COLD WAR ERA HUMAN SUBJECT EXPERIMENTATION

HEARING

BEFORE THE

LEGISLATION AND NATIONAL SECURITY SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

SEPTEMBER 28, 1994

Printed for the use of the Committee on Government Operations

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COLD WAR ERA HUMAN SUBJECT EXPERIMENTATION

WEDNESDAY, SEPTEMBER 28, 1994

HOUSE OF REPRESENTATIVES,
LEGISLATION AND NATIONAL SECURITY SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2154, Rayburn House Office Building, Hon. John Conyers, Jr. (chairman of the subcommittee) presiding.

Members present: Representatives John Conyers, Jr., Al McCandless, and William F. Clinger, Jr.

Also present: Representative Gary A. Condit.

Subcommittee staff present: James C. Turner, staff director; Bennie B. Williams, clerk; and L. Stephen Vincze, minority professional staff, Committee on Government Operations.

OPENING STATEMENT OF CHAIRMAN CONYERS

Mr. CONYERS. The subcommittee will come to order.

Today's meeting will examine a tragic chapter from the cold war era—the many cases, where our government sponsored secret experiments on Americans in the name of national security.

Last year, Secretary of Energy O'Leary revealed that during the cold war the government conducted widespread radiation experiments upon soldiers, school children, hospital patients, and other private citizens, many of whom had not volunteered to be experimental subjects.

The radiation experiments are only part of the story. We have learned that during the cold war the Department of Defense and other government agencies also conducted chemical and biological warfare experiments on Americans, as well as tests with various drugs and incapacitating agents.

Because of security concerns, subjects of the cold war era tests were often not informed that they were participating in an experiment, and in other instances were not fully informed of potential health risks.

Including the radiation experiments, we have learned that nearly a half million Americans were subjected to some cold war era tests.

In addition to being secret, this national security research was often conducted on individuals who had little choice in the matter, including members of the military, prison inmates, hospital patients, and institutionalized individuals.

In one case, we have evidence that in the late 1950's the Army Chemical Corps conducted a biological warfare test from an aircraft

flying over Detroit and dispersing particles of a cancer-causing compound. Although the Army assured us there was no likelihood of injury, I am deeply concerned about using our citizens as guinea pigs, no matter how safe the Army might think a test is.

In other cases, the military and the CIA contracted with various universities to do research on the influences of psychochemical agents on combat troops. How did they accomplish this? They did it by administering LSD and other psychochemical agents to people who had no idea what had happened to them. They had become part of an experiment without their knowledge or consent.

Sadly, this chapter from the cold war is not over. Today, individuals who were injured in these experiments and their families are still trying to find out the truth about what happened, and to secure assistance from the government.

After Secretary O'Leary's disclosures, President Clinton established a special advisory committee to review the radiation experiments and to recommend remedial steps. But this body has only a limited mandate—radiation experiments; it is not examining other potentially damaging cold war experiments on Americans.

So this hearing is to begin an examination of the full scope of the cold war experiments, and to begin a process of trying to provide assistance to Americans who may have suffered injuries in them.

The General Accounting Office, the investigative arm of Congress, has been very helpful. We have also received cooperation from the Department of Defense. And we now have relatives of individuals who lost their lives in the tests who will tell about their families' experience.

Finally, we have a distinguished panel, that will discuss the many troubling aspects of this sad chapter from our national history.

Now, in addition to the radiation tests, the subcommittee will consider Army biological warfare tests using potentially carcinogenic compounds in 239 American cities between the years 1949 and 1956; atmospheric nuclear tests from 1945 to 1962 involving over 212,000 individuals; Naval Research Laboratory full body mustard gas exposures on 3,000 subjects; Army and Navy skin tests during the 1940's with blistering agents and ointments, 60,000 people involved; Army Chemical Corps tests with nerve agents and psychochemicals on 7,120 subjects; CIA program of drug testing and behavior control experiments during the 1950's on several hundred subjects.

This hearing reads like a chapter from a science fiction novel. It is hard still for me to believe that all this occurred after World War II. It is a very sad chapter in our history, but one that needs to be revealed, because hundreds if not thousands of people are now coming forward. The only way we can make sure that this does not go on is to continue to expose every part of it, every plan, every diabolical strategy that was involved in these awful experiments. And this committee is determined to make sure that just that happens.

Before recognizing the chairman of the Budget Committee, Martin Sabo, I am pleased to recognize Mr. Al McCandless, the ranking minority member from California, who is also winding up a very distinguished career in Congress as a leader on this committee. As

one whose helpfulness has been very important to the legislative products of the committee, his absence in the next Congress will be sorely missed.

Mr. Al McCandless.

Mr. MCCANDLESS. Thank you, Mr. Chairman.

Today our committee addresses a topic of serious and tragic dimensions: government-sponsored human experimentation during the cold war period. The value our Nation and society places on individual human life separates us from the vast majority of nations in the world. In America, everyone's life deserves equal protection.

The sanctity of human life in our culture is largely responsible for the hope that the United States historically has represented to the people around the world.

The cold war, however, confronted our Nation and indeed the world with the prospect of complete annihilation. The fear and urgency of the time remains with those of us who lived through it. As we increasingly learn about some of the measures that our government undertook to fight and win the cold war, we realize what a high price our Nation and the brave citizens in uniform paid to prevail.

It is also clear that regardless of the fear and urgency of the time, serious mistakes were made. Today's hearing will examine some of the tragic lessons and legacies of the cold war. We must indeed never forget the horrors posed by possible nuclear annihilation of the entire human race and the horror of losing a single individual life, regardless of the purpose.

Accordingly, Mr. Chairman, I look forward to hearing from our witnesses today and hope that they can help us prevent the future recurrence of the tragic mistakes that we experienced in the past.

Thank you.

Mr. CONYERS. Thank you very much. Without objection, we have a statement from Bill Clinger of Pennsylvania that will go into the record, as will the statements of any other members of this subcommittee.

[The prepared statement of Mr. Clinger follows:]

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Statement
of the Honorable William F. Clinger, Jr.
Subcommittee on Legislation and National Security
September 28, 1994

Thank you, Mr. Chairman. I certainly concur with my distinguished colleague from California -- the legacies of the Cold War are ones that we should never forget.

Today, we will examine one of the more troubling legacies of the Cold War era -- human experimentation. Certainly, for those citizens and their families who suffered as a result of these tests, nothing can recoup the precious life that was harmed or lost. As my colleague has stated so well, the value we Americans place on individual human life sets us apart from most nations in the world. We should never lose this distinguishing trait.

In keeping with our concern for the lives of our citizens, we should go back and re-examine after every war or armed conflict what we did and why, and what mistakes were made that cost lives. The Cold War is no exception.

Accordingly, I welcome today's hearing with the hope and expectation that we will all join together in a constructive effort to understand what happened and what we are or should be doing today to ensure the same tragedies are not repeated.

###

Mr. CONYERS. One of our great leaders in the Congress, Martin Sabo, is here. We are delighted that he is with us today. We have a letter from your Senator, Paul Wellstone, that without objection we will include in the record. If you have not seen it, I would like you to have a copy of it as well.

[The prepared statement of Mr. Wellstone follows:]

PAUL D. WELLSTONE
MINNESOTA

United States Senate

WASHINGTON DC 20510-2303

September 27, 1994

The Honorable John Conyers Jr.
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

I want to commend you for holding a hearing Wednesday to shed light on the sad secret of U.S. government experimentation on its citizens during the Cold War. One aspect of this testing is of grave concern to many Minnesotans and other Americans, and I would like to submit the enclosed pertinent materials for the record.

During the 1950s and 1960s, the U.S. Army conducted numerous open-air experiments of biological and chemical warfare methods in Minneapolis and other areas of greater Minnesota, the United States and Canada. These tests involved the spraying of varying quantities of zinc cadmium sulfide, a fluorescent powder, to simulate dispersion patterns of actual biological or chemical agents.

At the time, the Army considered zinc cadmium sulfide to be a harmless substance. However, numerous Minnesotans, including former students of an elementary school downwind of several tests conducted in Minneapolis in 1952, now suffer from various adverse health effects ranging from reproductive difficulties to cancer. They wonder if their illnesses are linked to the tests to which they were unwittingly subjected.

The enclosed reports detail the known or probable adverse human health effects of cadmium, the most toxic ingredient in zinc cadmium sulfide. One of the reports, a paper by Dr. Leon Prodan published in 1932 -- a full two decades before the Minneapolis sprayings, asserts that inhalation or ingestion of even small amounts of cadmium or its compounds can pose serious dangers to human health.

Also enclosed is a 1973 paper that cites potential health hazards of zinc cadmium sulfide and urges caution in the handling and use of the fluorescent powder in open atmospheric experiments. The final report enclosed is the U.S. Agency for Toxic Substances and Disease Registry's toxicological profile of

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cadmium and cadmium compounds.

It is clear from these documents that zinc cadmium sulfide is harmful to people who are exposed to it and that further study is needed. To that end, Congressman Martin O. Sabo and I have secured funding in next year's defense budget for an independent study by the National Academy of Sciences.

Your hearing is an important part in the federal government's ongoing disclosure of the nature, extent and effects of Cold War experimentation on U.S. citizens. I appreciate your consideration of testimony regarding the zinc cadmium sulfide experiments, and I hope that these documents I have supplied for the record will be helpful.

Sincerely,

Paul Wellstone

Paul David Wellstone
United States Senator

PDW:krb

Mr. CONYERS. Congressman Sabo, we are delighted to begin the hearing with your testimony.

STATEMENT OF HON. MARTIN OLAV SABO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MINNESOTA

Mr. SABO. Well, thank you, Mr. Chairman.

It is a privilege to be here again. I appreciate your invitation to testify. It is different being here on a subject other than budget process. I appreciate this opportunity.

And to Mr. McCandless, let me say I wish him well in his future endeavors. We are going to miss you in the Congress. I know you will enjoy yourself and work on that golf game.

But I want to thank you for holding this hearing. The broad outlines of the Army's biological testing program have been known for many years. When details emerged earlier this year about spraying of zinc cadmium sulfide in Minneapolis, however, people in my district were stunned.

The idea that the government would use its own citizens as guinea pigs is appalling, and I condemn it in the strongest possible terms. We need a complete release of all relevant information, and an independent assessment of the damage the spraying might have caused. Your hearing will help us achieve these goals.

As we know, the Army conducted extensive spraying of zinc cadmium sulfide at several locations in Minneapolis in 1953. Citizens were not warned of the program. Indeed, I assume the program's value to the Army would have been eliminated if people had known about the testing, since many would have left the affected area. Among the sites was the former Clinton school, where as many as 600 children were exposed to this compound.

In 1953, little was known about the adverse health effects of exposure to cadmium, which was an essential element in this compound. Now we know that cadmium causes certain types of cancers, and the substance has been labeled as carcinogenic.

