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

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Now, *Serratia marcescens*, as has been mentioned before, has been used for a long time. It has been recognized, as was mentioned earlier, from prebiblical times. And again, the reason was because of the color of most of the strains that were detected. If I had my choice, I would never use this organism or expose anyone to it at any time. That is my own opinion. I consider there is some risk here. Certainly, for the future this has to be considered, whether for defensive work, or anything else because there is some chance that somebody can get hurt. Many of the strains that have been found in people that are ill, are not treatable, they simply do not respond to antibiotics.

You can also find this organism, by the way, in sewage as well as in water. You can find it in the normal gut contents of some people who are not ill; we find it frequently in the urinary tract where it causes serious difficulty in some people. Generally speaking, the infections that are detected are in people who have been catheterized in hospitals. There is a fair percentage of association between catheterization and infection with that particular organism.

That is all I have.

Senator SCHWEIKER. Thank you very much, Dr. Connell. Dr. Meselson?

Dr. MESELSON. Thank you very much. I am Matthew Meselson, chairman of the Department of Biochemistry and Molecular Biology at Harvard University.

Regarding the properties of Serratia marcescens, there is little that I can add to the testimony of the previous witnesses. Generally—as they have also indicated—I would support their views that any organism dispersed as an aerosol over a human population can lead to trouble. Often our knowledge of the disease potential of an organism is based on cases in which the aerosol route is not the primary route, and that leads us to have confidence that some organisms are not very hazardous. However, the situation can be quite different if the organism is in aerosol form. An example is anthrax, which is a common soil bacterium. We do not commonly come down with anthrax infections. But, if there is exposure to aerosolized anthrax spores, it can be very serious. Fortunately, in nature one seldom encounters high concentrations of aerosol particles small enough to penetrate beyond the outer defenses of the respiratory system into the more susceptible and vulnerable alveoli deep in the lungs.

Another consideration regarding possible hazards in dispensing aerosols of microorganisms is that in the general population there are individuals who may be on antibiotic therapy, suppressing their natural population of microorganisms and therefore allowing an available niche for invasion by foreign organisms. There are also other specially sensitive members of the general human population.

Specifically regarding the use of Serratia marcescens as a marker for the study of airborne infections by the military, it seems to me that it was unnecessary. I believe that the total amount of knowledge that has resulted from that type of simulation in order to learn about possible vulnerability to BW attack is very meager.

But now, in any event, one hopes that our country—and other countries—are in a quite different environment regarding biological warfare. Under President Nixon in 1969 and early 1970 the United States

unilaterally declared it would give up all preparations for biological warfare of any kind against man, crops, plants, and animals. And subsequently in the form of the Biological Warfare Convention of 1972, a treaty came into being which binds all parties to not engage in production, development, transfer, and acquisition of biological weapons or their delivery vehicles.

This puts the United States in a different posture from the one that existed in the 1940's and 1950's. What I have in mind here is the absence of a need for classification. If there is general openness, the public interest side is weighed more heavily than if there is classification and secrecy. In some cases this may lead to more complexity in reaching decisions, but it is a broad general principle to which we as a Nation are dedicated.

Our new national policy, by removing classification can make it far less likely that there will be serious mis-use of the science of microbiology. One might ask, what provisions can be made to reduce classification. I would cite a particularly relevant study which was done by the President's Scientific Advisory Committee in 1970, just after the United States had changed its policy, following President Nixon's two announcements. This study was done by a committee under the chairmanship of Dr. Ivan Bennett, now of the New York University School of Medicine. The panel studied various aspects of U.S. biological defense programs and other biological areas to see whether classification was needed. They found in nearly every area that there was no need for classification. The panel concluded that there was no need for secret biological laboratories or secret biological experimentation.

Whether or not that study has led to any explicit Government policy declaration regarding nonclassification of biological research, I am not aware. It may well be that there is still a need for explicit guidelines on the nonclassification of biological research. I am sure such a policy would be a useful one as insurance against misapplications.

