere of the cold war when the threat of biological attack was considered a potential threat to our security, I think we can all agree and the Defense Department spokesman did agree in the earlier hearing, that such open air testing with the unwitting exposure of civilian and military populations should not and cannot be tolerated.

Senator Schweiker, the ranking minority member of the subcommittee has been extremely concerned, as I have, with the protection of human subjects in all areas of scientific research. He shares my concern that past deficiencies in the protection of the human subjects must be remedied and that people must not be put at risk without their full knowledge and consent and adequate review procedure.

Human experimentation legislation to expand the jurisdiction of the National Commission for the Protection of Human Subjects in these areas will be introduced soon.

Limited open air testing of biological simulants is continuing at one military installation. Is it safe? Are we sure? Do scientists agree?

To assist us in a better understanding of these problems and how we might profit from our past experiences we have asked four eminent scientists to share with us today the benefit of their knowledge and views.

As I indicated in my statement, this has been an area of particular interest to Senator Schweiker of Pennsylvania, a member of the Intelligence Subcommittee of the Armed Services Committee. He followed these particular issues with great interest and provided extremely important leadership for this committee in this area. Our interest has been in the fashioning of protection of human subject panels, which I think provided very substantial help and assistance to the National Institute of Health and other governmental agencies in assuring protection and adequate notification of those who have been affected by a wide range of human experimentation.

One aspect that has not been covered and which has been the subject of hearings has been those who were the subject of DOD and CIA testimony. We have had hearings over a period of these last few years, but this particular area of biological testing is really a complement, I think, of the justification and rationale for important legislative conclusions. Senator Schweiker has enormous interest in this and has urged these hearings. It was at his request that the hearings were held, and I think they will be extremely helpful to us in sharing the legislative remedy for protecting human subjects. So, I want to acknowledge his leadership and welcome his comments; and he will chair the hearings this morning.

Opening Statement of Senator Schweiker

Senator Schweiker. Thank you very much, Mr. Chairman. I appreciate your kind remarks. I also appreciate your cooperation and your leadership in the broad area of the protection of human subjects. I think the issues raised by the Department of Defense testing program ties in very closely with the subcommittee's work in this field, and I appreciate your inclusion of these issues in our program of hearings relating to the protection of human research subjects.

In March, the Health and Scientific Research Subcommittee received from the Department of Defense the most comprehensive report on biological warfare testing ever prepared and released to the public. Officials of the Department of Defense offered detailed testimony on the chemical and biological warfare programs, with particular emphasis on open-air testing of biological agents and simulants.

We discovered that open-air tests were conducted in populated areas all over the United States. Many of these tests involved live biological organisms which we know can affect human beings, particularly those in a weakened state. We learned that the Defense Department continued to use a certain organism, which they apparently believed to be harmless, long after some medical experts had published reports describing human illness, and even death, resulting from infection with the same type of organism. We received assurances that no open-air tests in population centers are even being contemplated at the present time.

Today we have with us a panel of scientists and public health experts who will be able to offer observations on this controversial testing program from a different perspective. The Health and Scientific Research Subcommittee bears primary responsibility in issues of research ethics and the protection of human subjects of research, and the panel will be able to help us carry out this mandate so that experiments which put human health at risk without informed consent are never again conducted.

We will raise issues of safety in the choice of organisms and simulants used in these tests. The problem of containing the spread of test organisms is another important consideration. Even if open-air experiments are conducted in remote military test areas, can we be sure that no one will be exposed without their informed consent? What controls do we need to insure that the American people are never again used, either directly, or indirectly, as Guinea pigs in biological or chemical warfare testing? Although the present atmosphere militates against such experimentation, what sort of mechanism to insure adequate safeguards in the future should be put in place now?

Concern over the public health and ethical implications raised by disclosure of these open-air experiments has been widespread. Distressed citizens have contacted their elected representatives to express outrage that biological tests were conducted. We have an obligation to be responsive to this deeply felt concern. In Congress, specific legislation to require notification of local civilian officials at least thirty days in advance of any planned biological or chemical agent or simulant test has been proposed. This subcommitee will be exploring the possibility of giving the Commission on the Protection of Human Subjects authority over any research proposals in this area.

Our system of democratic government is stronger when we demonstrate our ability to look critically at past actions and learn from our mistakes. The purpose of this hearing is to bring the public health issues raised by the CBW program into sharper focus, so that we can act effectively to make absolutely certain the errors of the past are not repeated.

I thank Senator Kennedy very much for his cooperation in scheduling this followup hearing, and I also want to express my appreciation to the members of this panel for the interest and concern they have demonstrated by their presence here today.

Thank you, Mr. Chairman.

Senator Kennedy. We have a very distinguished panel, and I will introduce them: Dr. Stephen Weitzman, Department of Microbiology, School of Basic Health Sciences, Health Science Center, State University of New York, at Stony Brook; Dr. J. M. Joseph, director, Laboratories Administration, Maryland State Department of Health and Mental Hygiene; Dr. George H. Connell, assistant to the director, Center for Disease Control; and Dr. Matthew Meselson, chairman, Department of Biochemistry and Molecular Biology, Harvard University. Dr. Weitzman ,would you start off, please?

STATEMENT OF STEPHEN WEITZMAN, M.D., DEPARTMENT OF MICROBIOLOGY, SCHOOL OF BASIC HEALTH SCIENCES, HEALTH SCIENCE CENTER, STATE UNIVERSITY OF NEW YORK, STONY BROOK; J. M. JOSEPH, PH. D., DIRECTOR LABORATORIES ADMINISTRATION, MARYLAND STATE DEPARTMENT OF HEALTH AND MENTAL HYGIENE; GEORGE H. CONNELL, PH. D., ASSISTANT TO THE DIRECTOR, CENTER FOR DISEASE CONTROL, ATLANTA, GA.; MATTHEW MESELSON, PH. D., CHAIRMAN, DEPARTMENT OF BIOCHEMISTRY AND MOLECULAR BIOLOGY, HARVARD UNIVERSITY

Dr. WEITZMAN. Thank you, Senator. I am pleased to be here today to be given the opportunity to testify on what I consider a very, very important subject, and that is biological warfare research that has been and is still being conducted in this country today.

I studied these two volumes of unclassified Army reports, the one dated February 24, 1977, and this will probably be the main source of my comments on the history, nature, and the extent of production and testing biological simulants.

Reviewing the Army report leads to a consideration of two things. First it raises the question about the morality and safety of several large-scale tests that the Army conducted on civilian population without informed consent. The second point involves an examination of the military and political limitations and problems inherent in pursuing biological warfare research.

The most disturbing aspects of the Army's biological warfare program in 1950–69 concerns the open-air tests conducted on a number of U.S. cities between 1950 and 1966. In particular the San Francisco test has received a lot of attention since it first appeared in the newspapers in November of 1976. In addition, the Army spent about a dozen pages defending the test. Since the San Francisco open-air test seems to be the center of controversy, I would like to discuss it in some detail and use it as a model for examining a number of problems inherent in doing biological warfare research.

In brief, the test conducted in 1950 involved exposing the city of San Francisco to an aerosolized live bacteria called Serratia marcescens. The Army's rationale for carrying out this large-scale, open-air test was to increase our knowledge "related to the vulnerability of the United States and/or its personnel to biological warfare attacks both covert and overt." The live bacteria Serratia marcescens was considered a biological simulant "defined as living micro-organisms, not normally capable of causing infection." Around this I would really like to discuss and raise three objections.

The first is, our understanding of a biological simulant, that is, a live bacteria that does not produce disease, is based on our past experiences with that agent under certain very definite conditions; and once these conditions change, the bacteria can cause disease.

Now, there are at least two components to these conditions. One is the number of bacteria and the second is the state of health of the people exposed. Now, the early studies revealed that exposure of a healthy person to a low number of Serratia never caused infections.

What was not known was whether exposure to large numbers of Serratia could cause infection; nor what the response of a sick person would be to Serratia. Now, since these tests have been carried out it has been learned that an increase in the number of Serratia can cause disease in a healthy person and that Serratia can cause serious disease in sick people. In fact, these days most major hospitals have recurring problems with Serratia infections in hospitalized sick patients.

Now, while it is true that in 1950 the scientific and medical professions were unaware of these facts, the main point to learn is that experience gained in controlled, experimental laboratory situations cannot be assumed to be applicable to large-scale tests on big cities. Aerosolization might lead to dispersion of organisms, but the possibility cannot be ruled out that peculiarities in wind conditions or ventilation systems in buildings might concentrate organisms, exposing people to high doses of bacteria. In addition, unlike the individual volunteers used in laboratory experiments, the population of a city is quite heterogeneous. Infants, elderly persons, people with cancer, people with lung disease, et cetera, are all found on the streets in larger cities and their ability to fight off infection by Serratia marcescens is difficult to estimate.

In summary, too many uncontrolled variables are present to consider vulnerability testing safe of large civilian populations with a biological simulant.

Now, the Army used a number of consultants for the tests, and I can only conclude that their advice was inadequate.