I have two specific goals relating to this spraying. First is the release of all relevant data. Responding to the encouragement of my colleague from Minnesota, Senator Paul Wellstone, the Army has released hundreds of pages of documents. I am not convinced that everything has been made public, however, and we must push for continued document searches at Army archives. Along these lines, I will be writing to the Secretary of the Army Togo West within the next few weeks on behalf of current and former Minneapolis residents who have asked the Army to release any individual medical records it may have.

Second, we need an independent assessment of the possible health effects from the spraying. The Army has concluded that the levels of cadmium were so low that no adverse health effects were possible. However, the residents of Minneapolis would feel more comfortable with a study conducted by an organization other than the Army, since it clearly has some institutional incentives to minimize the spraying's impact. Therefore, at my request, the House Appropriations Committee has added $1 million to the Army's fiscal 1995 budget for a health effects study by the National Academy of Sciences.

The release of all pertinent information coupled with the completion of an independent health study will shed light on a clouded part of our cold war history. We owe it to the American people to investigate the impact of the chemical separation and to share our findings with those who may have been affected.

Again, Mr. Chairman, thank you for scheduling this hearing. I look forward to hearing from the remaining witnesses and your conclusions.

Thank you very much.

Mr. CONYERS. Thank you very much, Mr. Sabo.

Here we are dealing with the spraying of zinc cadmium sulfide, a poison which enters the body mainly through the respiratory system, and second through the gastrointestinal tract. That doesn't sound like harmless biological testing to me. Have there been citizens from your State that have come forward with complaints that they tracked to this activity?

Mr. SABO. There are numerous questions. There clearly are many residents of that area, including particularly the students who were at the school, who are very concerned. Many of them have thought that they have noted over the years different health patterns emerging from students who were at the school at that point of time. I am not in a position to make a judgment as to whether that is accurate or not.

That is one of the reasons we pursued the separate funding for a separate and independent study of the impact of the spraying in Minneapolis in 1953 and some other communities around the country, including St. Louis.

Cadmium, as I understand it, has been labeled a carcinogenic in recent years and clearly has the potential of having had an adverse impact on people involved.

Mr. CONYERS. Well, I think that is an important appropriation that you have added and, of course, we support it completely. I think that the study goes just beyond Minnesota; it is of national consequence. We have medical studies going back to the 1930's that have pointed out that there is a very dangerous potential to this particular poison. I am amazed that it can be brushed off as something that is probably not consequential. So we will be looking forward to the medical results of the people that are coming forward who are probably now, what, in their 40's?

Mr. SABO. Or older. Probably—could be late 40's, early 50's. I might indicate, as background to the amount of money and using the Academy of Sciences, we inquired of our department of health in Minnesota whether they thought this was an appropriate agency to do the study and whether the amount of money we had appropriated was enough to have a thorough study.

They indicated in both cases they thought the amount of money and resources involved was approximately right, and that this was a good agency to do the study.

Mr. CONYERS. Well, I will be joining with you and Senator Wellstone to ask the Secretary of the Army, Togo West, to expeditiously release all of the medical records and related papers dealing with this subject. It is very important.

One thing that we should establish at the outset of this hearing; we are trying to find out what happened. It is very important that

we know what happened. As tragic as it is, the worst thing would be that we brush past this—to try to conceal it or cover it up in any way. I am hoping that the entire defense establishment cooperates with this committee and other committees in the Congress that will be working on this.

I want to commend you for joining us here, and ask Mr. McCandless if he has any questions.

Mr. MCCANDLESS. I have two very quick ones, Mr. Sabo. First, have you been able to find out the intended purpose of this experiment at the location using the ingredients we have been talking about?

Mr. SABO. I think it involved—it is an urban area, it involved certain climate, certain wind, and the impact of all of those things.

Mr. MCCANDLESS. In going through this material, I keep coming back to the same question: At what point in the chain of command does someone have the authority to order this type of an experiment carried out? Have you come across anything that would shed some light on that?

Mr. SABO. Who made the decision, that, I do not know. Apparently there were some conversations with some officials in the city about this spraying, but they clearly had no idea of what its impact was. And as relates to some of the individual medical records, we have asked the Army or will be asking the Army to search their archives to see if they exist. Some of the students recall going through some medical examinations at school after they didn't know what those were about, and we are very curious whether any such records still exist. I must say that the Army has released many, many documents relating to the study, but we want them to continue to see if these individual medical records also exist.

Mr. MCCANDLESS. What I am trying to put into perspective here is, obviously, this had medical overtones to it of some nature, so we would assume that someone in the hierarchy of the medical part of the Defense Department was the instigator or promoter of this, and did that person or persons then require the approval of the Secretary of Army, the Secretary of Defense, or the President?

Mr. SABO. That I don't know. That information might be in the records. If it is, I do not know the answer to it.

Mr. MCCANDLESS. Thank you.

Mr. CONYERS. Marty, we have 239 cities involved in what happened to your city. Minneapolis, St. Louis, Detroit, Toledo, Springfield, IL—we are trying to make sure that the names of these cities are declassified so they can be released. If they are not declassified, I am going to ask that that happen right away.

But through the line of flight, we can determine some of these cities. If cadmium is as dangerous as we suspect it might be, the estimated half million people who were involuntarily involved in testing would rise exponentially. We are talking about a lot of people who could be involved. So we will be working very closely with you and Senator Wellstone.

Mr. SABO. I appreciate it.

Mr. CONYERS. We thank you for joining us today.

I am pleased now to call the Assistant Comptroller General of the United States, Mr. Frank Conahan, who is accompanied by Mr.

Glenn Furbish, senior evaluator at GAO. Mr. Conahan has overseen an overview on cold war experimentation.

At the outset I want to commend him for beginning the first thorough study of the cold war era tests. The revelations of particular experiments goes back to the Church Committee hearings in the mid-1970's. GAO tries to provide a wider understanding of this matter than that revealed by Secretary O'Leary, when she made the first stunning release of these materials as they affected her particular Department.

We would invite you to proceed in your own way.

STATEMENT OF FRANK C. CONAHAN, ASSISTANT COMPTROLLER GENERAL, NATIONAL SECURITY AND INTERNAL AFFAIRS DIVISION, U.S. GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY GLENN D. FURBISH, SENIOR EVALUATOR

Mr. CONAHAN. Thank you, Mr. Chairman, Mr. McCandless. We do appreciate the opportunity to be here today at this very important undertaking.

Let me start by emphasizing at the outset that precise information on the scope and magnitude of government tests and experiments involving human subjects is not available, and exact numbers may never be known. I think that is a point we need to understand up front.

There are a number of reasons for this. No. 1, government information is incomplete. We have established that, and I can talk more about why. In addition, some records have been lost or destroyed, and existing documentation is limited in several respects. One important respect, is that the names of individuals who have been subject to testing and experimentation is not always included in the documentation. It may be available with contractors or other institutions, but government agencies, in many cases, have not gone after it.

So, I think that there are continuing areas of inquiry, but as things stand presently, that information is not available. Therefore, it remains to be seen as to precisely how much will be known at the conclusion of this terribly difficult situation we find ourselves in.

Notwithstanding, as you said, hundreds of tests have been conducted over the years involving hundreds of thousands of people. These tests involve exposing people to hazardous substances, such as radiation, blister, and nerve agents, biological agents and LSD. As you also mentioned, various groups of people have been subjected to these tests, both with and without their knowledge and/or consent.

My prepared statement which you have entered into the record, describes several of the cases which we think are important for consideration in this hearing. You cited a number of examples in your own opening statement and Mr. Sabo talked about one that is of particular interest to him. Therefore, I am not going to cite too many additional. But what I would like to do, is talk about the particulars of two or three which I think are important.

In a series of experiments in the 1940's and 1950's, the Atomic Energy Commission and the U.S. Public Health Service did research on a large number of individuals exposing them to doses of

radiation. This involved children as well as adults. It wasn't however until many years after those experiments that the individuals realized the nature and risk associated with the exposures. This is important because long periods of time often expire before people really become aware of what they have been subjected to in the radiation area.

The subjects of chemical testing have not fared any better. Tests in the chemical area have been done without the knowledge or consent of individuals, and without their knowing the full risks involved.

One of the problems we face in dealing with those groups is that in many cases, records were not kept in a manner that readily identifies the participants. I will talk a little bit later about recommendations we have made to improve that situation. But we will have to reserve judgment on how far we can go down that road.

In addition to in-house tests, there were also a number involving contractors. The Army Chemical Corps, for example, contracted with universities, hospitals, and other institutions to research the destructive influence of psychochemical agents on combat troops. The Air Force did likewise. I believe you referred to one series of Air Force experiments in your opening statement where approximately 100 people received LSD. We can talk further about that, if necessary, during the Q&A.

You talked about other agencies such as the CIA. Of course, the record shows those agencies were indeed involved in this kind of experimentation.

Now, our information on biological tests and experiments is not as extensive as it is in the other areas. I just need to note that. I don't know what additional work would show, but as has already been said here, between 1949 and 1969, several hundred biological tests were conducted. For the most part, the subjects, unaware populations were sprayed with bacterial tracers or simulants.

Mr. Sabo talked about one of particular concern to him. Some of these were wide area experiments but others were localized, such as right here at the Washington National Airport, and a similar experiment in the vicinity of the New York City subway system. So these things went across the board. Although the government has clearly sponsored extensive research, the effects of the experiments and tests were often difficult to determine. At the time of the test, some people were clearly harmed. In other cases, it took a long period of time to determine what the harm, if any, was. As a result, we have to look at these things individually, and generalizations should not be made in that regard.

We did a report in February 1993 where we discussed the results of claimants looking for redress against harm done by chemical testing. What we found, was that a good number of those people could not prove their health problems were caused by participation in tests. One of the big factors, again, was information, although there were some other problems, too.

Now, let me turn—yes, sir.

Mr. CONYERS. Mr. Conahan, how could a citizen prove to his government that there was a causal connection between a secret experiment and his illness?

Mr. CONAHAN. When the government, one, has the information, is willing to make that information available, and the individual indeed has an illness or ailment that matches up with what the agent of that experiment would cause, and that match can be made. Under the current regulations that individual is able to get redress from the government.

The key here is the information, in the very first place.

Mr. CONYERS. Exactly. You can see that is one hell of a burden that we are putting on citizens.

Mr. CONAHAN. I think that citizens in this case need the help of government to the extent that government is going to provide that redress.

Mr. CONYERS. Right. I know there are problems on both sides, but I am just thinking of the recently concluded health care debates that got us nowhere. Thirty-eight million people without any health insurance whatsoever. They can't get contemporary health care, much less research a problem unless there is a lot of government help, and that is what you are pointing out here, is that we need more resources on the government's side helping to try to make sense of where we are on this.

Not that every allegation proves the point; but that we have a mechanism that would facilitate us determining this in an expeditious and hopefully uncostly manner to the people that are involved.

Mr. CONAHAN. I think we need to describe where the real fault lies. We do have programs within the Veterans Administration and within the Department of Labor that provide both medical care and disability benefits for people who have been harmed by these experiments.

The key is in the individual's ability to prove that fact, and I think that we need to spend a good bit of time dealing with that issue. That is the key and it goes to your issue of resources and greater emphasis.