I would like, if I may, to diverge from this to a related subject, the legality of working with biological organisms in order to produce weapons. That has been prohibited by the Biological Warfare Convention, and it is renounced by U.S. unilateral policy. But oddly enough, the prohibition may not apply to individual U.S. citizens. The Biological Weapons Convention of 1972, to which the United States is a party, stipulates in article IV that each state party to the convention shall in accordance with its own constitutional processes take any necessary measures to prohibit and prevent the development, production, acquisition, or retention, stockpiling of weapons and means of delivery specified by article I of the convention within the territories of the states under its jurisdiction or control.

Several parties to that treaty have now done so. The British Government has enacted the Biological Weapons Act of 1974 which provides as a maximum penalty life imprisonment for any individual under the jurisdiction of the United Kingdom who engages in these prohibited acts.

Such legislation was submitted to our Congress in 1970, but for reasons with which I am not familiar, no such legislation has been enacted. I assume there will be no great objection to it since our country is party to the treaty. By enacting such legislation we would be fulfill-

ing our national obligation under article IV of the Biological Warfare Convention.

So, to summarize I would say first that there can be serious hazards in releasing live microorganisms in aerosol form over human populations.

Second, such misapplication of microbiology and other misapplications could be inhibited by eliminating secrecy in the conduct of microbiological research.

And third, some additional protection against misapplication of biological technology could be achieved by enactment of a domestic law under the provisions of the Biological Warfare Convention.

Senator SCHWEIKER. Thank you very much, Dr. Meselson.

Now, let me address some questions to the panel. I realize that in some cases you may have touched on some of these general questions in your statements. I will give each person an opportunity to answer the questitons for the record and summarize a little bit what his individual response is.

If the U.S. Government is to do some kind of defensive biological research—it is clearly not going to be called offensive research and I understand there is some relationship between defensive and offensive—what kind of protection would you recommend that Congress enact by statute, or carry out otherwise, for the protection of the population?

I realize that some of you have already touched on that question. It would be helpful if you could come up with a brief summary of your positions for the record.

Dr. WEITZMAN. Well, let us just consider immunizations as an example. Immunizations, which have been developed pretty highly, still have multiple problems, as was evidenced with the swine flu. The problem with immunizations are the side effects many times, which you cannot predict. So, even in a defensive, pure kind of research like immunization, there are individual dangers and risks to the individuals involved.

So, first and foremost, it seems to me, that the problem of informed consent has to be worked out, and that includes the military population, as well. There have been some indications, where have been some communications that the Army no longer uses civilian populations and they indicate that may solve the problem. But even if the military population is used, they have to be used with informed consent, without coercion; that has to be the primary principle.

Along the issue that Dr. Meselson raised I would like to second his suggestion that the more open and public these kinds of programs are, the more feedback there would be from scientific-medical communities, the less likely it is—there is no absolute guarantee—the less likely it is that serious problems would arise.

So, I would say that would be my feeling about the kinds of regulations and safeguards you would want for any kind of defensive research, that people outside the Defense Department and outside the U.S. Army would be involved and carrying out programs, not necessarily as consultants.

Senator SCHWEIKER. Dr. Joseph?

Dr. JOSEPH. I certainly agree with the comments that have just been made. I recognize there is need for some defensive research; certainly

the development of vaccines that resulted from defensive kinds of research have been useful and helpful. But I think to protect the public against what we now have been made aware of, there is need, certainly, for use of unclassified kinds of research. Certainly public awareness has pointed out that is absolutely essential, and informed consent is a necessity.

Senator SCHWEIKER. Dr. Connell?

Dr. CONNELL. On this matter of immunization, which a lot of people take as the end of all problems, I would like to point out that it is possible to make your own organism which could not be immunized against. If the opposition does this and you immunize against standard strains, you are not immunizing people at all. So, it is a very limited factor; you can use it just against organisms that you have, that you understand, that you may have generated, as a matter of fact. But to depend on it as the absolute does not work.

I think the other thing that I would discuss here is publicity. It seems to me that there is a very important need here to somehow or other through publicity bring the people, the American people in this case, away from the basic fear that they have against infection and infectious diseases. For instance, we have atomic explosions of the military type, and we have other atomic explosives, and these certainly have an impact. But when you are talking about biological warfare you are talking about something that seems to me to bring a lot more fear into the minds of the people than the others do. I think there is a way around that and it would take a lot of publicity and declassification, to do it.

