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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:]

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

linical 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 pathogenicity 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 ablo 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.

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 fulfilling 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 micro-organisms, 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:]

7) 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 medical 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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