Now, there have been special efforts since the 1970's to help certain individuals. But this has been particularly in the area of radiological experimentation, and efforts such as those, are as far along in the area of chemical and biological experimentation.

Again, our February 1993 report laid out the problems with respect to chemical experimentation, and we made a series of recommendations. I am happy to report the Department of Defense responded in a positive way to those recommendations. The Department of Defense did set up a Chemical Weapons Exposure Task Force to identify the information that individuals needed, and tasked the services to provide that information.

So while the response was positive, I have to report that the actual implementation has not been as positive. No. 1, the task force has but one full-time investigator and the Army and the Navy have not yet designated points of contact. And to date, none of the services have really conducted thorough or complete searches of their data bases.

Without this assistance, the Veterans Administration continues to have great difficulty in assisting claimants. Earlier this month, as a matter of fact, the Veterans Administration told us that they

still misdirect as many as 100 applications per month because adequate information is not available.

In recognition that the situation with respect to biological experimentation is very, very similar to the chemical area, the Department of Defense extended the response to our recommendations to include the biological area. Also, as Mr. Sabo reported earlier, the fiscal year 1995 appropriations bill includes $1 million to further study the possible effects of one of the simulants used in a series of biological tests, one of which was discussed by Mr. Sabo.

I would like to point out, or perhaps remind, the panel at this time that because of the difficulty that individuals have had over the years in pursuing their interests, there has been a need for special efforts. We have seen these come through the courts, we have seen these come through the Congress, and as a matter of fact, there has been special legislation providing benefits to some people. Some of these are included in my statement.

Finally, let me say a few words about government efforts to strengthen the protection of human participants. Guidance in this regard has been available since right after the Second World War but it simply was not always followed. We have example after example of that.

It was not until the 1970's, that the Congress and the executive agencies focused on this in any great way whatsoever, at which time I think we have to take note that there was a rather significant event in 1974, when the then—HEW did prescribe regulations to strengthen informed consent procedures and institutional review requirements. That was further strengthened by HHS in 1991, and it was adopted by some 16 other agencies, to include the Department of Defense, the CIA, and others.

So those requirements have now been clarified and strengthened. The consent procedures and the review requirements are fairly explicit. They have not, as far as I know, been reviewed very well. And I can report that we are currently reviewing the implementation of those regulations, and will report to the Congress upon completion of that work.

I suppose, Mr. Chairman, that is all I need to say for summary purposes. We are available for your questions.

[The prepared statement of Mr. Conahan follows:]

United States General Accounting Office

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Human Experimentation

An Overview on Cold War Era Programs

Statement of Frank C. Conahan, Assistant Comptroller General, National Security and International Affairs Division

GAO/T-NSIAD-94-266

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the use of humans in tests and experiments conducted for national security purposes by the Department of Defense (DOD) and other agencies between 1940 and 1974. As you requested, we collected information on the scope of these experiments and their possible impact. We obtained information on (1) the magnitude and scope of human subject experimentation, (2) the potential effects of the experiments on human subjects, (3) government efforts to assist those who may have been injured or suffered adverse health effects as a result of the tests or experiments, and (4) measures to ensure that informed consent is secured and that volunteers are protected in government-sponsored experiments.

BACKGROUND

As you requested, we focused our work on defense-affiliated programs that used human test subjects between 1940 and 1974. The programs included tests and experiments conducted or sponsored by the Departments of the Army, the Navy, and the Air Force; the Defense Nuclear Agency; the Central Intelligence Agency (CIA); the Department of Energy; and the Department of Health and Human Services. The tests and experiments involved radiological, chemical, and biological research and were conducted to support weapon development programs, identify methods to protect the health

of military personnel against a variety of diseases and combat conditions, and analyze U.S. defense vulnerabilities.

RESULTS IN BRIEF

During World War II and the Cold War era, DOD and other national security agencies conducted or sponsored extensive radiological, chemical, and biological research programs. Precise information on the number of tests, experiments, and participants is not available, and the exact numbers may never be known. However, we have identified hundreds of radiological, chemical, and biological tests and experiments in which hundreds of thousands of people were used as test subjects. These tests and experiments often involved hazardous substances such as radiation, blister and nerve agents, biological agents, and lysergic acid diethylamide (LSD). In some cases, basic safeguards to protect people were either not in place or not followed. For example, some tests and experiments were conducted in secret; others involved the use of people without their knowledge or consent or their full knowledge of the risks involved.

The effects of the tests and experiments are often difficult to determine. Although some participants suffered immediate acute injuries, and some died, in other cases adverse health problems were not discovered until many years later--often 20 to 30 years or longer.

Federal programs provide benefits to former military and federal civilian employees who suffer from injuries or adverse health effects as a result of federal service. However, it has proven difficult for participants in government tests and experiments between 1940 and 1974 to pursue claims because little centralized information is available to prove participation or determine whether adverse health effects resulted from the testing. To address these problems, special efforts have been made by some involved agencies to help groups of test participants obtain the information necessary to pursue claims. For example, the Department of Veterans Affairs (VA) relaxed its requirement that participants link their health problems to those tests or experiments. Also, since 1978 DOD has had a program to identify and provide information to participants in atmospheric nuclear tests that were conducted between the 1940s and 1960s. More recently, in January 1994, the administration established an advisory committee to identify participants in other government-sponsored radiation research. We are reviewing the efforts of the committee at the request of the Senate Committee on Governmental Affairs.

In other areas, however, special efforts to make information available on test participants are not as far along. For example, DOD recently recognized a need to identify and assist participants in chemical tests conducted prior to 1968, but to date limited resources have been applied. We were told earlier this month that

the VA continues to have difficulty processing claims because it cannot obtain necessary information from DOD. Some participants or their survivors have pursed benefits or compensation, outside existing federal programs, through specific congressional action or court awards.

Although military regulations in effect as early as 1953 generally required that volunteers be informed of the nature and foreseeable risks of the studies in which they participated, this did not always occur. Some participants have testified that they were not informed about the test risks. Government testing and experimentation with human subjects continues today because of its importance to national security agencies. For example, the Army's Medical Research Institute for Infectious Disease uses volunteers in its tests of new vaccines for malaria, hepatitis, and other exotic diseases. Since 1974, federal regulations have become more protective of research subjects and, in general, require (1) the formation of institutional review boards and procedures and (2) researchers to obtain informed consent from human subjects and ensure that their participation is voluntary and based on knowledge of the potential risks and benefits. We are in the process of reviewing the effectiveness of these measures. A National Institutes of Health official has stated that no mechanism exists to ensure implementation of the key federal policies in this area.

THE GOVERNMENT HAS SPONSORED EXTENSIVE TESTING, BUT PRECISE INFORMATION ON TESTS AND PARTICIPANTS IS NOT AVAILABLE

Precise information on the scope and magnitude of government tests and experiments involving human subjects is not available, and exact numbers may never be known. However, our review of available documentation and interviews with agency officials identified hundreds of tests and experiments in which hundreds of thousands of people were used as subjects. Some of these tests and experiments involved the intentional exposure of people to hazardous substances such as radiation, blister and nerve agents, biological agents, LSD, and phencyclidine (PCP). These tests and experiments were conducted to support weapon development programs, identify methods to protect the health of military personnel against a variety of diseases and combat conditions, and analyze U.S. defense vulnerabilities. Healthy adults, children, psychiatric patients, and prison inmates were used in these tests and experiments.

Documenting the precise number of tests and participants is difficult because government information is incomplete. Some records have been lost or destroyed, and existing documentation contains limited information and often does not identify names of participants. Moreover, these records are spread throughout the country at the National Archives, Federal Record Centers, other government offices, and the military commands or organizational units that created them. Some of the records measure thousands of

linear feet, and the availability and quality of indexes to the records vary widely.

I will describe a few of the radiological, chemical, and biological research projects that illustrate the scope and magnitude of governmental experimentation.

Radiological Tests and Experiments

To date, over 200 radiation tests and experiments have been identified involving over 210,000 test participants. Although not involved in a test or experiment, another 199,000 people were exposed to radiation through work. This latter group is of concern because the effects of the exposure are the same as those incurred by test participants. The radiation tests are generally recognized as involving the largest number of test participants.

The largest known test program was the atmospheric nuclear test program conducted from 1945 to 1962. The purpose of this program was to develop weapons and to gain a better understanding of the tactical effect on troops. Over this 17-year period, approximately 210,000 DOD-affiliated personnel, including civilian employees of DOD contractors, scientists, technicians, maneuver and training troops, and support personnel, participated in 235 atmospheric nuclear tests. We reported on two of these tests, known as

Operation Crossroads, in 1985.[1] In some tests, participants were directly exposed to radiation. For example, in one test, five individuals were located directly beneath a high-altitude test. In other tests, 37 individuals were located in trenches from 2,000 to 2,600 yards from ground zero, and in others, approximately 26,000 individuals occupied trenches, bunkers, and armored vehicles from 2,500 to 5,500 yards from ground zero. According to DOD officials, as many as 150,000 of the 210,000 participants may have been exposed to fallout. In addition, 195,000 U.S. service members may have been exposed to radiation during the occupation of Hiroshima and Nagasaki, and over 4,000 other service members may have been exposed during cleanups at Bikini, Enewetak and Johnston Atolls after nuclear tests were conducted. Some participants have alleged that they were not fully informed or did not understand the potential health risks of exposure to radiation.

In a series of experiments conducted between the 1940s and 1960s, the Atomic Energy Commission and the U.S. Public Health Service funded research of the potential medical effects on people from fallout after a nuclear attack or accident. In some of the experiments, university researchers exposed mentally disabled children to low doses of radiation. Years after the experiments were completed, a task force found that researchers failed to satisfactorily inform the subjects' families about the nature and

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[1]Operation Crossroads: Personnel Radiation Exposure Estimates Should Be Improved (GAO/RCED-86-15, Nov. 8, 1985).

risk of the experiments in order for them to make an informed decision when they gave their consent. The president of one of the universities involved in the experiments later apologized for the use of children and the failure to provide full information about the nature and risk. We are not aware of what, if any, further action was taken in this case.

Chemical Tests and Experiments

During World War II and the Cold War era, the Army and the Navy conducted two major chemical research experiments in which thousands of service members were used as test subjects. An unknown number of other chemical tests and experiments were conducted under contracts with universities, hospitals, and medical research facilities. In some of the tests and experiments, healthy adults, psychiatric patients, and prison inmates were used without their knowledge or consent or their full knowledge of the risks involved.

During World War II, the Army conducted tests of protective clothing and equipment in which thousands of people were exposed to mustard gas and lewisite agents. In addition, the Army developed and tested offensive chemical weapons and evaluated the effectiveness and persistency of mustard agents in different environments. In February 1993, we reported that the Army's records of its mustard test activities were not kept in a manner

that readily identifies the participants.[2] However, the available records show that 1,002 soldiers were commended for their participation in tests in which they subjected themselves to pain, discomfort, and possible permanent injury for the advancement of research in protection of the armed services.