I would like to make a comment now on the specific legislation that would require notification of local civilians at least 30 days in advance of any biological or chemical agent. It seems to me what would have to be qualified here is that when we get to the next point, informed consent, it seems to me that local officials really do not have any more right to grant consent per se than the Army or the Department of Defense conducting research. And then I go to the next point, which is the problem of informed consent. It seems to me that when you come to the fact that you want to test the civilian population or the military population, actually the people involved have to be consulted in addition to whatever the local officials might say.

So, the second major objection I would want to make is that the problem of informed consent was not used in the open-air tests in the 1950's and 1960's, and that really stands in contrast to other actions conducted by the Army during the period where they were very concerned and in fact almost admirably used informed consent on Operation Whitecoat; their behavior was exemplary. In addition the Army took exceptional care in instituting safety procedures for personnel working on projects, for insuring against accidents during transportation, and for decontamination of facilities during demilitarization. So, a real contradiction can be seen here between the Army's concern for individual human life and the ethical problems of human experimentation in many situations, and yet the disregard for many of these same values, on the other hand, when they conducted these open-air tests in complete disregard for some of the same values used previously.

The final point I want to make about open-air tests is that it never really dealt with, in any convincing detail, in the Army report, and

that was the necessity for using actual cities for the open-air tests. It is unclear to me what additional information was gained by releasing bacteria in the New York City subways, for example, that could not be gathered by a similar experiment done in the tunnels of a deserted mine shaft; or why in studying aerosolization patterns unpopulated areas could not be used, instead of populated cities. So, why the tests were conducted in populated cities certainly remains unclear to me.

The only unique information that can be concluded from these tests is that the cities are in fact obviously vulnerable to biological warfare attack. This vulnerability is so obvious that it leads to a consideration of the major point I would like to make.

Since the offensive biological warfare research program was dismantled in 1969, there would seem to be little purpose in spending time analyzing actions taken 20 years ago. Still, some degree of biological warfare research continues in the Department of Defense with a budget in 1975–76 of close to $18 million. While this research emphasizes "defensive research," the distinction between "offensive" and "defensive" is often no more than a semantic one. This was realized in Army reports where they quote as early as 1946 that:

> * * * it should be emphasized that while the main objective in all these endeavors was to develop methods for defending ourselves against possible enemy use of biological warfare agents, it was necessary to investigate offensive possibilities in order to learn what measures could be used for defense. Accordingly, the problems of offense and defense were closely interlinked in all the investigations conducted.

That biological warfare research continues in this and probably other countries is disturbing, and that was noted also, in 1946:

> It is important to note that, unlike the development of the atomic bomb and other secret weapons during the war, the development of agents for biological warfare is possible in many countries, large and small, without vast expenditures of money or the construction of huge production facilities. It is clear that the development of biological warfare could very well proceed in many countries, perhaps under the guise of legitimate medical or bacteriological research.

This question was in fact discussed in great detail by Dr. Meselson in a Carnegie endowment report several years ago, in which they really made the point that in the context of a tactical and strategic war it is very much in the U.S. interest to preserve and strengthen the restraints that prevent chemical warfare and the proliferation of chemical weapons. It seems that the wealth of the United States allows it to expend enormous quantities of weapons to be used, and in particular we are talking about conventional munitions and tactical combat; very few other countries approach this capability.

The lesson that was really learned from the San Francisco tests was the fact that an individual person, or a small group of people could, in fact, expose the population to large numbers of bacteria; and that once the technology of biological warfare has been developed, it becomes then easy for small countries, or small groups to use this technology.

To summarize, the proliferation of lethal chemical weapons would risk a major increase in the level of death and devastation in wars of all kinds. Proliferation would provide forces less wealthy and sophisticated than the United States with greatly enhanced capability for threat, harassment, and destruction.

In summary, I have tried to establish the following points:

The first point is that testing in offensive and defensive biological warfare research, and, in particularly large-scale, open-air testing, is unpredictable and thus potentially dangerous. Unique conditions develop what are distinct from the usual laboratory or hospital experience.

The second point is that the Army acted irresponsibly in carrying out the vulnerability open-air tests on large urban populations in the 1950's and 1960's. They ignored the ethical problem of informed consent and the potential health problem we already discussed.

The third point is that the continuation of biological warfare research is not in the military interest of the United States since once the techniques are developed, biological warefare can be used by small countries, terrorist groups, and individuals. The proliferation of biological warfare weaponry and techniques can only erode military advantages that the United States now has since biological agents are cheap to produce and can be delivered by a small force in a clandestine manner.

Based on these three points, I would make the following two proposals:

If further biological warfare research is to be considered necessary because of the development of biological warfare techniques by foreign powers, then the work should be more strictly regulated by groups outside the Department of Defense than has been done in the past. These might include the Department of Health, Education, and Welfare, congressional committees, and/or independent scientists. At a time when Federal guidelines are being established for regulating recombinant DNA research conducted in universities and industries, the same principle of providing outside checks and balances for Department of Defense biological warfare research would seem to be appropriate.

Finally, and most importantly, the United States should intensify efforts to ban biological warfare research internationally and consider integrating such a policy into its strategic arms limitation treaty negotiations.

Thank you very much.

Senator Schweiker (presiding pro tempore). Thank you very much. Dr. Weitzman. We will give each panelist a chance to make an opening statement before we go on to questioning. So, let's go right down the panel in order. Dr. Joseph, would you proceed?

Dr. Joseph. Thank you.

I would like to direct my comments primarily to some of the characteristics of this organism, its possible association with disease; and a little bit about the health hazards associated with the study that was conducted using Serratia marcescens on the population.

Now, this organism has a long remarkable history with accounts of its existence going back to pre-Biblical times. The coloration of this organism, the red pigmentation, was the basis for the indicator as a tracer organism, and certainly it has been recorded in history. In the 19th century the scientific approach to a study of its characteristics shows that it is truly a micro-organism, and even though it occurred in numerous instances on food, there was no report of

clinical illness, at least in the early centuries, from the existence of this organism.

In the 20th century, of course, the early period, there were few occurrences of disease, and thus the bacterium developed the characteristic of having no pathogenic potential for man. That attitude existed for many years.

But since the discovery of the organism in the early 1800's, it was recognized as a biological entity and during its early history was considered to be a saprophyte relatively avirulent for man. It might occasionally cause illness. It was further shown that the organism was widely distributed in nature—we know it exists in water and soil, and as a contaminant of food.

Senator Schweiker. Is Serratia normally found airborne in nature? When you say it is widely distributed in nature, does that include the air?

Dr. Joseph. Not as a natural habitat, no; soil and water. It is not normally present in air.

The techniques used to isolate this organism in the early period depended upon its red pigmentation, but that fact was one of the reasons it was not recognized earlier as an important agent for the production of disease in certain segments of the population. It since has been shown that the majority of strains actually do not produce pigment. In a study done in the 1950's at the Center for Disease Control it was shown that about 75 percent of those strains isolated from human disease did not have this red pigmentation, and therefore they would not have been recognized by many laboratories around the country, or hospitals would not have identified the organism. So, the failure to recognize that the organism existed without the red pigment accounted for the infrequent discovery of disease in man. But, of course, as soon as this fact was recognized and, of course, as a result of extensive use of antibiotics and the new medical manipulation of patients—the managing of patients—the incidence of infection by this organism appeared to increase.

In 1957, at the Boston City Hospital, an increase of incidence of isolations of the Serratia organism was noted. In fact, the study indicated again that the nonpigment strain was more common in clinical disease than the typical red variety; and many laboratories around the country were unable to correctly identify this form.

But since 1913, when the first cases of infection were described in man, there have been isolated reports that stress the potential pathegenicity of this organism for man. Again, in the early 1960's hospitals identified in primary urinary tract infections, respiratory tract infections this organism in man. But before these outbreaks there were instances of infection that occurred prior to the time the testing was held by the Army. So, there was an indication of potential pathogenicity for a certain segment of our population. Infections, of course, have been noted in debilitated individuals, as was pointed out, individuals whose defenses have been compromised. That was not clearly evident in the early 1950's, but there was enough indication that it was potentially dangerous for man.

The outbreaks occurring, of course, again indicated primarily that water might be a possible means of spread, and that airborne spread was less evident at that time.

Prior to 1960, then, *Serratia* was considered a common garden variety micro-organism which was so benign that it was not capable of producing clinical illness in man in its own right. But, because of its apparent nonpathogenic potential and its characteristic red pigmentation and ease of isolation, *Serratia* was commonly used as a tracer bacterium in numerous studies.

It was intentionally spread in some hospitals to study bacterial drifting and settling as an aid in trying to understand the spread of hospital cross-infections. So, classical experiments were routinely conducted to demonstrate to students the basic principle of establishing the index case of infection by a micro-organism. Aerosolization of the test organism was used in courses in microbiology to demonstrate bacteriological air sampling techniques. The organism was intentionally painted on the gums of patients following dental extractions to demonstrate its passage from the oral cavity to the bloodstream. So, there was widespread use of it as something that was not able to cause disease in man.