Senator SCHWEIKER. I do not disagree with you, but living in the city that had the "Legionnaires" disease, and having seen the fear and paranoia it caused—and the "Legionnaires" disease was obviously just an unknown infection—I think that may be that sort of fear is inherent in disease, period. It doesn't seem to be limited to BW, though fear of BW may make the scare and dread worse. Still, for a while last summer our city of Philadelphia was greatly disturbed, actually gripped by a sort of hysteria. Hotel bookings dropped to nothing; the hotel went bankrupt and never recovered. So, this fear can arise with any infectious disease, quite apart from BW. As you point out, our particular horror of biological weapons, the consequences of a BW accident or anything related to the BW program may actually be an outgrowth of our basic dread of infectious diseases.

Let me ask you, Dr. Connell, what your feelings are about the need for informed consent or other forms of protection for human subjects in this area of defensive testing.

Dr. CONNELL. Informed consent is a necessity in this kind of matter. If these agents are going to be used for test purposes, it seems to me highly unethical to expose people to them without their prior knowledge and consent.

Senator SCHWEIKER. Dr. Meselson?

Dr. MESELSON. At the risk of repeating myself a little bit I will repeat that I think nonclassification, openness, is the best guarantee of all. In order to insure that, we may need some policy more explicit than we now have, whether that be legislative, or by Executive order, I do not know. But, as I said, I am not aware of any explicit national policy statement about classification and nonclassification of biological

research. If there are areas in which it is necessary to conduct continued classified work, I feel very strongly that such area does not include the development of new candidates, micro-organisms. I see no reason whatsoever for that kind of research, not even a defensive need.

It seems to me the argument that the enemy might have an organism against which we have no defense is first of all outdated. Nature has produced quite a number of such organisms which could indeed be used. Our society, and indeed all societies are vulnerable to the spread of infection. The fact that it has not been done says something about what its evaluation is about military effectiveness and moral and political acceptability. The reason we do not have biological warfare is not the absence of organisms because nature has provided them in abundance.

Furthermore, even the argument that we ought to know what organisms can be developed, so that we can defend ourselves against specific ones, I think is not a good argument because there are so many organisms that an agent-by-agent defense is almost out of the question.

Besides that, there is the argument not for trying to develop all possible organisms ourselves, but for conducting an effective intelligence operation to make sure if there is a chance of anybody doing such things—and I am not aware that anybody is doing this—but if such activity were going on, we would have a chance of detecting them, principally in order to apply a moral and political deterrent, and other kinds of deterrents.

Senator SCHWEIKER. You say it is impossible to develop any kind of defense?

Dr. MESELSON. Pardon me, I could not hear the question.

Senator SCHWEIKER. You say it is impossible to develop adequate defenses to protect the public against a BW attack, because of the wide variety of possible agents or other factors?

Dr. MESELSON. No, I am saying it is impossible to develop certain kinds of specific defenses. It depends on how many people you want to protect. If it is just a small number of military personnel, it is much easier than protecting a whole city. If you want to protect a city, the procedures are not going to be anything like 100 percent effective, and they are largely identical to those that you need for proper public health surveillance, anyway, the availability of medical care, antibiotics, diagnostic techniques.

I see no military justification for the development of new organisms. We do need continued study of new organisms, but that is a need that is great in the field of public health protection anyway. There is no need for any classified military program for that kind of research.

As far as the threat to ourselves and our institutions from misapplications of biology, I would like to add a postscript. I think by renouncing biological warfare, and by increasing the domain of nonclassification we gain important protection.

I have some concern about the more distant future of biology and biochemistry. These fields are progressing at a very rapid rate. As

time goes on, over decades, we will know a great deal about life processes and we will have the capability to manipulate them. There is no way to keep that from happening. I would argue strongly that this particular area of knowledge ought to be kept on a completely open and nonclassified level, to guard against misapplications of the revolutionary advances that surely lie ahead—not only involving 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 ex~~ist 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:]