Similar to the Army's tests, the Navy conducted tests of clothing and equipment that exposed thousands to the effects of mustard gas and lewisite agents. These experiments involved (1) gas chamber tests, in which service members were completely exposed to mustard and lewisite agents while wearing protective clothing, and (2) skin tests, in which amounts of mustard agent and antivesicant ointments were applied to service members' forearms. The Navy has a list of the names of approximately 3,200 sailors who participated in mustard and lewisite agent tests performed by the Naval Research Laboratory. Additionally, Navy officials told us that between 15,000 and 60,000 Navy recruits had participated in skin tests conducted by a contractor but that the Navy had no record of the recruits' names.

From 1952 to 1975, the Army conducted a classified medical research program to develop incapacitating agents. The program involved testing nerve agents, nerve agent antidotes, psychochemicals, and irritants. The chemicals were given to volunteer service members

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[2]Veterans Disability: Information From Military May Help VA Assess Claims Related to Secret Tests (GAO/NSIAD-93-89, Feb. 18, 1993).

at the Edgewood Arsenal, Maryland, and four other locations. Army documents identify a total of 7,120 Army and Air Force personnel who participated in these tests, about half of whom were exposed to chemicals. The Army's Medical Research and Development Command in Fort Detrick, Maryland, has the names and service numbers of all test participants and a list of the chemicals to which the service members were exposed. Some service members have testified before congressional committees that they were not fully informed of the risks involved.

During the same period, the Army Chemical Corps contracted with various universities, state hospitals, and medical foundations to research the disruptive influences that psychochemical agents could have on combat troops. The Air Force also conducted experiments on the effects of LSD through contracts at five universities. According to Air Force officials and records, approximately 100 people received LSD in these experiments. No effort has been made by the Air Force to determine if the participants' names are available in the universities' records.

According to a CIA official, from 1953 to about 1964, the CIA conducted a series of experiments called MKULTRA to test vulnerabilities to behavior modification drugs. As a part of these experiments, LSD and other psychochemical drugs were administered to an undetermined number of people without their knowledge or consent. According to the official, the names of those involved in

the tests are not available because names were not recorded or the records were subsequently destroyed. However, some tests were done under contract, and no effort has been made by the CIA to determine if names are available in contractors' records.

Biological Tests and Experiments

The Army conducted a series of biological warfare experiments and tests between 1949 and 1974. The purpose of these tests was to determine U.S. vulnerabilities to biological warfare. For example, between 1949 and 1969, the Army conducted several hundred biological warfare tests in which unaware populations were sprayed with bacterial tracers or simulants that the Army thought were harmless at that time. Some of the tests involved spraying large areas, such as the cities of St. Louis and San Francisco, and others involved spraying more focused areas, such as the New York City subway system and Washington National Airport.

In another Army experiment conducted between 1959 and 1974, approximately 2,200 volunteers were exposed to biological pathogens, such as Venezuelan Equine Encephalitis and Tularemia, as part of research to develop vaccines and antidotes. A list of all studies and medical records of all volunteers are located at the Army's Medical Research Institute of Infectious Diseases in Fort Detrick, Maryland. It appears that the participants were adequately informed.

EFFECTS OF EXPERIMENTS
ARE OFTEN DIFFICULT TO DETERMINE

The effects of government tests on participants' health have been difficult to determine. At the time of the tests, some people were clearly harmed. However, in other cases, possible adverse health effects related to the substances used were unknown or did not become apparent until years later.

Available records show that people suffered immediate acute injuries in some tests and that people died in at least two tests. For example, available records show that some participants in the Army's and the Navy's mustard and lewisite tests suffered burns and required hospitalization. Also, in a highly publicized case, an Army employee died in 1953, a short time after participating in a CIA experiment using LSD.

However, for some test participants, the test effects were not readily apparent. In these cases, claimed adverse health problems did not appear until many years later. For example, in our February 1993 report on the Army's chemical testing program, we noted that the first health problems for most of the veterans who sought assistance appeared many years after their military service and at a time when these same ailments typically show up in their general age population. Further, only a few of the veterans alleged that their health problems were long term in nature, dating

back to their active military duty. We reported that 97 of 145 veterans seeking assistance could not prove that their health problems were caused by participation in a test or experiment.

Research studies have also shown that exposure to some of the substances used in the tests may create health problems that often will not appear for many years. For example, the National Academy of Sciences concluded in 1993 that exposure to mustard agents could cause many serious diseases that would not immediately appear, such as leukemia, emphysema, respiratory and skin cancers, and eye diseases, and that lewisite agents could cause some of these same diseases.

INFORMATION AVAILABLE TO ASSIST
TEST PARTICIPANTS VARIES

Two federal agencies, the VA and the Department of Labor, have programs to provide medical care and disability benefits to former military and federal civilian personnel who have experienced health problems as a result of their participation in government tests or experiments. However, because there is not complete information on those who participated and the precise adverse health effects of their participation, it has often proven difficult for former test participants to pursue claims. To address these problems, special efforts have been made by some involved agencies to help groups of test participants obtain the information necessary to pursue

claims. Other involved agencies, however, are not providing the information test participants need. Apart from the information issue, some participants or their survivors have sought compensation or benefits directly through civil or specific congressional actions.

The largest special information assistance effort is the Nuclear Test Personnel Review program, established by DOD in 1978. This program, administered by the Defense Nuclear Agency, has assisted veterans by compiling data on atmospheric nuclear tests, including the names of participants, the locations of the tests, and the amount of radiation administered during the tests.[3] This program also involves an extensive outreach program that provides documents about the tests and informs participants of the availability of VA-provided health care and disability benefits.

Other special actions have also been taken to help some veterans pursue health claims related to their participation in testing. In 1988, the Congress directed the VA to relax its claims adjudication procedures for veterans exposed to radiation resulting from atmospheric nuclear detonations. For veterans with certain ailments that may be attributable to radiation exposure, the VA presumes that the ailments are service connected. In 1992, the VA

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[3]In October 1979, DOD expanded the program to include U.S. service personnel who had participated in the postwar occupation of Hiroshima and Nagasaki.

amended its regulations so that veterans of mustard testing receive similar treatment if they develop certain diseases. In 1994, the regulations were further amended to include lewisite.

Earlier this year, the administration initiated a large effort to gather data on people who participated in experiments involving intentional exposure to ionizing radiation and intentional environmental releases of radiation. The Presidential Advisory Committee on Human Radiation Experiments, established in January 1994, is conducting this review. We are currently reviewing the efforts of the advisory committee at the request of the Chairman, Senate Committee on Governmental Affairs.

Let me describe some areas in which information is still needed.

Our February 1993 report stated that the military services lacked complete information on their chemical test activities and recommended that DOD aggregate the information and provide a point of contact within each service to assist veterans in obtaining information about their test experiences. DOD, in turn, established the Chemical Weapons Exposure Task Force to identify chemical test information and tasked the Secretaries of the Army, the Navy, and the Air Force to provide information related to the tests to the task force. However, to date (1) the task force employs only one full-time investigator, (2) the Army and the Navy have not designated points of contact to lead this effort, and (3)

the services have not conducted a complete and thorough search of their records. Without this assistance, the VA continues to have difficulty assisting former test participants. For example, we were told in September 1994 that VA claims adjudicators misdirect over 100 test information requests monthly because they do not know which agency should receive them.

A similar situation exists with some other groups. For example, some agencies have made little effort to assist test participants by identifying test locations and participants in experiments conducted by contractors. The CIA, in fact, has not released the names of 15 of the approximately 80 organizations that conducted experiments under the previously discussed MKULTRA program because the organizations do not want to be identified.

Conclusive information on the effects of some biological simulants used in the Army's testing is not available. Recently, the Army had the Centers for Disease Control review its risk assessments for one simulant used in some of its biological warfare tests. The Center determined that adverse health effects from the levels of exposure to the simulant, zinc cadmium sulfide, at those sites were very unlikely. However, the Fiscal Year 1995 Defense Appropriation Bill provides $1 million to further study possible adverse health effects of exposure to this simulant.

Finally, in the case of civilian government employees, whose claims for compensation are processed through the Department of Labor, we were told that the rules have not been relaxed in the same way as they have been at the VA. In some cases, civilian employees participated in the same testing as military service members.

In selected cases, test and experiment participants have received compensation as a result of a civil action or specific congressional action. For example, in 1976 the President signed legislation providing $750,000 to the family of an LSD test participant who died in 1953 shortly after being administered LSD.[4] Also, the Justice Department settled a suit brought by another group of LSD test participants for $750,000. Another example of a specific congressional action is the establishment of a $100 million fund to cover claims from individuals who lived downwind from locations where above-ground nuclear tests were conducted.[5] Similarly, another act authorized $184 million for Marshall Islands citizens who may have been exposed during nuclear testing.[6] These funds are distributed to individual islands and disbursed by the local governments.

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[4]Private Law 94-126.

[5]The Radiation Exposure Compensation Act (P.L. 101-426).

[6]The Compact of Free Association Act of 1985 (P.L. 99-239).

GOVERNMENT EFFORTS TO STRENGTHEN THE PROTECTION OF HUMAN PARTICIPANTS

Although guidance for protecting human subjects has existed since the post-World War II Nuremberg trials, the principles were not always followed by U.S. government researchers. It was not until the 1970s that the Congress and some agencies became actively involved in examining human research ethics and establishing laws and regulations that became progressively more protective of human subjects. In 1974, the Department of Health, Education, and Welfare issued a regulation strengthening the Department's informed consent procedures and institutional review requirements. In 1991, the Department of Health and Human Services issued a revised, uniform regulation for the protection of human subjects that was adopted by 16 federal agencies, including DOD, CIA, and other national security agencies.

The 1947 Nuremberg Code of Ethics established the fundamental principles for scientists and physicians involved in using people as subjects in experiments and tests. In the Nuremberg Code, the respect for the human rights of patients, including their voluntary consent and their safety from undue physical or psychological harm, was of paramount consideration. A 1953 memorandum from the Secretary of Defense to the secretaries of the military services directed them, in essence, to adopt the Nuremberg Code as a guide for human experimentation. However, according to defense

officials, some of the rules, including those related to the quality of informed consent and the capability of the subjects to withdraw without prejudice, were not followed in the 1950s and 1960s.

In 1964, the Declaration of Helsinki emphasized that clinical research using people as subjects should be (1) based on laboratory and animal experiments or on scientifically established facts, (2) conducted by scientifically qualified medical persons, (3) preceded by a careful assessment of the inherent risks versus benefits, and (4) generally done with disclosure of the risks to the subjects and with the subjects' free consent. In November 1966, the American Medical Association adopted the ethical principles of the Helsinki Declaration to guide physicians engaged in clinical research and investigations of new drugs and procedures.

The federal regulation issued in 1974 by the Department of Health, Education, and Welfare covers the protection of humans in experiments and tests and requires all institutions carrying out research funded by the department to have an Institutional Review Board. The boards are to review the risks and benefits of the proposed research, the specific procedures to be followed, and the process of informing the human subject and obtaining consent. The regulation also requires institutions to describe the test procedures and the foreseeable risks or discomforts and explain that subjects can refuse to participate at any time. In general,

federal departments incorporated parts or all of this regulation in their policies on human experimentation.