I think of particular significance in regard to airborne spread was an instance in 1958 when in the University of Wisconsin Hospital a child was cultured and found to be colonized by an organism which was shown to be *Serratia marcescens*. A study conducted on the family failed to reveal this organism, there was no evidence of a family spread. It was them discovered that aerosol studies were being conducted in a biochemistry laboratory at the university hospital and in an adjacent building where genetic studies were being conducted. There was indication then of possible aerosol spread that could have caused the colonization of the intestinal tract of the infant.

Another occurrence indicating aerosol spread occurred in the early 1960's in a London hospital where there was concern over the spread of *Staphylococcus* infections. *Serratia* organisms were spread around the elevator shaft on the lower floors, and it was then detected throughout the hospital on each floor around the elevator areas. But what was unexpected was the occurrence of several cases of *Serratia marcescens* necrotizing pneumonia among hospitalized patients, presumably by aerosol transmission. Soon thereafter the use of the organism as an indicator was discontinued in many facilities around the country, and in fact throughout the world, as we began to recognize the serious potential the organism had to produce disease in man.

Even though the organism was often regarded as a nonpathogen, or of low virulence of healthy individuals, it was found that occasionally in conditions where host resistance is diminished, and a patient's defenses are compromised, there were a variety of disease conditions identified at that time.

While it is difficult to assess how much bacterial invasion by this organism contributes to disease in a patient, if a patient is debilitated, it might account for the disease process.

It should also be reemphasized that infections with this organism occur mainly in patients that are debilitated; that a spread can occur by the airborne route and can cause disease, if the dose is sufficient in normal, healthy individuals.

At the time the simulated testing was done in San Francisco by the Army the organism was considered to be an innocuous sapropyte water organism which was nonpathogenic to man and animals.

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Since the 1960's, however, infections due to the organism have been reported with increasing frequency in a variety of illnesses.

The ability of this organism to cause disease was established on sufficient basis to question the use of the organism for the simulant testing that was done. We no longer, of course, consider this organism as a harmless saprophyte, and I think at that time it should not have been considered as harmless, either.

Whether or not the illnesses in which the organism was isolated from hospitalized patients in the San Francisco area immediately following the study, and the relationship of that organism, was due to those tests, cannot be established with certainty from the data accumulated at that time.

However, I believe that the environmental studies that were conducted, the environmental conditions, could have been simulated as well as using simulated organisms. I do not believe it was necessary to conduct these open-air studies on the masses, that we could have gotten adequate information from the use of a simulated environmental condition to determine airborne spread, drift, survival, and consequent infection. Mass environmental exposure on the scale conducted by the Army was apparently unnecessary on its scientific merit and constituted an unjustifiable health hazard for a particular segment of the population. It was inconceivable and unconscionable, and the study should never have been conducted on the unsuspecting population. No way can we rationalize the validity of that study.

Thank you.

Senator Schweiker. Thank you very much, Doctor. We will now hear from Dr. Connell.

Mr. Connell. I do not have a prepared statement. I have been ill for several days, trying to recover from a fractured skull.

I would like to talk a little bit about this group of organisms. I worked with these things over a period of many years when I was at Fort Detrick and Pine Bluff back in the early 1950's, we worked with *Serratia marcescens*. We used that organism in such unbelievable numbers that you would have to see the kinds of experiments that were done, and none of us thought there was any problem; nobody got sick, as a matter of fact.

At the present time, at the Center for Disease Control where I am employed, we are finding infections, hospital infections, in surprising numbers; and again, these are people who are largely debilitated, or whose defense mechanisms are compromised for some reason or other.

We found something else, that some of these so-called strains that do not produce pigment do produce pigment if you grow them at different temperatures from normal body temperatures. We have done that on a number of them. The idea that the organism has a red pigment and is therefore a good marker does not always work because there are a lot of strains that will grow without color whatsoever if you grow them at other than body temperature.

In my own opinion there is no such thing as a microorganism that cannot cause trouble. When you look at a microorganism to use as tracer, or something of that sort, I think you have to keep that in mind. If you get the right concentration at the right place, at the right time, and in the right person, something is going to happen.

Now, *Serratia marcescens*, as has been mentioned before, has been used for a long time. It has been recognized, as was mentioned earlier, from prebiblical times. And again, the reason was because of the color of most of the strains that were detected. If I had my choice, I would never use this organism or expose anyone to it at any time. That is my own opinion. I consider there is some risk here. Certainly, for the future this has to be considered, whether for defensive work, or anything else because there is some chance that somebody can get hurt. Many of the strains that have been found in people that are ill, are not treatable, they simply do not respond to antibiotics.

You can also find this organism, by the way, in sewage as well as in water. You can find it in the normal gut contents of some people who are not ill; we find it frequently in the urinary tract where it causes serious difficulty in some people. Generally speaking, the infections that are detected are in people who have been catheterized in hospitals. There is a fair percentage of association between catheterization and infection with that particular organism.

That is all I have.

Senator SCHWEIKER. Thank you very much, Dr. Connell. Dr. Meselson?

Dr. MESELSON. Thank you very much. I am Matthew Meselson, chairman of the Department of Biochemistry and Molecular Biology at Harvard University.

Regarding the properties of Serratia marcescens, there is little that I can add to the testimony of the previous witnesses. Generally—as they have also indicated—I would support their views that any organism dispersed as an aerosol over a human population can lead to trouble. Often our knowledge of the disease potential of an organism is based on cases in which the aerosol route is not the primary route, and that leads us to have confidence that some organisms are not very hazardous. However, the situation can be quite different if the organism is in aerosol form. An example is anthrax, which is a common soil bacterium. We do not commonly come down with anthrax infections. But, if there is exposure to aerosolized anthrax spores, it can be very serious. Fortunately, in nature one seldom encounters high concentrations of aerosol particles small enough to penetrate beyond the outer defenses of the respiratory system into the more susceptible and vulnerable alveoli deep in the lungs.

Another consideration regarding possible hazards in dispensing aerosols of microorganisms is that in the general population there are individuals who may be on antibiotic therapy, suppressing their natural population of microorganisms and therefore allowing an available niche for invasion by foreign organisms. There are also other specially sensitive members of the general human population.

Specifically regarding the use of Serratia marcescens as a marker for the study of airborne infections by the military, it seems to me that it was unnecessary. I believe that the total amount of knowledge that has resulted from that type of simulation in order to learn about possible vulnerability to BW attack is very meager.

But now, in any event, one hopes that our country—and other countries—are in a quite different environment regarding biological warfare. Under President Nixon in 1969 and early 1970 the United States

unilaterally declared it would give up all preparations for biological warfare of any kind against man, crops, plants, and animals. And subsequently in the form of the Biological Warfare Convention of 1972, a treaty came into being which binds all parties to not engage in production, development, transfer, and acquisition of biological weapons or their delivery vehicles.

This puts the United States in a different posture from the one that existed in the 1940's and 1950's. What I have in mind here is the absence of a need for classification. If there is general openness, the public interest side is weighed more heavily than if there is classification and secrecy. In some cases this may lead to more complexity in reaching decisions, but it is a broad general principle to which we as a Nation are dedicated.

Our new national policy, by removing classification can make it far less likely that there will be serious mis-use of the science of microbiology. One might ask, what provisions can be made to reduce classification. I would cite a particularly relevant study which was done by the President's Scientific Advisory Committee in 1970, just after the United States had changed its policy, following President Nixon's two announcements. This study was done by a committee under the chairmanship of Dr. Ivan Bennett, now of the New York University School of Medicine. The panel studied various aspects of U.S. biological defense programs and other biological areas to see whether classification was needed. They found in nearly every area that there was no need for classification. The panel concluded that there was no need for secret biological laboratories or secret biological experimentation.

Whether or not that study has led to any explicit Government policy declaration regarding nonclassification of biological research, I am not aware. It may well be that there is still a need for explicit guidelines on the nonclassification of biological research. I am sure such a policy would be a useful one as insurance against misapplications.

I would like, if I may, to diverge from this to a related subject, the legality of working with biological organisms in order to produce weapons. That has been prohibited by the Biological Warfare Convention, and it is renounced by U.S. unilateral policy. But oddly enough, the prohibition may not apply to individual U.S. citizens. The Biological Weapons Convention of 1972, to which the United States is a party, stipulates in article IV that each state party to the convention shall in accordance with its own constitutional processes take any necessary measures to prohibit and prevent the development, production, acquisition, or retention, stockpiling of weapons and means of delivery specified by article I of the convention within the territories of the states under its jurisdiction or control.

Several parties to that treaty have now done so. The British Government has enacted the Biological Weapons Act of 1974 which provides as a maximum penalty life imprisonment for any individual under the jurisdiction of the United Kingdom who engages in these prohibited acts.

Such legislation was submitted to our Congress in 1970, but for reasons with which I am not familiar, no such legislation has been enacted. I assume there will be no great objection to it since our country is party to the treaty. By enacting such legislation we would be fulfill-

ing our national obligation under article IV of the Biological Warfare Convention.

So, to summarize I would say first that there can be serious hazards in releasing live microorganisms in aerosol form over human populations.

Second, such misapplication of microbiology and other misapplications could be inhibited by eliminating secrecy in the conduct of microbiological research.

And third, some additional protection against misapplication of biological technology could be achieved by enactment of a domestic law under the provisions of the Biological Warfare Convention.

Senator SCHWEIKER. Thank you very much, Dr. Meselson.

Now, let me address some questions to the panel. I realize that in some cases you may have touched on some of these general questions in your statements. I will give each person an opportunity to answer the questitons for the record and summarize a little bit what his individual response is.

If the U.S. Government is to do some kind of defensive biological research—it is clearly not going to be called offensive research and I understand there is some relationship between defensive and offensive—what kind of protection would you recommend that Congress enact by statute, or carry out otherwise, for the protection of the population?

I realize that some of you have already touched on that question. It would be helpful if you could come up with a brief summary of your positions for the record.

Dr. WEITZMAN. Well, let us just consider immunizations as an example. Immunizations, which have been developed pretty highly, still have multiple problems, as was evidenced with the swine flu. The problem with immunizations are the side effects many times, which you cannot predict. So, even in a defensive, pure kind of research like immunization, there are individual dangers and risks to the individuals involved.

So, first and foremost, it seems to me, that the problem of informed consent has to be worked out, and that includes the military population, as well. There have been some indications, where have been some communications that the Army no longer uses civilian populations and they indicate that may solve the problem. But even if the military population is used, they have to be used with informed consent, without coercion; that has to be the primary principle.

Along the issue that Dr. Meselson raised I would like to second his suggestion that the more open and public these kinds of programs are, the more feedback there would be from scientific-medical communities, the less likely it is—there is no absolute guarantee—the less likely it is that serious problems would arise.

So, I would say that would be my feeling about the kinds of regulations and safeguards you would want for any kind of defensive research, that people outside the Defense Department and outside the U.S. Army would be involved and carrying out programs, not necessarily as consultants.

Senator SCHWEIKER. Dr. Joseph?

Dr. JOSEPH. I certainly agree with the comments that have just been made. I recognize there is need for some defensive research; certainly

the development of vaccines that resulted from defensive kinds of research have been useful and helpful. But I think to protect the public against what we now have been made aware of, there is need, certainly, for use of unclassified kinds of research. Certainly public awareness has pointed out that is absolutely essential, and informed consent is a necessity.

Senator Schweiker. Dr. Connell?

Dr. Connell. On this matter of immunization, which a lot of people take as the end of all problems, I would like to point out that it is possible to make your own organism which could not be immunized against. If the opposition does this and you immunize against standard strains, you are not immunizing people at all. So, it is a very limited factor; you can use it just against organisms that you have, that you understand, that you may have generated, as a matter of fact. But to depend on it as the absolute does not work.

I think the other thing that I would discuss here is publicity. It seems to me that there is a very important need here to somehow or other through publicity bring the people, the American people in this case, away from the basic fear that they have against infection and infectious diseases. For instance, we have atomic explosions of the military type, and we have other atomic explosives, and these certainly have an impact. But when you are talking about biological warfare you are talking about something that seems to me to bring a lot more fear into the minds of the people than the others do. I think there is a way around that and it would take a lot of publicity and declassification, to do it.

Senator Schweiker. I do not disagree with you, but living in the city that had the "Legionnaires" disease, and having seen the fear and paranoia it caused—and the "Legionnaires" disease was obviously just an unknown infection—I think that may be that sort of fear is inherent in disease, period. It doesn't seem to be limited to BW, though fear of BW may make the scare and dread worse. Still, for a while last summer our city of Philadelphia was greatly disturbed, actually gripped by a sort of hysteria. Hotel bookings dropped to nothing; the hotel went bankrupt and never recovered. So, this fear can arise with any infectious disease, quite apart from BW. As you point out, our particular horror of biological weapons, the consequences of a BW accident or anything related to the BW program may actually be an outgrowth of our basic dread of infectious diseases.

Let me ask you, Dr. Connell, what your feelings are about the need for informed consent or other forms of protection for human subjects in this area of defensive testing.

Dr. Connell. Informed consent is a necessity in this kind of matter. If these agents are going to be used for test purposes, it seems to me highly unethical to expose people to them without their prior knowledge and consent.

Senator Schweiker. Dr. Meselson?

Dr. Meselson. At the risk of repeating myself a little bit I will repeat that I think nonclassification, openness, is the best guarantee of all. In order to insure that, we may need some policy more explicit than we now have, whether that be legislative, or by Executive order, I do not know. But, as I said, I am not aware of any explicit national policy statement about classification and nonclassification of biological

research. If there are areas in which it is necessary to conduct continued classified work, I feel very strongly that such area does not include the development of new candidates, micro-organisms. I see no reason whatsoever for that kind of research, not even a defensive need.

It seems to me the argument that the enemy might have an organism against which we have no defense is first of all outdated. Nature has produced quite a number of such organisms which could indeed be used. Our society, and indeed all societies are vulnerable to the spread of infection. The fact that it has not been done says something about what its evaluation is about military effectiveness and moral and political acceptability. The reason we do not have biological warfare is not the absence of organisms because nature has provided them in abundance.

Furthermore, even the argument that we ought to know what organisms can be developed, so that we can defend ourselves against specific ones, I think is not a good argument because there are so many organisms that an agent-by-agent defense is almost out of the question.

Besides that, there is the argument not for trying to develop all possible organisms ourselves, but for conducting an effective intelligence operation to make sure if there is a chance of anybody doing such things—and I am not aware that anybody is doing this—but if such activity were going on, we would have a chance of detecting them, principally in order to apply a moral and political deterrent, and other kinds of deterrents.

Senator Schweiker. You say it is impossible to develop any kind of defense?

Dr. Meselson. Pardon me, I could not hear the question.

Senator Schweiker. You say it is impossible to develop adequate defenses to protect the public against a BW attack, because of the wide variety of possible agents or other factors?

Dr. Meselson. No, I am saying it is impossible to develop certain kinds of specific defenses. It depends on how many people you want to protect. If it is just a small number of military personnel, it is much easier than protecting a whole city. If you want to protect a city, the procedures are not going to be anything like 100 percent effective, and they are largely identical to those that you need for proper public health surveillance, anyway, the availability of medical care, antibiotics, diagnostic techniques.

I see no military justification for the development of new organisms. We do need continued study of new organisms, but that is a need that is great in the field of public health protection anyway. There is no need for any classified military program for that kind of research.

As far as the threat to ourselves and our institutions from misapplications of biology, I would like to add a postscript. I think by renouncing biological warfare, and by increasing the domain of nonclassification we gain important protection.

I have some concern about the more distant future of biology and biochemistry. These fields are progressing at a very rapid rate. As

time goes on, over decades, we will know a great deal about life processes and we will have the capability to manipulate them. There is no way to keep that from happening. I would argue strongly that this particular area of knowledge ought to be kept on a completely open and nonclassified level, to guard against misapplications of the revolutionary advances that surely lie ahead—not only involving microorganisms, but involving all aspects of living processes, including neurobiology.

The principle of nonclassification has an importance that goes beyond the immediate concern of today, of providing protection to institutions and values which we value, as our knowledge of how to manipulate the life process deepens.

Senator SCHWEIKER. My next questions relate to the use of simulants. First, is there such a thing as a safe biological simulant? And, second, is there anything else that could be used, or some other mechanism, like chamber testing, that might be satisfactory for this kind of testing? For example, one scientist has suggested an algae organism might be safe to use. I would like to hear if there is a safe simulant, and if the algae group is a good suggestion. What is your reaction, Dr. Weitzman?

Dr. WEITZMAN. Well, I think the answer to the first part of the question is, no, there is on safe simulant. That particular statement was actually in the Army report where they admitted there is no ideal simulant. And the reason that is, I think, the more we learn about interactions of micro-organisms and human hosts, the more we realize that almost any organism can do anything, given the proper condition, or the improper condition, as the case is.

And again, realizing that in large cities in particular we are dealing with a heterogeneous population, there are all kinds of problems, on the one hand; on the other hand, you are dealing with a unique, or at least unexplored method of exposing them to bacteria and there is really no way to protect them. That would be true of the algae. Maybe the algae in 1977 seems to be harmless, and I know of no disease that is caused by algae. But on the other hand, we do not have the type of experience that would allow us to say that exposing people to algae in some significant number might not cause disease.

So, I think we are really caught in a bind if people keep thinking that way and are looking for a simulant, that we keep coming back to the same answer, that any organism, given the proper alterations, different methods of exposing people to them. Certainly, if anyone asked my informed consent to almost anything they could think of, my answer would be, no, especially to algae.

Senator SCHWEIKER. What about an organism that would not survive or reproduce at body temperature, would that qualify as safe or as a better choice for a simulant? I am not a microbiologist. I have to rely on you gentlemen's expertise. But organisms that would not live at body temperature, would those be suitable for use as simulants, or not?

Dr. WEITZMAN. Well, people have been interested in those types of organisms, and there have been experiments done on viruses, where they will not multiply at body temperature. The problem again here is that genetic changes would occur in the bacteria spontaneously, and

here again is an area of speculation. If you are talking about very large numbers of bacteria there may be spontaneous mutation, and suddenly the bacteria can grow at body temperature. I mean, if you are talking about really temperature-sensitive micro-organisms, there is a rate that is pretty high. One-in-a-million bacteria might easily revert to an organism that can grow at body temperature. So, I do not depend on that type of genetic characteristics, there is too much of instability in micro-organisms to feel confident that there is a nonpathogenic condition.