The Department of Health and Human Services' 1991 regulation replaced previous federal policies and regulations and clarified requirements for researchers to obtain informed consent from human subjects and ensure that their participation is voluntary and based on knowledge of the potential risks and benefits. The regulation was subsequently adopted by 16 other federal agencies.

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This concludes my prepared statement, Mr. Chairman. I will be happy to answer any questions.

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Mr. CONYERS. Thank you very much.

First I want to thank Mr. Furbish and the rest of your organization that has done a remarkable amount of research in a short time so that this hearing could be convened before the conclusion of the 103d Congress. We are indebted to you.

Mr. CONAHAN. We appreciate that, Mr. Chairman, because it has been a short time, and we hope that we are able to give you what you need.

Mr. CONYERS. Well, it is coming along. Without your organization, we would spend all of our efforts just on one subject, and as you know, we have about two dozen subjects pending in the Government Operations Committee.

Could you comment on the Nuremberg Code and the Helsinki agreements as they impact upon the protection that citizens have against improper government research among the countries that recognize these principles?

Mr. CONAHAN. I think that we all have been reminded often enough of the atrocities that were committed by the Nazi regime during World War II. The Nuremberg Code was intended to in part redress those atrocities. I think that there are two essential ingredients that people focused in on at that time. One was to ensure that the individual has the information necessary to know what he or she is agreeing to be subjected to. Second, that there is a mechanism in place to gain adequate consent. That theory—the fundamental right of individuals—was carried through the Nuremberg Code, the Helsinki Accord, and up through our own regulations adopted in 1974 and subsequently amended.

I think they are the two key fundamentals that happily have been recognized and brought along these years.

Mr. CONYERS. So we have got to make sure first of all that we are fully complying with these principles, and that informed consent is commonplace. Now, what about the violations that appear to have occurred anyway? Do those principles provide any relief to citizens of any country whose rights may have been violated?

Mr. CONAHAN. I am not aware of specific relief that is covered under any of those accords. In our own government, I would say that the Veterans Administration and the Department of Labor would be in a position to provide appropriate benefits for harm that was done as a result of the experiments.

Mr. CONYERS. Do you agree with our analysis that the President's Advisory Committee only includes radiation experiments and therefore we have got some more work to do in fashioning a relief mechanism for all of these other experiments—some of which are combinations and others are completely different from radiation?

Mr. CONAHAN. Not only, Mr. Chairman, do I agree with that, that is a fact that the President's Advisory Commission covers only radiological experimentation and not chemical, biological, and other medical tests, and therefore let me say a word about that.

I believe we have to wait and see the results of the President's Advisory Commission as I think it is a step in the right direction. I think they are going down the right track. I think they have publicized it so that folks who are in a position to help move things along can come in and help. I understand there will be a hearing

later this year, in the other body, at which time the progress of commission will be explored.

When it comes to chemical and biological, I don't believe we are near where we need to be in that regard. As I said, the Secretary of Defense, in response to the recommendation in our 1993 report, did set up this task force in order to explore the chemical question and its jurisdiction was later expanded to the biological area. But it has not received the kind of emphasis, resources, or commitment that I think are needed. Let me say here, because I think it is very important, that the individuals who are working in this area right now are very diligent, and I think that they are trying their very, very best to do a good job. So I am not talking about the individuals that are out there plowing this ground. They are doing a very good job, it has been our observation, and it has been the observation of others who have sought out their help. We are talking about the institutional commitment behind that effort.

Mr. CONYERS. We will be working toward fashioning relief mechanisms. I am not very enthusiastic about one commission after another—we will have a commission on this and a commission on that, and a commission on the other. It seems that we may have to go back to the drawing board to put together something more universal, so we can really look to one source as we review this unhappy part of American history rather than a variety of commissions. Although I have not consulted with anybody on the committee about it, we are going to be examining that facet as well. If you or Mr. Furbish have any recommendations that you would care to make to us, we would be glad to receive them.

Mr. CONAHAN. Thank you. We would do that, Mr. Chairman.

I would say at the outset that I fully agree that commissions seemingly don't do the job. We have seen commissions come and go, and not much in the way of results.

What we need to do is to institutionalize the mechanisms that are required in order to, one, provide the information, and two, find a way to make access to it user friendly for both the claimant, as well as, the adjudicators in the Veterans Administration and the Department of Labor. That is what is necessary.

Mr. CONYERS. I think you are right.

President Clinton may also want to come out and make an expanded statement, now that we have a lot more than was brought forward initially by Secretary O'Leary, whom I personally called to commend for her revelations. Obviously, her point of view is from the Energy Department, but these issues are far wider.

Our Veterans Administration is also deeply involved in this, because many of those involved in the military experiments are veterans now. It reminds me of Agent Orange, where we fought medically, legislatively, and administratively to get some understanding of what seemed to be a fairly obvious causal relationship between an event and injuries that resulted from it. It still took years. It seems to me that we ought to be looking very carefully at the Veterans Administration. I have plans for having public hearings involving them because their role becomes inordinately large, and it is important that we learn something from these past episodes like Agent Orange so the government does not go into this fighting and resisting the obvious.

Now, we are not here to judge with finality the allegations that are now being brought forward—some of them may not be able to be medically connected or related. But there are ways that the government goes about redressing the wrongs that have been committed which show that we are seriously concerned about changing what used to happen.

It is going to be very important that the VA play a constructive role in creating the positive outreach that will publicize this matter and get everybody in front of it that needs to be. I am very worried about the burden that a private citizen will have to bear to prove a medical history. I am also troubled by your work showing that we have only one or two people on these jobs at DOD. I don't know what the VA situation is, but we have to step it up on the government side so that we can solve this problem rather than try to drag it out. Your work has been very helpful in that regard.

Lastly, let's talk about the CIA. What is this MKULTRA program that they had going at one time? Second, what is the basis for the CIA's reluctance to release the names of the 80 organizations that conducted experiments under their sponsorship?

Mr. CONAHAN. The CIA during the 1950's and early 1960's conducted a series of tests to determine vulnerabilities to behavior modification drugs. LSD and other psychochemical drugs were administered to an undetermined number of people. We don't know the number because that information has never been released, but there is sufficient information to show that it was done without their consent or knowledge. Also, the names of the people involved are not available—primarily because the records have been destroyed. Some of these tests were done under contract with universities, but the CIA has not moved to determine the names of these individuals from the universities.

Mr. CONYERS. Do you get the feeling that this is something like a science fiction novel in which the unbelievable is being revealed? I mean, how does this affect us as government representatives who have the unhappy task of bringing this forward to the American people?

I know you don't enjoy this. You don't relish this investigations. But there is something eerie about this. It is beyond most people's rational anticipation, that their government could have been doing this after World War II and into the 1960's.

Mr. CONAHAN. I think, Mr. Chairman, we all agree that if our national security is truly at risk by divulging information, we can all agree to find an alternative to releasing that precise information. It strains me, however, in too many cases dealing with our national security agencies, to include specifically the Central Intelligence Agency, why they contend that information such as this needs to be protected for national security purposes.

Mr. CONYERS. It should be declassified at this point.

Mr. CONAHAN. I don't know why it hasn't been. As I say, in those cases where the demonstration has been made, fine. But in the absence of that demonstration, it should not remain classified.

Mr. CONYERS. Thank you.

The Chair recognizes Mr. Al McCandless.

Mr. MCCANDLESS. Thank you, Mr. Chairman.

Mr. Conahan, you have given us a pretty thorough overview and history of the period, particularly 1940 to 1974. To your knowledge, what tests if any have been continued beyond that point of 1974?

Mr. CONAHAN. Mr. McCandless, this is not in way of explaining away why I can't give you a full answer to that question, but it is important for me to say that in preparing for this hearing, we focused on the period up through 1974, since that is where the real problems seem to be.

Beginning in 1974, we did have government regulation, and continuing or new involvement and control mechanisms in this area. So we thought that at least the basic fundamental conditions were beginning to be corrected. Now, having said that, although we didn't focus on a later period, it is clear that medical research continues, hopefully, it continues under the ground rules of the 1974, as amended, regulations. We have instruments within the Department of Defense, within the military establishment, that have as a principal objective, the continuation of medical research. For example, at Fort Detrick in Fredericksburg, MD, we have a medical research facility.

While we have not reviewed that facility, it is my hope, of course, that they are complying with the current ground rules which require them to provide adequate information as to what the subjects are involved in and to gain their consent. But yes, it continues.

Mr. MCCANDLESS. The overriding concern here that just boggles my mind, having in recent years been involved extensively with the Environmental Protection Agency and the rules and regulations being promulgated there relative to water quality control, air quality control, environmental controls of all types, that we find ourselves in, on a daily basis, on the one hand, and here in this panel we are talking about all of these things that are taking place with the full knowledge and consent of the same government that is bringing about all of these regulations to attempt to clean up the environment and make a more healthy atmosphere for us to live. There is a certain contradictory part of that.

So we are saying here, in essence, that the Federal Government, through whatever authority that they deem that they have in some size, shape and form, are continuing to conduct what they consider to be valid experiments relative to our environment and the humans that live in it?

Mr. CONAHAN. I think that there is a legitimate basis for some experimentation. We have to develop new weapons programs to counter whatever the threat is, at any point in time, to our national security.

Mr. MCCANDLESS. Let me interrupt you here. I am not talking about an experiment of the nature that is performed within a laboratory environment. I am talking about what we have been talking about here, subjecting people and locations and geography to certain experiments without their knowledge or consent.

Mr. CONAHAN. We do not have information, as I said at the outset, on the situation since 1974. As we have gone around and talked to the people who are working in these areas throughout the Federal Government, there was a feeling that the 1974, as amended, regulations are generally being complied with.

However, we have not found a mechanism anywhere along the way to ensure that that is the case. There is not a reporting mechanism to assure that. And a very well-placed individual at the National Institutes of Health had that very concern, and shared us, that as he looks across the horizon, we don't have a mechanism in place to assure that those things aren't occurring.

Mr. MCCANDLESS. Let me conclude by asking, in your investigatory role, have you tracked a particular set of circumstances from the incident through the process, to the point where an agreement to proceed became a decision on the part of some level of government and/or persons involved?

Mr. CONAHAN. What we have in the 1993 report is, we have traced claims made by individuals for benefits in response to their ailment. And we showed how they went through the process and what the outcome of that was, yes, sir.

Mr. MCCANDLESS. I didn't frame my question correctly. I am talking about the actual performance of this experiment. Let me be hypothetical here for purposes of illustration.

A scientist feels that it is essential for his or her project that they move beyond the laboratory and perform certain exterior-to-the-laboratory functions relative to the overall subject matter under investigation or experimentation.

And so this laboratory person goes to someone, and that someone says, well, I see where you are coming from, yes, to me there would be a value, let's proceed to explore how we might be able to bring this about. And so they explore on how to bring this about.