Senator SCHWEIKER. Thank you. Dr. Joseph?

Dr. JOSEPH. I personally do not know of any safe simulant that we could use. When you are talking about aerosolizing an organism we are getting down to a very, very small particle size that may get deep into the lungs, and this creates a different kind of problem than the normal organism would by contact, by exposure through some other mechanism. So, the size of the particles used as a simulant is very critical; they normally pass the clearance mechanisms in the body, they are not the type that is deposited in the nose or throat—those have already been mentioned, and they are very important considerations. In the population that is going to be exposed you are going to have individuals who are debilitated in one way or another, where their defense mechanisms may be compromised; so, there is always a risk to that segment of the population.

In regard to the use of algae, I do not know what the effect would be on the individual who has his defense mechanism altered in some way.

In the use of temperatre sensitive kinds of mutants, again, we do not know the risk of changing back the mutation of the organism, which has already been mentioned.

In regard to the direct disease process, as sensitizing an individual, there are all kinds of conditions we are not clear on about these organisms. This may be a component of invasion in producing disease. So, I know of no safe substitute.

Senator SCHWEIKER. Dr. Connell?

Dr. CONNELL. In my opinion there is no such thing as a safe simulant. You can modify any organism that can grow and retain it in your lungs or by ingesting by aerosol. If the particles are too large, they can not taken in; if they are too small, they are not taken in; but there is a range, and that is easily done in the laboratory where you can make it possible for a number of people to retain these things. That is an unusual route, and there is no telling what to expect.

Another example, I think, that is a little farther out, is the recognition that there is no reason to believe that simulants cannot be subjected to processes, and you will come up with some kind of organism that does not exist today. It might still look like a simulant, but it can have other characteristics. Things can be done in the laboratory today like this, and they have happened in the normal body.

As far as algae is concerned, I do not know of any pathogenic algae, but I think the answer to that is time and study; 20 years from now we may know something about this area. At the present time, I do not think there are any known pathogenic algae.

Where body temperature is concerned, there are some interesting problems. We have a strain of organism called *bacillus stearothermo-*

philus, which is deliberately used in the food industry, the pharmaceutical industry, and other kinds of testing industries because of its unusually high heat resistance, which is way above any known virus and considerably above most vegetative bacteria and spore forms. In the typical culture of that organism you find a range of these things that will grow now only at 50 degrees centrigrade, but at 37 degrees, too. These are not known pathogens today, but under the right circumstances they may be.

Senator SCHWEIKER. Dr. Meselson?

Dr. MESELSON. I agree with the other statements, I know of no completely safe simulant.

Senator SCHWEIKER. Dr. Meselson, I did not ask this before and I should have—the Army also used glass beads, zinc sulfide particles, and so forth in open-air testing. Are these things safe?

Dr. MESELSON. I was talking about live micro-organisms.

Senator SCHWEIKER. I switched gears a minute.

Dr. MESELSON. Well, take zinc sulfide. Zinc sulfide could be detected by its fluorescence, and it was used as a simulant in tests by the military in Los Angeles and several other cases. No known illness resulted from it. Nevertheless, I would still say that exposing a large population of very diverse people, that even nonbiologic simulants should be avoided; but I cannot pose as an expert about those. Regarding the biological ones, I am convinced that there is none now known to be safe.

But beyond that I see no reason for conducting such tests. All of the many tests that have been done, to my knowledge, have not increased our security by one iota so far as I am aware. No measures have been taken that seriously would increase our security as a result of knowledge gained from these simulation tests. I think they were idle exercises.

So, my answer to your question is to say that testing of gas masks and other protective equipment can be done in containment chambers. But as to the dissemination of particles of any kind over a large population, I see no sense in doing that—there is no need.

Senator SCHWEIKER. Dr. Weitzman, in your statement you mentioned the DOD CBW program report published in the Congressional Record of April 6, 1977. I wonder whether any material included in that report gave you any cause for concern or alarm. Can you tell from the report whether the current program poses any public health risks?

Dr. WEITZMAN. I am not sure I understand your question.

Senator SCHWEIKER. I gathered from your testimony that you looked over the Department of Defense report that was put in the Record this year, April 6, 1977, describing the present CBW program. My question is, did any of the material that you saw there give you any cause for alarm, that any of the projects might entail a risk to public health. Do you think this committee should be concerned about anything you saw in the April 6 report?

Dr. WEITZMAN. Well, first of all, the report was somewhat unclear, there were a lot of generalities. There was nothing very specific mentioned about exactly what was going on. However, what did cause concern was the fact that things were still going on. And one of the

questions, I think, we would all like answered is, what are the specifics because it is really impossible to evaluate, given the information that was in the Congressional Record at this point. But it seems, then, they are expecting about $18 million a year to do specific biological work, defensive research. Some of that seems quite in line and important, that is theoretical analyses we are trying to develop; means to detect aerosolization clouds. On the surface that seems fine unless they use that to put up their own aerosolization to see how the detection system works.

It was unclear exactly what experiments were going on using human subjects, but there is evidence that is going on, in this report.

So, outside the general feeling that it is worrysome that $18 million is being spent and it is unclear what it is being spent on—it would be nice, you know, to know exactly what is going on, the exact types of experiments that are being conducted.

I think that is exactly what we are all talking about, about declassification, and these things might not even be classified, they are just not made public. You know, the Army is just not publicizing it.

Senator SCHWEIKER. Thank you. Dr. Joseph, I gather from your testimony on that it is often not possible to determine the source of infection when organisms are dispersed in the air, for example. You gave some very good specific background information on what was learned about SM at different points in time. Of course, it is virtually impossible to determine the source of the SM which led to those infections in San Francisco now. But if we had been alerted to the danger then back in San Francisco, could we have determined the source? Once the disease was discovered, would it have been possible to locate the source, Dr. Joseph?

Dr. JOSEPH. That may have been, but it would be quite difficult primarily because of what we know now about the distribution of the organism; there are no common factors. I imagine it might have been possible, had we had better epidemiological information, to incriminate the source. I cannot be more specific.

Senator SCHWEIKER. What do you think of the proposal in the House of Representatives that before any exposure to subjects in a populated area to open-air testing, local civilian or public health officials must be informed? What is your reaction to that?

Dr. JOSEPH. Well, I think that certainly should be done. I think that is a major responsibility for State and local health departments, and I think they should be informed of this kind of testing that is essential.

Senator SCHWEIKER. Dr. Connell, drawing upon your background and looking in retrospect at the San Francisco situation, what do you think we might do differently in the future to avoid this kind of thing? In other words, forgetting use of the specific SM organism which is now known to be pathogenic, what other safeguards should we be looking at to avoid a recurrence of the sort of thing that happened in San Francisco?

Dr. CONNELL. Well, it seems to me that a lot of static resulted from that effort. To me it seems the most simple thing to do would be to avoid this kind of thing in the future; there must be better ways of doing that. Now, there are enclosures of all sorts that are avail-

able, that can be built, rooms that are germ proof, if one wants to call it that. It is entirely possible to use testing equipment, recovery equipment that will give you very good information as to distribution, depending on the volume, for instance, and the concentration of what you are using. That kind of thing is not difficult to do, as compared to exposing a lot of people to an organism that might have a potential impact on them.

Senator SCHWEIKER. Dr. Meselson, you raised the basic issue of what the defense policy of our country is in the biological welfare area of course, our immediate concern in this subcommittee today relates to our responsibility for the protection of human subjects of research. We have to obviously, focus on that. The other issues, the broader and deeper defense policy questions, affect committees other than our own.

With that in mind, would the Commission on the Protection of Human Subjects of Biomedical and Behavioral Research be a logical place to trigger, or write into the law, appropriate protections and safeguards for those who might be exposed to this sort of testing? Or could you suggest some other way?

That is the larger issue which has been raised here: How will we protect our people, not knowing exactly what the policy of the new administration is? Is the panel on human subjects of Bio-medical Research the best mechanism we have, or can you suggest some others?

Dr. MESELSON. Are you talking about outdoor testing?

Senator SCHWEIKER. I am talking about almost any kind of testing that the military services may be doing. Outdoor testing, yes; but also, any other kind of testing which could expose people to some risk. It seems to me we have to write some protection here for almost any kind of testing, not knowing what our testing policy will be in the future.

Dr. MESELSON. Obviously, one of the more potent restraints would be the requirement for informed consent, that would totally rule out any larger-scale testing.

Senator SCHWEIKER. There is still some concern about the possibility of outdoor testing, particularly on military bases. The Army has the right to test on military bases, and yet, obviously, that could well be outdoors. That does not necessarily mean that only the military base is involved since there may be a problem of containment. How do we get a handle on this?

Dr. MESELSON. I am not very familiar with the legislation proposed in the House of Representatives. If it would require merely the approval of public health officials in order to conduct outdoor tests, I would be concerned that such legislation would act to undercut the Biological Weapons Convention.