And so my question is, who in the echelons above this theoretical situation, at what level does someone say, that is a great idea, let's go ahead and involve a neighborhood, a community, a group of people who have no idea that they are a part of that experiment? This is the thing that concerns me.

Mr. CONAHAN. An excellent point, Mr. McCandless, and I think it is key to what we are talking about here. The HHS regulation does require independent review groups be established within each of the agencies to address this very question that you are raising. We have that work underway right now but I cannot report a conclusion as it simply is not completed. It is very, very key, and I agree with you that it needs to be addressed and as I said we are addressing it.

Mr. MCCANDLESS. One further comment—I thank the chairman for the time—it boggles my mind going through this that we give someone who has been sentenced by a court and a judge to death, 13 years of—or whatever number of times, years it may take, to preserve his or her rights to the maximum degree possible in a court of law, and to explore every avenue of the activities that led up to this sentence, and whether or not the sentence is valid, and yet we are out here somewhere doing something with what it is we want to do, with people who have no knowledge of it, and there is a legal contradiction there somewhere. I don't expect to you respond unless you want to. But this boggles the mind.

Mr. CONAHAN. Well, I will accept your invitation to respond. Chairman Conyers talked earlier about the need for some mechanism beyond this commission activity and all the rest of that sort of stuff. I think that something is absolutely required and would

suggest that it include such things as establishing milestones for doing the things that need to get done. Then I think there is a second part as well. What you are getting at is accountability. I think we have to hold people accountable for approval actions when they sign off on these experiments, because these are signed off on.

Mr. MCCANDLESS. Thank you.

Mr. CONYERS. Thank you. Mr. Bill Clinger.

Mr. CLINGER. Thank you, Mr. Chairman.

We know all of these issues involve very sensitive, delicate, ethical, moral questions, and we are reminded of that in this morning's Post which refers to recommendations with regard to embryo research that are coming forward. The only question I would ask you is, you have conducted very extensive review on these tests from 1940 to 1974, did you find any evidence that these tests resulted in positive or beneficial results or scientific discoveries?

Mr. CONAHAN. I think there are two things that can be said in that regard. Yes, a series of tests have resulted in advances in nuclear medicine in the radiological experimentation area, and there are individual cases where other experimentation has resulted in antidotes, vaccines and so on. Not all experiments are to be faulted. There are experiments that are being done properly, and we came across a few of those as we did our review.

But I must confess that the scope and magnitude of those of concern really stood out during that earlier period.

Mr. CLINGER. So the question always is, do the benefits outweigh the possible harm, or should you ever engage in it if there is going to be harm to the individuals being tested? What are the tradeoffs?

Mr. CONAHAN. Yes, I think there is that tradeoff. If we get in place the proper guidelines and mechanisms for enforcement, then we can all deal with that much better than we can today.

Mr. CLINGER. Thank you.

Thank you, Mr. Chairman.

Mr. CONYERS. I have one final observation. Did you mention the Air Force's LSD tests, which was information that came to the subcommittee rather late?

Mr. CONAHAN. I think I made a passing reference to it. It did involve a fairly large number of individuals. As I recall, there were about a hundred individuals and five universities involved.

LSD was administered. I do have a listing of the universities involved here: Duke University, New York University, Baylor University, and then one principal researcher did work at both the University of Minnesota and the University of Missouri.

The Air Force does not have the names and has not gone to the contractors to ask them for their names, so I suppose as to the question as to whether these people actually knew whether they were subjected to the experiments remains simply to be answered. In view of everything else we have seen here, I would not hold out that we would get a very warm answer to that question.

Mr. CONYERS. Well, I would like to continue to enlist the services of GAO in this regard. This is more than just a sensational hearing. This really goes to the fundamental nature of a government's relationship to its citizens.

It is important not only because the rights of so many people were blatantly disregarded, but also because if there is to be any

trust in this system, if there is to be a contract between our citizens and its government, then this has to be diligently exposed and finally resolved.

It is in that sense that I again want to thank you, Mr. Conahan, and you, Mr. Furbish, and the rest of your staff that worked to help us make this much available to the American people today.

Mr. CONAHAN. Thank you, Mr. Chairman, Mr. McCandless.

Mr. CONYERS. Thank you very much. The Chair is now pleased to call Dr. Eric Olson of Frederick, MD, and Ms. Elizabeth Barrett of New York City, to the witness table. Dr. Olson and Ms. Barrett are here today to provide testimony about bizarre incidents revolving around the deaths of their parents during secret experiments conducted by the government.

First of all, I want to express on behalf of our committee our deep respect to you for coming forward. This is not just an unhappy part of American history, but for you and your families, it is a much deeper, more personal matter. So I understand that it could have been much simpler for you to have declined to come before this committee. But you did so voluntarily, both of you, and we are deeply grateful to you. Without your assistance and work that you have done for years long before this hearing, we probably wouldn't have reached this point in revealing what has gone on. So I thank you very much.

Dr. Olson, I will ask you to begin.

STATEMENT OF ERIC OLSON, Ph.D., FREDERICK, MD

Dr. OLSON. Thank you. Mr. Chairman, members of the committee, I want to begin by thanking you for inviting me to come here and speak about my family's experience with U.S. Government testing on unwitting subjects, which begins more than 40 years ago.

In November 1953, my father, Dr. Frank Olson, was given a dose of LSD, without his knowledge and without his consent, in an after-dinner drink. This bizarre incident occurred during a meeting of Fort Detrick scientists, organized by Dr. Sidney Gottlieb, who at that time was in the early stages of what became a very long program of mind manipulation research at the CIA.

At the time of that strange meeting, which one hesitates to call scientific even though it was organized by and for a small group of scientists, my mother was still a young woman. She was 38 years old. I was 9, my sister was 7, and my brother was 5.

Nine days after that meeting at Deep Creek Lake, in the predawn hours of November 28, 1953, which was the Saturday after Thanksgiving, I was awakened to be told that my father was dead. I was told he had died from a fall out of the window of a New York hotel room.

For me on that predawn morning, it was as if the lights went out. I could not understand what I had been told. I remember seeing my mother sitting on the sofa across from me, motionless, with a frozen expression on her face. I remember an overwhelming feeling of isolation, a crushing sensation that the world in which I had been living was suddenly gone forever.

Our family did not know what hit us. We did not know that my father had been the subject of an experiment. We did not know

why he had been suddenly whisked away to New York to get some kind of psychiatric help, if indeed that was the purpose of his visits to a CIA consultant named Harold Abramson. We did not learn these things for 22 years, until 1975, and even then we learned them by accident.

On June 11, 1975, one day after my mother was told by her doctor that she had cancer, The Washington Post reported that an unnamed scientist had plunged to his death in 1953 after being drugged with LSD by the CIA. We deduced that this unnamed scientist must be my father, and eventually Vincent Ruwet, one of my father's colleagues, confirmed for us that this was in fact the case.

But we were never officially notified by either the Rockefeller Commission, in whose report this story first appeared, or by the CIA, whose failure to contact us rendered that agency's subsequent apology rather empty in our ears. It was as if a body long missing in action had at last been found, but the family were not notified.

Later that summer we were invited to the White House to receive a formal apology from President Gerald Ford. And we received from William Colby a set of heavily censored documents which he assured us contained everything the CIA had on this case.

White House attorneys helped our lawyers draft a bill that would compensate our family financially for my father's death and for the 22-year coverup that followed it. After months of discussion with participation by the White House, the CIA, the Justice Department, the Treasury Department, and the Labor Department, we arrived at an agreement, supported by all these agencies, with which we were satisfied. White House attorneys assured us that Congress was overwhelmingly in favor of the bill, and that it would face no serious opposition.

On the day of the vote, however, we discovered that a single Congressman opposed the bill. We were also informed that private bills require unanimous support and that due to the opposition of this Congressman, the bill could not pass. This individual later agreed to support the bill only if the proposed financial amount, carefully negotiated over many months, were cut by 40 percent.

We had no choice but to accept the terms dictated by this individual, even though the makeshift quality of this emergency compromise deprived us of a feeling of integrity in the settlement process.

I remember my mother's comment to this Congressman, who had refused even to meet with us. My mother said, "This bill represents an apology from the American people for what our family has suffered. If you compromise an apology, you don't have an apology."

And I remember, too, this Congressman's response to my mother, "Oh, Mrs. Olson, I would never want to compromise your pain or your suffering."

No one ever did compromise my mother's pain or suffering. She had it in full measure. She bore her burdens with great dignity, but she paid a very heavy price.

She never remarried. After my father died, my mother maintained her public stance in the community as a woman of great, almost incredible strength. But privately she began a 20-year decent

into alcoholism from which, after repeated hospitalization, she only narrowly escaped with her life.

My mother's serious drinking began shortly after my father's death. At the time of day when my father would normally have been returning home from work, one of my father's colleagues began coming to our house to have a drink with my mother. In 1975 we learned from the documents we received from William Colby that this colleague had been directed by the CIA to, "keep track of the wife." Unfortunately, keeping track did not include telling my mother the truth.

My brother, sister, and I grew up in a home from which our father had inexplicably vanished and in which our mother was gradually becoming severely alcoholic. On the surface we lived a remarkably normal life; most of the pain was hidden from those who knew us and even from ourselves.

We received financial compensation from the CIA 3 days after my father's death so that we had at least a moderate income.

My father's death affected each of the members of my family differently. For all of us, though, there was a feeling of shame—shame not only that our father had vanished, had perhaps committed some inexplicable kind of suicide, but shame especially because we didn't know how to speak about his death; that we had no idea what to say to our friends.

My brother, sister, and I used to dread the moment when anyone would ask us how our father died. We eventually learned to reply to such questions by saying our father had died of a nervous breakdown, although we had no idea what that might mean.

It is easier for me to speak about my own reactions than about those of my brother and sister. I was 9 years old when my father vanished, a delicate age when interruptions to the logic of cause and effect can have a crushing impact on one's confidence that the world is a reasonable place and that one can trust people and events.

My son, who is here with me today, will never know his grandfather. I have to explain to him why, just as my brother has tried explain this to his children. My sister, her husband and their 2-year-old child were all killed in an airplane crash in 1978 while they were flying to upstate New York to consider an investment of their share of the money we received in the settlement of my father's case in 1975.

The best way in which I can convey the depth of impact which the revelations of 1975 and the settlement we made with the government made upon me is that, beginning in the late 1970's, after finishing my Ph.D. at Harvard, I spent nearly a decade and a half living outside the United States. I moved to Sweden to live in the country from which my father's parents had immigrated as optimistic immigrants to the United States in the 1890's.

I relate these things to stress the way in which an incident like this reverberates for decades through the generations of a family and its close friends.

During the last year of his life, my father spoke of wanting to leave his job in bacteriological warfare research and reeducate himself as a dentist. Dentistry is in fact the profession my brother has taken up. I suspect that the atmosphere of eerie silence in our fam-

ily around my father's death strongly influenced my sister's decision to become a speech therapist and to teach deaf children to speak. I know that it determined my decision to become a psychologist as well as the particular path I have followed within that discipline.

When I started graduate school in psychology in the early 1970's, I was still strongly motivated by the need to understand what had happened to my father and the consequences this loss had for the history of my family. I chose to work with the well-known psychiatrist Robert Jay Lifton at Yale, the sequence of whose research comprised a virtual curriculum in the issues raised by my father's death. Lifton's early work concerned the psychology of brainwashing. Later he studied the psychology of survivors of massive trauma, identity formation without the father, and the psychology of weapons scientists. In more recent work he has concentrated on the motivations of Nazi doctors who performed immoral experiments on human subjects in the Nazi death camps.

After World War II, in a project known as Operation Paper Clip, many of those Nazi scientists were in fact recruited by the American military to work side by side with American scientists preparing the experiments whose effects we are considering today. This fact helps us to understand that, in other circumstances, the perpetrators of these acts would not be enjoying their retirements. They would be prosecuted as war criminals.

How did my father die? Sadly, I believe that we still don't know for sure.

For a brief moment in 1975 I thought the lights had been turned on again. But, unfortunately, the feeling of illumination did not endure. In the years after 1975 my brother and I became increasingly convinced that we still did not know the truth about what had happened to my father.

In fact, I believe we cannot be certain about anything concerning my father's death, except that he died just outside the Statler Hotel in New York City—or it was in the hotel room itself?—after falling some 13 stories from the room he had shared with Dr. Robert Lashbrook, who was Sydney Gottlieb's associate at the CIA.

The documents we received from the CIA in 1975 are so riddled with contradictions, omissions, and outright lies that it is difficult to have any confidence in them at all. The documents that would have been really informative were almost certainly shredded by Sydney Gottlieb when he retired from the CIA in 1975. What we have are remnants of the coverup within the CIA itself, that began immediately after my father's death, and which included the financial compensation we received so quickly.

Over the past two decades my brother and I have been increasingly convinced that in fact my father was murdered. In June of this year, we had his body exhumed so that a full-scale autopsy, blocked by the CIA in 1953, could now be performed.

For the first time in 41 years my brother and I saw my father's body, which was remarkably intact. No one in my family had ever seen my father's body after he died. At the funeral the casket was closed, because my mother had been told that my father's body was so maimed that we would not want to see it. Now, in its mum-

mified state, we discovered that this had not been true. Even that bit of consolation had been denied us.

Professor James Starrs of the George Washington University National Law Center is now overseeing an exhaustive investigation of my father's remains. Professor Starrs' findings will be reported in a press conference to be held in late November, on the anniversary of my father's death. Professor Starrs's forensic investigation is not yet complete but its preliminary results, which increasingly point toward the likelihood of homicide, are tending to confirm our most dire suspicions.

Meanwhile, I have managed to locate a former CIA employee who worked in Gottlieb's small group during the years after my father's death. This source has confirmed that the members of that small group all believed that my father was murdered.

My father's case—still unresolved after four decades—illustrates what can happen when civil liberties are violated in the name of national security research. Once one starts on the dangerous path of poisoning one's own citizens in order to develop the weapons allegedly needed to protect them, one enters a zone of lunacy where anything is possible, where sadists can disguise their maliciousness as patriotic duty. In such a situation, any experiment if it goes awry can quickly become a risk to the careers of the experimenters themselves.

The path from experimental mind manipulation to murder may then be a short one, for how else can one guarantee the security of an immoral research program in which one's fellow citizens are used as guinea pigs?

My brother and I can only hope that our father's case, and our family's experience, remain a lesson in the risks posed to a free society by pretentious pseudoscience, self-serving secrecy, and bureaucratic arrogance.

Thank you.

[The prepared statement of Dr. Olson follows:]

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**Testimony to the Committee on Government Operations,
United States House of Representatives**
September 28, 1994

I.

The unending event.

My family's experience with U.S. government testing on unwitting subjects begins more than forty years ago. In November 1953 my father, Dr. Frank Olson, was given a dose of LSD, without his knowledge and without his consent in an after-dinner drink. This bizarre incident occurred during a meeting of Ft. Detrick scientists, organized by Dr. Sidney Gottlieb who at that time was in the early stages of what became a very long program of mind-manipulation research at the CIA.

At the time of that strange meeting, which one hesitates to call "scientific" even though it was organized by and for a small group of scientists, my mother was still a young woman. She was thirty-eight years old. I was nine, my sister was seven, and my brother was five.

Nine days after that meeting at Deep Creek Lake, in the pre-dawn hours of November 28, 1953, which was the Saturday after Thanksgiving, I was awakened to be told that my father was dead. I was told that he died from a fall out of the window of a New York hotel room.

For me on that pre-dawn morning it was as if the lights went out. I could not understand what I had been told. I remember seeing my mother sitting on the sofa across from me, motionless, with a frozen expression on her face. I remember an overwhelming feeling of isolation, a crushing sensation that the world in which I had been living was suddenly gone for ever.

Our family did not know what hit us. We did not know that my father had been the subject of an experiment. We did not know why he had been suddenly whisked away to New York to get some kind of psychiatric help — if that was indeed the purpose of his visits to a CIA consultant named Harold Abramson.

We did not learn these things for twenty-two years, until 1975; and even then we learned them by accident. On June 11 of 1975 — one day after my mother was told by her doctor that she had cancer — the Washington Post reported that an unnamed scientist had plunged to his death in 1953 after being drugged with LSD by the CIA. We deduced that this unnamed scientist must be my father. Eventually Vincent Ruwet, one of my father's colleagues, confirmed for us that this was in fact the case. But we were never officially notified by either the Rockefeller Commission, in whose report this story first appeared, or by the CIA, whose failure to contact us, rendered that agency's subsequent apology rather empty in our ears. It was as if a body long missing in action had at last been found, but the family were not notified.

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II.

Widening reverberations.

No one ever did compromise my mother's pain or suffering: she had it in full measure. She bore her burdens with great dignity, but she paid a heavy price.

She never re-married. After my father died my mother maintained her public stance in the community as a woman of great, almost incredible strength. But privately she began a twenty-year descent into alcoholism from which, after repeated hospitalizations, she only narrowly escaped with her life.

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III.

Struggling to learn the truth.

How did my father die? Sadly, I believe that we still don't know for sure.

For a brief moment in 1975 I thought the lights had been turned on again. Unfortunately the feeling of illumination did not endure. In the years after 1975 my brother and I became increasingly convinced that we still did not know the truth what about what had happened to my father.

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In such a situation any experiment, if it goes awry, can quickly become a risk to the careers of the experimenters themselves. The path from experimental mind-manipulation to murder may then be a short one, for how else can one guarantee the security of an immoral research program in which one's fellow citizens are used as guinea pigs?

My brother and I can only hope that our father's case, and our family's experience, remain a lesson in the risks posed to a free society by pretentious pseudo-science, self-serving secrecy, and bureaucratic arrogance.

Mr. CONYERS. Dr. Olson, that is one of the most moving statements I have ever heard in this committee.

I would like now to call Ms. Elizabeth Barrett, a daughter of the late Mr. Harold Blauer, a psychiatric patient who lost his life in a secret government experiment.

STATEMENT OF ELIZABETH BARRETT, NEW YORK, NY

Ms. BARRETT. Thank you, Mr. Conyers. I am afraid I am not quite as poised as Dr. Olson.

I am very grateful that you have given me this opportunity, although I am frightened and still quite bitter. Like Dr. Olson, I don't believe anything like all the facts have been revealed. I won't go into the details of why I believe that in an oral presentation, but there are many reasons to believe it.

The only reason I can bring myself to do this is because I have the hope that you are approaching Walter Lippmann's definition of an ideal public man. He said, "Those in high places are more than the administrators of government bureaus, they are more than the writers of laws. They are the custodians of a nation's ideals, of the beliefs it cherishes, of its permanent hopes, of the faith which makes a nation out of a mere aggregation of individuals."

In the hope that you try to live this ideal, let me try to take you back to 1952. Divorce was much less common than today and a father with custody of his daughter was unknown. That was my life. I adored my father. I went to work with him whenever I didn't have school. I only remember him leaving me once during that period, to join a friend for an evening, and I really had to insist that he go.

When he died, my world came to an end. My mother moved us to Mexico, where it was much cheaper to live. Unlike Dr. Olson, we didn't get any money at all.

She put me in a Mexico City boarding school and went to Cuernavaca with my sister to live. I was one miserable, lonely 13 year old. I don't think my mother or sister were very happy either.

I loved my father. I think of him every day. But 16 years of dealing with the most horrendous legal and political roadblocks I experienced every step of the way haven't made it any easier.

Although this is probably my last opportunity to get things changed to make all these battles meaningful, I have been depressed and frightened ever since I got your invitation to testify. I have been afraid ever since the true nature of my father's death was revealed.

Friends warned me the government considered me a threat and if I didn't settle the case, something terrible might happen to me. Columnist Jack Anderson said he had the same concerns with his safety. He told me to take proper precautions and go on with my life. But I am still always looking over my shoulder. I am frightened because I don't believe all the facts have been revealed.

For example, I was supposed to have seen all the original documents, the ones that were in the Edgewood arsenal safe, were supposed to be brought forth at trial. We had seen Xeroxed copies of them but never the originals. The government refused to provide them.

The absence of my father from my life will always hurt. This is true for all children. But I also feel I lost my country at the same time. This is something no American, brought up as I was to believe in our system almost as a religion, expects.

There doesn't seem to be any way to understand or heal this pain. My country destroyed my family, as well as my father, with grossly negligent and purposeful acts by professionals—doctors and lawyers who were supposed to protect us from harm, not cause it. These people are protected by our immunity laws and other legal precedents that need to be changed.

The potential victims we are talking about could be you, your wife, husband, daughter, son, mother, or father. It could happen again. Secrecy, lying, and lack of accountability enable continuation of criminal activity. You who represent us need to change this.

My father sought help from physicians who killed him for chemical warfare research purposes. How would you feel if you found out your father died not in Nazi Germany, but in the United States, 8 years after we hanged war criminals for the same events?

My father was forcibly given a chemical tested only on mice. Harold Blauer was a civilian. He never gave his consent. The hospital record shows he objected to all four injections given to him in the last month of his life.

According to the Army's Inspector General's report, Dr. James Cattel, who gave my father the deadly injection, said the chemical was an Army secret, and "We didn't know whether it was dog piss or . . ." The Army Chemical Corps provided the untested chemical to the New York State Psychiatric Institute's Hospital because it wanted to develop psychotropic substances into chemical weapons. They were in a hurry to find answers, without regard for the safety of their human subjects. My father was told the chemicals were "therapy."

On January 8, 1953, my father was given a chemical dose more than 15 times the size of the first experiment. As described in the book, The Mind Manipulators, "On the morning of January 8, 1953, tennis pro Harold Blauer was taken from his room at the New York State Psychiatric Institute to receive an injection. Blauer did not want it. Four injections he had been given the previous month had made him ill and he was scheduled to return to his family the very next day. He was well. He knew it, the doctors knew it, the staff knew it and his family knew it. Why should he have to take this last needle? It must have made him very apprehensive because the last shot had upset him mentally and physically for a week."