As far as I know, it is our policy not to do such tests any more. If that is not our policy, it ought to be stated very explicitly, so we know what we are talking about.

Senator SCHWEIKER. It depends, if I understand the policy, and I believe it is not very clear, on whether you are talking about doing offensive or defensive work.

I agree that there is quite a direct relationship between defensive work and offensive work, and one could be a subterfuge for the other. This is where the policy may not be very clear.

Dr. Meselson. By such tests, I mean tests involving individuals whose informed consent is not available. My understanding is that our present policy is not to conduct any such tests, and I know of no military justification for conducting such tests under our current national policy, which is a purely defensive policy.

So I would think that anything that would seem to enable one to conduct such tests would have the effect of undermining international confidence in and adherence to the treaty.

I think the real issue is not whether we will have effective defenses for the civilian populations because I do not think we can ever have such defenses beyond good public health and medical provisions which are needed quite aside from the military considerations. Otherwise, the best strategy against the use of biological weapons is to prevent others from contemplating it, to not pioneer the technology ourselves, and to make sure that there are strong political, moral, and legal, deterrents.

I was very disappointed to learn that a microbiological aerosol was distributed in the New York subway by an employee of the Central Intelligence Agency only a few years ago.

I would have thought that this kind of activity would generate no useful information for us, and could only set the worse possible example for others.

So I would hate to see any legislation that would seem to do anything other than confirm a State of total compliance with our policy in not conducting research in this area, and that means no tests whatever, over unsuspecting populations.

Senator Schweiker. All right.

I want to thank the panel very much for appearing here today. If someone wants to make an additional remark or statement at this point, please feel free to do so. Since I have been asking all the questions, I may have missed something, so if there is any area that I knowing what we are talking about here, and therefore we cannot to do so.

Dr. Connell. Referring to one of your earlier questions about these report, there is a whole list of classified projects in one of these books that simply cannot be interpreted. There is no way in the world of knowing what we are talking about here, and therefore you cannot discuss them very well. They are listed as classified.

Senator Schweiker. We have a problem there, because there is a classified study and an unclassified study, and, of course, this committee cannot declassify material at this point. Some material is classified, and we may not have all of the information ourselves at this point, since these reports are compilations of other reports.

You raise a very good point. I do not know if I can add anything to clarify further what is in the report you have, since this is an open hearing. I would be glad to follow us in some way if we can do so without violating security restrictions.

By the same token, there may well be good reason to have the material you refer to declassified. That may be one result of this hearing, to get more information out in the open. There is no question that through our efforts we were able to get this first report out in unclassi-

fied form. Most of it had been classified for many, many years, and I saw no reason for it to be classified.

I have to give the Army a lot of credit, because they did bite the bullet and pull out a lot of material for this report. They came up with what is probably the most comprehensive report that any government has ever given out on its own efforts in this area.

So while I have been critical, I also want to be complimentary, because I think we did achieve something that had not been done before by making this information public. I think it may well mean we should be doing some more in this area, and be doing it on a regular basis.

Dr. WEITZMAN. I would just like to kind of suggest, to kind of construct an experiment that could conceivably be going on, and perhaps not even be called biological warfare per se, or biological warefare research per se, but which might have these kinds of ramifications.

That is, it would certainly be within the realm of the Army's boundaries, biological research type of work, to experiment with live vaccines, and these would be live viruses, that supposedly were nonpathogenic, and could be injected into troops, and live vaccines are well accepted in the community, and used, but this is just following up one of your questions, in which you were kind of pushing us to suggest what further things could be done.

The gross type of testing that no one seems to be doing any more, namely spraying bugs over a city, that is not going on, but what else might be going on that could be dangerous? So this is just an example of something that might be, and I think that the kind of answers that people have been giving today could also direct itself toward that type of program which has potential danger, and it may not be as nonpathogenic as originally hoped.

I think the answer to that type of thing again rests in several major points that have been made. One is this problem with informed consent. I do not think you have to stop there.

I worry about that problem, particularly in the military, that is, if a sergeant asks his platoon does anyone not want to receive this vaccine, that might be considered informed consent if no one objects.

So I think in the military one might have additional problems. To safeguard this there is this question about consultation to overlook the work going on, I am concerned about this, not only because of classified projects, but also ambiguities, in the Department of Defense report about how exactly they are spending their budget on this.

Senator SCHWEIKER. One of our limitations in this committee which should be mentioned is that we basically do not have primary jurisdiction in the area of biological warfare policy. Perhaps I did not make that clear enough in the beginning.

The broader subject of defense testing would come under the jurisdiction of the House and Senate Armed Services Committees. That is why some of the basic questions Dr. Meselson asked do not directly relate to us as a committee, but do relate to us as individual Senators in our review of Government policy.

Our role here in the health subcommittee is to deal with the public health aspects and protection human subjects aspects of the testing program. We have to come at it this way because this is our primary responsibility, and that is why these hearings have been framed it in

terms of the need for legislation in the area of protection or human subjects—legislation of the type that Senator Kennedy originally authored, which would tie in to the provision of some basic safeguards.

But, as you point out, Dr. Weitzman, there is some danger of implicit consent when any sort of testing goes on in the military, even vaccine testing. I cannot disagree on that point. I think we have to look into that problem as we review new legislative proposals.

Part of our problem is we are seeing just a portion of this area and not the whole testing picture. We are a little bit limited in terms of what the committee can do without working in conjunction with another committee.

Dr. JOSEPH. One final comment. I would like to follow up on the statement about informed consent. I think this is a problem area.

I think in the kind of work the military are doing there is an opportunity for thorough informed consent, and quite often it is uninformed approval by not giving complete details of the risks to which they are exposed, possible complications of participation.

So informed consent, designed informed consent, has been a major concern of many groups.

Another aspect of the research, biomedical research on human subjects, is that there is an associated hazard to the community when these kinds of experiments are conducted on military installations, on military personnel. They certainly get out in the community. They may be carriers out in the community. They may not be ill individuals. There is always that component.

There is the need to know, the local health, or State health agency needs to know what is going on within their boundaries. I hope the pattern will be developed for recombinant DNA research by the committee to keep the community informed of what is going on.

What is going to take place within the boundaries is an important way to deal with this kind of research.

[The prepared statements of Dr. Weitzman and Dr. Joseph follows:]

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May 23, 1977

Testimony to be Delivered to the Senate Subcommittee on Health and Scientific Research of the Human Resources Committee on May 23, 1977 by Stephen Weitzman, M.D., Assistant Professor of Microbiology, State University of New York at Stony Brook.

* * * * * *

I am pleased to be given the opportunity to testify today on a very important subject involving biological warfare research in this country. I have carefully studied the two-volume, unclassified Army report dated February 24, 1977 entitled, "U.S. Army Activity in the U.S. Biological Warfare Programs". I will use this as my main source to comment on the history, nature and extent of production and testing of biological simulants and pathogens.

Before starting, I would like to present my credentials in this field. I received my M.D. degree from New York University Medical School in 1969. After three years of clinical training at Montefiore Hospital and Medical Center in the Bronx, New York, I became a Diplomate of the American Board of Internal Medicine. Following two additional years of clinical and laboratory experience, I was certified by the American Board of Medicine in the subspecialty of Infectious Disease. In 1975 I was appointed to the Department of Microbiology as an Assistant Professor. I am the principal investigator on a grant from the National Science Foundation to study problems in immunology, the course director for the Microbiology course at the Stony Brook Medical School, and Infectious Disease Consultant at the Northport V.A. Hospital in Long Island. In addition, I have published a number of articles in both the scientific and infectious disease journals.

Reviewing the Army report leads to a consideration of two points. The first raises questions about the morality and safety of several large-scale tests that the Army conducted on civilian populations without informed consent. The second point involves an examination of the military and political limitations and problems inherent in pursuing biological warfare research. Finally, I would like to make several proposals which hopefully would prevent any past difficulties from recurring.

The most disturbing aspects of the Army's biological warfare program, 1950-1969, concerns the open-air tests conducted on a number of U.S. cities between 1950 and 1966. In particular, the San Francisco test has received a lot of attention in the press since it first appeared in the Long Island newspaper, NEWSDAY on November 21, 1976. In addition, the Army report spends 11 pages defending this test (II-E-1 to II-E-5, and F-1 to I-F-2). (Note: all numbers in parenthesis refer to pages in the 2/24/77 Army report). Since the San Francisco open-air test seems to be the center of some controversy, I would like to discuss it in some detail and use it as a model for examining a number of problems inherent in doing biological warfare research.

In brief, the test conducted in 1950 involved exposing the city of San Francisco to an aerosolized live bacteria called *Serratia marcescens*. The Army's rationale for carrying out this large-scale, open air test was to increase our knowledge "related to the vulnerability of the U.S. and/or its personnel to biological warfare attacks both covert and overt" (E-7). The live bacteria *Serratia marcescens* was considered a biological simulent "defined as living micro-organisms, not normally capable of causing infection..." (E-6). There are three main objections to be raised at this point:

1) Our understanding of a biological simulant, that is, a live bacteria that does not produce disease, is based on our past experiences with that agent under certain definite conditions. If these conditions change, the bacteria can cause disease. There are at least two components to these conditions: One is the number of bacteria and the second is the state of health of the people exposed. Early studies revealed that exposure of a healthy person to a low number of *Serratia marcescens* (1000-10,000 bacteria) never led to infections. What was not known was whether exposure to large numbers of *Serratia marcescens* (10-100 million bacteria) could cause infection; nor what the response of a sick person would be to *Serratia*. Since these tests were carried out it has been learned that an increase in the number of *Serratia marcescens* can cause disease in a healthy person and that *Serratia marcescens* can cause serious disease in sick people (see pages F-3, II-E-3, F-4). In fact, most major hospitals today have recurring problems with *Serratia marcescens* infections in hospitalized sick patients. While it is true that in 1950 the scientific and medical professions were unaware of these facts, the main point to learn is that experience gained in controlled, experimental laboratory situations cannot be assumed to be applicable to large-scale tests on big cities. Aerosolization might lead to dispersion of organisms but the possibility cannot be ruled out that peculiar wind conditions or ventilation systems in buildings might concentrate organisms, exposing people to high doses of bacteria. In any event, these factors are beyond control. In addition, unlike the individual volunteers used in laboratory experiments, the population of a city is quite heterogeneous. Infants, elderly persons, people with cancer, people with chronic lung disease, etc., are all found on the streets in a large city and their ability to fight off infection by *Serratia marcescens* is difficult to estimate. In summary, too many uncontrolled variables are present to consider vulnerability testing safe, of large civilian populations with a biological simulant.

2) A major objection which has to be made of the open-air experiments, such as the one in San Francisco or in the New York City subways, is that they were carried out on people without informal consent. This action stands in dramatic contrast to other examples in which the Army used admirable and exemplary procedures in dealing with volunteers in Operation Whitecoat (Annex K). In addition, the Army took exceptional care in instituting safety procedures for personnel working on projects. for insuring against accidents during transportation, and for decontamination of facilities during demilitarization. A real contradiction can be seen here between the Army's concern for individual human life and the ethical problems of human experimentation in many situations, and yet the disregard for many of these same values in the vulnerability tests.

3) A question that is never really dealt with in any convincing detail in the Army report is the necessity for using actual cities for the open-air tests. It is unclear to me what additional information is gained by releasing bacteria in the New York City subways that cannot be gathered for example, by a similar experiment done in tunnels in a deserted mine. Similarly, aerosolization patterns could just as well have been analysed using an unpopulated area. If reasons existed to do the testing in actual cities, nowhere are these reasons explained. The only unique information that can be concluded from these tests is that these cities are in fact vulnerable to biological warfare attack. This vulnerability is so obvious that it leads to a consideration of the major point I would like to make.

Since the offensive biological warfare research program was dismantled in 1969, there would seem to be little purpose in spending time analysing actions taken over 20 years ago. Still, some degree of biological warfare research continues in the Department of Defense with a budget in 1975-76 of close to $18,000,000 (Congressional Record-Senate; April 6, 1977, S5701). While this research emphasizes "defensive research", the distinction between "offensive" and "defensive" is often no more than a semantic one. This was realized as early as 1946: "It should be emphasized that while the main objective in all these endeavors was to develop methods for defending ourselves against possible enemy use of biological warfare agents, it was necessary to investigate offensive possibilities in order to learn what measures could be used for defense.... Accordingly, the problems of offense and defense were closely interlinked in all the investigations conducted" (A-5). That biological warfare research continues in this and probably other countries is disturbing. This problem was noted also in 1946: "It is important to note that, unlike the development of the atomic bomb and other secret weapons during the war, the development of agents for biological warfare is possible in many countries, large and small, without vast expenditures of money or the construction of huge production facilities. It is clear that the development of biological warfare could very well proceed in many countries, perhaps under the guise of legitimate madical or bacteriological research." (A-8). In addition, I would like to quote here from a Carnegie Endowment report written in 1971 by Stewart Blumenfeld and Matthew Meselson. Although they were discussing chemical warfare, I would propose that the exact same arguments can be made for biological warfare.

"U.S. Interest in Preventing the Proliferation of CB Weapons.

In the context of both tactical and strategic war, it is very much in U.S. interest to preserve and strengthen the restraints that prevent chemical warfare and the proliferation of chemical weapons. Today, "limited" wars are fought with conventional weapons which individually have limited area effect. Although such wars can be exceedingly destructive, they become so only when great quantities of weapons are used. The wealth of the United States allows it to expend enormous quantities of conventional munitions in tactical combat. Very few countries even approach this capability. However, the proliferation of lethal chemical weapons would greatly enhance the destructive and disruptive capability of smaller and less wealthy nations. This is because these weapons have the potential of large area coverage at relatively low cost. Many of the types of munitions used in limited war could be filled with lethal chemicals. In that case, the "kill area" of light weight munitions such as mortar shells and rockets would be increased by a large factor. Even though troops can be provided with protective masks and suits, such weapons would be devastating to military units caught off guard and to the civilian population. In many situations lethal chemical weapons would favor guerrilla forces. Such forces generally have no shortage of targets. They know the locations of military installations such as base camps and support facilities. Their problem is their great inferiority in fire power. For anti-guerrilla forces, the reverse is usually true, their main tactical problem being location of the enemy. In this situation, any major enhancement of the area coverage of light weight weapons disproportionately favors less sophisticated forces operating in smaller units and capable of dispersing or mingling with the civilian population. Moreover, the proliferation of lethal chemical weapons would create greatly expanded opportunities for terror attacks on urban centers by small groups of men firing chemical rockets or mortars from the outskirts. Thus, the proliferation of chemical weapons would seriously reduce the military advantage that great wealth confers, while at the same time threatening a major increase in the violence of war and its toll among civilians.

At the strategic level, the hazard of proliferation of lethal gas weapons is also serious. Countries not possessing nuclear weapons might well be tempted to acquire a population-killing capability based on nerve gas. Under suitably chosen meteorological conditions, a small bomber force could deliver enough nerve agent to kill a large proportion of persons in a major city. Although it is unlikely that a poor nation could successfully deliver chemicals over a wide area of a country with modern air defenses, a surprise attack on one or a few coastal cities would be difficult to defend against.

Further, it should be noted that analysis and planning for the use of chemical weapons is likely to stimulate interest in the strategic possibilities of biological weapons and that the economics of anti-personnel and anti-crop biological weapons for threat or deterrence may seem particularly attractive to less wealthy nations.

To summarize, the proliferation of lethal chemical weapons would risk a major increase in the level of death and devastation in wars of all kinds. Proliferation would provide forces less wealthy and sophisticated than the United States with greatly enhanced capability for threat, harassment, and destruction. The acquisition of chemical weapons would stimulate interest in biological weapons, for the barriers against both are intertwined. The overriding objective of the United States in this area of policy should be to prevent the proliferation of chemical and biological weapons and to strengthen the barriers against their use." (The Control of Chemical and Biological Weapons, Carnegie Endowment for International Peace, New York/1971, pp. 85-87).

In summary, I have tried to establish the following points:

1) Testing in offensive or defensive biological warfare research, and, in particularly large-scale, open-air testing, is unpredictable and thus potentially dangerous. Unique conditions develop which are distinct from the usual laboratory or hospital experience.

2) The Army acted irresponsibly in carrying out the vulnerability open-air tests on large urban populations in the 1950's and 1960's. They ignored the ethical problem of informed consent and the potential health problem discussed in objection #1 on page 2 of this testimony.

3) The continuation of biological warfare research is not in the military interest of the United States since once the techniques are developed, biological warfare can be used by small countries, terrorist groups and individuals. The proliferation of biological warfare weaponry and techniques can only erode military advantages that the United States now has since biological agents are cheap to produce and can be delivered by a small force in a clandestine manner.

Based on these three points, I would make the following proposals:

1) If further biological warfare research is to be considered necessary because of the development of biological warfare techniques by foreign powers, then the work should be more strictly regulated by groups outside the Department of Defense than has been done in the past. These might include the Department of Health, Education and Welfare, Congressional Committees, and/or independent scientists. At a time when Federal guidelines are being established for regulating recombinant DNA research conducted in universities and industries, the same principle of providing outside checks and balances for Department of Defense biological warfare research would seem to be appropriate.

2) Finally, and most importantly, the United States should intensify efforts to ban biological warfare research internationally and consider integrating such a policy into its strategic arms limitation treaty negotiations.

MARYLAND STATE DEPARTMENT OF HEALTH AND MENTAL HYGIENE
LABORATORIES ADMINISTRATION

STATEMENT ON THE USE OF THE SIMULANT SERRATIA MARCESCENS
IN AEROSOL STUDIES OF HUMAN POPULATION CENTERS

My name is J. Mehsen Joseph, Ph.D., and I am Director of the Laboratories Administration, Maryland State Department of Health and Mental Hygiene, and Assistant Professor of Microbiology, University of Maryland, Baltimore, Maryland.

Because of the public concern over the conduct of experiments by the Army in which the bacterium Serratia marcescens was used as an aerosol over the city of San Francisco in the early 1950's, I wish to describe the early history of this bacterium, to discuss its potential for causing disease in man, and to comment on the health hazard associated with the study.

Serratia marcescens has had a long and remarkable history with classical accounts by historians of the appearance of "miraculous blood" appearing on bread dating back to the siege of Tyre in Lebanon in 332 B.C. This remarkable manifestation struck fear in the hearts of the superstitious and credulous people of the Middle Ages. However, early in the 19th Century the phenomenon was examined in a scientific matter and the causative agent identified and characterized. Doctor Bartolomeo Bizio, a young pharmacist, was the first to observe reddened polenta (corn meal mush), and by a series of lengthy and ingenious experiments, he concluded that the red mucilaginous substance was the result of activity of masses of very small bodies.

Numerous studies of red pigmentation of foods, particularly bread and starchy foods, were recorded in the history of this bacterium beginning in 332 B.C. and continuing through the 19th Century. However, during that period, reports of clinical illness among those who consumed these foods were extremely rare occurrences. Thus, the bacterium was considered to have little or no pathogenic potential for man.

Since its discovery in 1823 by Bizio, Serratia marcescens has been recognized as a biological entity and during its early history was considered to be a saprophyte which was relatively avirulent. The organism is widely distributed in nature and is found naturally in water, soil and as a contaminant of food. As standard bacteriological techniques were developed to distinguish among the microorganisms closely related to Serratia marcescens, investigators began to recognize non-pigmented strains of the latter. In 1959 the Center for Disease Control, USPHS, in Atlanta reported on a study in which 75 per cent of over 200 strains examined failed to produce pigment. Failure to recognize this fact probably accounted for the infrequent reports of recovery of this organism from infections in man. As a result of this finding, recognition of non-pigmented varieties of S. marcescens, combined with the extensive use of broad spectrum antibiotics among hospitalized patients, probably accounts for the increased frequency with which hospital-acquired infections by this organism are now being recognized.

In 1967 at the Boston City Hospital an increased incidence of isolations of Serratia marcescens was noted. In 1970 a study of the occurrence of Serratia infections at the same hospital revealed that non-pigmented strains of this bacterium were more common than the pigmented variety, and that many clinical bacteriology laboratories were unable to correctly identify these non-pigmented forms.

Since 1913 when the first case of Serratia infection in man was described, isolated reports have stressed the potential pathogenicity of this organism for man. In 1962 the Communicable Disease Center pointed out the nosocomial nature of most Serratia marcescens infections. Several hospital outbreaks involving urinary tract infections and respiratory tract infections and two epidemics in nurseries for newborn infants have been described. Infections also have been noted to occur at the site of indwelling urinary and intravenous catheters and after lumbar punctures or peritoneal dialysis. Previous antibiotic therapy and underlying chronic debilitating disease may also predispose to serious Serratia infection. Urinary tract infection has been the most frequent site of Serratia infections but the epidemiology of such hospital outbreaks is still unclear and any attempts to determine the source of the organism has been unrevealing. However, most patients had indwelling catheterization and urinary tract abnormality. Also, Serratia marcescens is isolated frequently from the respiratory tract but these isolations are infrequently of clinical significance.

Hospital outbreaks of respiratory infection are usually associated with Serratia contamination of respiratory equipment. Associated clinical illness was either pneumonia, empyema, or lung abscess.

Prior to 1960 Serratia marcescens was considered a common garden variety microorganism which was so benign that it was not capable of producing clinical illness in man in its own right. Because of its apparent nonpathogenic potential and its characteristic red pigmentation and ease of isolation, Serratia marcescens was commonly used as a tracer bacterium in numerous studies. It was intentionally spread in hospitals to study bacterial drifting and settling as an aid to understanding the spread of hospital cross-infections. Classical experiments in epidemiology were routinely conducted to demonstrate to students the basic principle of establishing the index case of infection by a microorganism. Aerosolization of the test organism was used in courses in Microbiology to demonstrate bacteriological air sampling techniques. The organism was intentionally painted on the gums of patients to demonstrate its passage from the oral cavity to the blood stream following dental manipulation and/or extraction. This organism has been used also by high school students in science fair projects without regard to its potential pathogenicity.

Of particular significance is the occurrence in 1958 of a condition referred to as "Red Diaper Syndrome" in a child born at the University of Wisconsin Hospital. The child was cultured

and found to have an overwhelming growth of the red pigmented Serratia marcescens in the intestinal tract. Exhaustive studies of the child's family failed to reveal carriers of the organism. Epidemiological sleuthing uncovered the fact that the organism was being used at that time in a study of aerosol techniques in a biochemistry laboratory within the hospital and in an adjoining building where genetic studies were being conducted. Aerosol spread from these sources could have accounted for the colonization of the intestinal tract of the infant soon after birth. Apparently the organism established itself in the child's intestine and replaced the normal flora, but the child continued in excellent health and required almost one year of treatment to eliminate this bacterium.

An experiment conducted in 1960 in a London hospital also aroused a great deal of concern over the use of S. marcescens as a tracer microorganism. In attempting to prove an hypothesis that Staphylococcus aureus (a bacterium associated with hospital-acquired infection) was spread from floor-to-floor up the elevator shaft by movement of elevator, the tracer organism Serratia marcescens was aerosolized near the elevator door on the lower floor of the hospital and air sampling was done on the upper floors. In time, S. marcescens was detected in the area around the elevator shaft on each floor. What was not expected was the occurrence of several

cases of S. marcescens necrotizing pneumonia among hospitalized patients presumably by aerosol transmission. Soon thereafter the use of S. marcescens as an indicator organism ceased in many countires, including the United States.

Even though Serratia marcescens is often regarded as a nonpathogen, or of low virulence for healthy individuals, it is found occasionally in conditions where host resistance is diminished (postoperative patients, burn cases, diabetics, cancer patients, steroid therapy), or in conditions predisposing to bacterial infection (frequent catheterization, malformation or obstruction of the urinary tract). Prolonged antibiotic therapy seems to favor the emergence of highly antibiotic resistant strains of S. marcescens. Generally the bacterium is considered an "opportunist". It is difficult to assess how much bacterial invasion has contributed to the underlying disease in many cases. Its presence in clinical materials is more frequent than generally suspected because of our failure to properly identify the bacterium due to the false belief that it is an obligate pigment former. Pigmentation is demonstrable in only about 20-30 per cent of the strains isolated from patients.

It should be reemphasized that infections with S. marcescens occur mainly in hospitalized individuals with some underlying disease. The mode of transmission has not been sufficiently elucidated

but contaminated hands and instruments, as well as droplet aerosols, have been incriminated. It probably spreads like other hospital-acquired bacteria. Infection may or may not cause clinical disease, and a fatal outcome is very rare.

At the time the simulated testing was done in San Francisco by the Army, Serratia marcescens was considered an innocuous saprophytic water organism which was nonpathogenic to man or animals, but was occasionally recovered from compromised hospitalized patients. Since 1960, however, infections due to this organism have been reported with increasing frequency in association with urinary tract infections, pneumonia, empyema, lung abscess, wound infection, meningitis, septicemia and endocarditis. The ability of S. marcescens to cause infection was once thought to be limited to patients with chronic debilitating disorders, but it is now clear that there are many predisposing factors such as broad spectrum antibiotic therapy, diabetes, indwelling catheters, mechanical ventilation therapy and corticosteroid therapy. This knowledge reemphasizes the hazard in using S. marcescens as a tracer organism in experimental studies of aerosols and related experiments involving humans.

No longer can we consider the disease potential of an organism simply a property in its own right, nor as an interaction of a parasite with a healthy host, but as a consequence of interaction with a compromised individual. Secondary invasion must also be viewed with

the same concern as regards primary infections because the consequences are equally hazardous and the former often result in prolonged hospitalization. Since it was known that a clear danger of S. marcescens infection existed for hospitalized and debilitated individuals, it is inconceivable and unconscionable that the organism would have been spread as an aerosol over unsuspecting masses of people, some of whom would have been at high risk. Whether or not the illnesses in which S. marcescens was isolated from hospitalized patients in the San Francisco area immediately following the testing in the early 1950's is impossible to establish with certainty because of the natural occurrence of this agent in the hospital environment and its wide distribution in nature.

Simulated environmental conditions, as well as simulated microorganisms, could have been employed and would have provided adequate information as to the airborne spread, drift, survival and consequent infection. Mass environmental exposure on the scale conducted by the Army was apparently unnecessary on its scientific merit and constituted an unjustifiable health hazard for a particular segment of the population. To rationalize the validity for the study would be sheer folly.

Respectfully submitted,

J. Mehsen Joseph, Ph.D.
May 20, 1977

Senator SCHWEIKER. All right. I want to thank the panel again for taking time to be with us today. I know you all have very busy schedules. We may well be coming back to you on an individual basis as we progress on developing some legislative proposals in this area, to consult with you and get your opinions on specific approaches.

The Senate Health Subcommittee will stand in adjournment until tomorrow morning, when we will begin a series of hearings on hospital cost containment.

[Whereupon, at 11:20 a.m., the subcommittee adjourned.]

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