The nurse's notes on my father's last day, just very, very briefly, shows the injection starting at 9:53 in the morning, "9:55, i.v.'s getting me now—restless movements—protesting injection, 9:57, injection ended, 9:59, very restless—has to be restrained by nurse—out of contact, wild flailing of arms. Sweating profusely; 10:01, patient pulled up in bed—generalized stiffening of body. Teeth clenched—frothing at the mouth." My father's pulse increased enormously and he finally lapsed into a coma. He died at 12:15 p.m. that day.

The record shows my father suffered from December 11, 1952, to January 8, 1953. On his last day he did not die instantly. The final deadly injection took 2 hours and 22 minutes to kill him, a torture comparable to those inflicted during the inquisition.

His death certificate stated that a chemical compound had activated a previously unknown heart condition. Harold Blauer did not have a heart condition. He was a tennis teacher, slim, active, all good things.

My father was not the only victim in this tragedy. My mother died with a broken heart because she felt her divorce was responsible in some part for his death. She never knew my father was murdered in an Army chemical warfare experiment.

My daughter, Amy, has been a victim, too. She was 13 when I found out about the reason for my father's death and its coverup. The already stressful years for an adolescent daughter of a single mother were enormously complicated because I took an active role in pursuing reason and justice.

I gave up my career in health education and became a secretary so I could spend the time necessary to find law firms to represent me. I had eight law firms, one law school, and the New York Civil Liberties Union at various times during those 16 years. I had to raise money for expenses and attend depositions around the country to get at the truth.

Now, I don't seem to be able to get my career back or even get a job. I tried to make my case, *Barrett* v. *the U.S.A.*, a springboard for new accountability laws and bills to prevent unethical experimentation from happening to others. There were discussions at the beginning about a settlement with the Justice Department, but I felt the truth was necessary to prevent more tragedies and would not agree to sweep hidden facts under the rug.

I didn't get much help. My friends and I wrote letters to Congress, getting the usual form-letter response. Marty Teitel, director of the CS Fund, provided a grant of $10,000 to help me get accountability from those responsible. I will always be grateful to him and his foundation for that support.

I fought my lawyers as much as the government. My lawyers wanted to settle or drop important defendants like Warren Burger and Jacob Javits. Mr. Burger was the Assistant Attorney General in the U.S. Justice Department in the 1950's. Mr. Javits was a major in the Army Chemical Corps during World War II, and then the New York State Attorney General who helped Mr. Burger deceive the court and my mother.

Even the press, which had been very interested in helping, became a problem. When the involvement of Burger and Javits was revealed, the stories about these horrors which had been on the front page of many newspapers and on the national television newscasts stopped. I was told by Lyle Denniston that Mr. Burger's press secretary told him that if he wrote another word, he would be sued.

CBS rushed me into their New York studio for an interview the day Burger was officially named in the suit, but they didn't run the story, saying their Washington legal correspondent wanted to check it first. It never ran.

The New York Times, which had run several front-page stories, not only stopped covering the story, but refused to cover the 8-week trial and never even did a story on the verdict.

As long as there is secrecy and a lack of accountability for one's actions, tragedies like what happened to my father will continue.

Please don't let these outrageous cases of human abuse be continued.

Now there is no personal accountability for unethical human experiments on humans. Those IRB boards that your previous person was testifying about are not really available to people that are doing secret classified experiments. Immunity is given to those officials who are supposed to be protecting American citizens, not hurting them.

A lawyer, Robert King, commented, "In the eyes of the law, the more responsibility that is placed on a government official, the less liability is associated with his official conduct."

In 1986, when he dismissed David Marcus, the Assistant New York State Attorney General assigned to defend the hospital in 1985, Judge Walter Mansfield stated that questionable or harmful conduct during Marcus's representation of the State was, "irrelevant. Immunity attaches to his function, not the manner in which he performed it."

It is this type of irrationality that needs to be changed. All the rules on immunity for people who violate the Constitution have been made by judges, not by Congress.

So my plea is, one, please pass a law to repeal this kind of immunity so the courts cannot continue this sham.

Who would have thought after Nuremberg that experiments like those of the Nazis would continue in this country? It can happen again, and we are painfully naive if we don't think so.

Nothing has really changed since the 1950's. Classified research still has no ethical scrutiny.

Two, Congress must pass laws to hold those people who have the most power over our lives—doctors, lawyers, government employees, and contractors—responsible for their actions.

David Rothman, of Columbia University says "Research by military or any Federal agency must receive special scrutiny, not just from their own boards, but from an independent body. This will help us be certain of the integrity of government research."

Three, everyone should have immediate access to their own medical records. This is illegal in many States. It should be illegal to deny anyone access to information about themselves. If patients have access to information, mistakes as well as harmful experimentation will be less likely to occur. If my father had been able to see his records, he might have had more help from friends when he protested.

Most legal cases about unethical military experiments have been settled out of court, without the victims or the general public ever knowing exactly what happened. How can we rectify the problem if these acts are still kept secret?

Health care costs, which you talked about earlier, as well as injuries, could be greatly reduced if people were aware of the risks of many of the drugs and other treatments that are prescribed. The "Physician's Desk Reference" is a best seller which shows that people are willing to try and understand.

Taxpayers who have been harmed by experiments are fighting for justice against a government using their tax dollars against them. I understand there has already been $50 million spent defending the radiation experiments. The Justice Department has a

reputation for dragging things on for years so the victim will run out of money or time.

Four, I suggest the government pay for the plaintiff's case as it pays for the defendant—the government—after the courts have decided the case has merit. This would provide more equal access to justice.

In my case, as mentioned in the letter submitted by Roger Parloff of the American Lawyer, "Attorneys suing under the Federal Tort Claims Act can't apply for reasonable attorney's fees from the defendant if the plaintiff wins. Instead, they take their fee—a contingency fee of 25 percent—out of the plaintiff's award. But, because of limits upon damages in Federal Tort Claims Act cases, the plaintiff's award will seldom fully compensate the plaintiff, and 25 percent of that award will seldom fully compensate the lawyer for the fees and expenses of bringing the suit. Accordingly, most lawyers will not want to bring the case in the first place. Though there is a limit on the percentage of the award that can be consumed by attorney's fees, there is no limit on the amount of that award that may be depleted by reimbursement of attorney's expenses."

Five, discretionary function should be reviewed. Our laws are made for a sovereign government. I was only allowed to sue for negligence. I was not allowed to sue for my father's intentional murder. Individuals working for the government are allowed to kill citizens for the greater good, and are protected by "intentional tort" or "discretionary functions" which are immune from suit.

Sovereign immunity is un-American. I thought we fought England in the 18th century because the King could do no wrong according to England's laws, and royal abuses of power made us want all people to be equal under the law here.

In the biological warfare case, *Nevin* v. *the U.S.A.*, the court ruled, "Thus, sovereign immunity is not waived if, as the government maintains in this case, the acts being sued upon were undertaken as part of the government's discretionary function. Specifically, the government contends the acts in question here constituted the discretionary function of providing for national defense so that they are not actionable under the Federal Tort Claims Act."

So, if you find victims from the wind dispersal experiments that have been previously described, they will not be able to sue, because the government just says, "We were doing it for national security."

Six, no statute of limitations should be in effect if the government causes the problem, especially if they try to cover it up.

My case was lost over the statute of limitations issue in the district court. I needed to appeal. After finding that fraud tolled the statute, the appellate court returned my case to the district court to be retried. If the statute of limitations is frozen by explicit law when there is a coverup or fraud, much time will be saved, and justice will be more likely.

My civil rights actions against Federal officials was blocked because of the obscure issue of "personal jurisdiction."

Roger Parloff of the American Lawyer comments, "Since many of the Federal officials responsible for your father's death were geographically disbursed around the country and had not actually

come to New York in order to injure Harold Blauer, Barrett's father, Barrett tried to sue them all in a single forum in New York, a place where she lived and her father was killed. But, while she would have been permitted to do just that had she been suing a defendant for almost any ordinary business injury, the law did not permit her to do so in a civil rights action against Federal officials. Instead, she was required to sue each of the individual defendants in the State where he or she currently lived, which would have meant filing numerous actions in different States—see *Green* v. *McCall,* 710 F.2d 29 (2d Cir. 1983). This procedural rule seems designed to serve no purpose except to make civil rights actions against Federal officials prohibitively expensive, regardless of their merit." Robert King believes the New York State Assistant Attorney, David Marcus—who participated in the coverup—acted as agent for these officials within the State and therefore subjected them to the jurisdiction of the courts in New York. I believe they were all part of the same action and should be sued one place at one trial.

Seven, we must make individuals who have no integrity accountable for their crimes, especially those politicians, scientists, and doctors who are held in the public trust. If we don't, as we have seen for ourselves, history will repeat itself.

Eight, punitive damages and prejudgment interest, should be the rule when individuals in government are so negligent. We can no longer make laws with the assumption that people are inherently good. We must create laws to prevent evil people from harming others.

In *Barrett* v. *United States,* Dave Side of Uncle Sam, New York Law Journal, May 13, 1987, Joseph and Robert Keiny said, "When an activity is so obviously grossly negligent, wanton or reckless, punitive damages should be awarded as a deterrent, whether the culprit be an individual or government agent, servant or employee."

And Mr. Parloff says, "That problem was exacerbated—in your case—by the fact that the plaintiff, under the Federal Torts Claim Act, can't get prejudgment interest either. In your case, the government had covered up the cause of your father's death for 22 years. The absence of prejudgment interest meant that anything you were awarded had to be paid in 1953 dollars. Should say: "anything you were awarded has to be paid in 1953 dollars. Not only were your father's lost earnings computed solely upon the earnings of a tennis instructor in 1953, uncorrected to inflation or interest, but even the award for his pain and suffering before he died was determined in terms of 1953 dollars."

Nine, in 1987, Judge Constance Baker Motley's opinion "said the question of prejudgment interest should be addressed by Congress." Well, I am here now, and I hope you will address and correct this wrong—if not for me, at least for the people who come behind me.

This congressional hearing is a breath of fresh air in a country that has avoided the truth about itself for decades. I hope we can now take action and make our laws fair to all, not privileges for the powerful. As Elie Wiesel said in his 1986 Nobel Peace Prize ceremony, "Action is the only remedy to indifference, the most insidious danger of all. One person of integrity can make a difference, a difference of life and death."

Will at least one of you help?

Ten, I suggest that as a representative victim of the laws as they are now, I could help you when you draft new laws to correct these problems. We can learn from our mistakes if we want to.

Eleven, at the very least there should be a public advocate or ombudsman for a plaintiff suing the government when a coverup or fraud is discovered. This person should be hired at taxpayers' expense to get the case on the "fast-track." Justice is not provided when cases are drawn out over many years. It can approach justice only if resolution is timely.

Twelve, I hope that you agree that a good symbolic start, other than your recognition and interest today, would be for my family to get a Presidential apology for my father's death.

This is only symbolic. Not one administration, Republican or Democrat, since 1975, when the truth was revealed, ever said, "I am sorry." Instead, they, through the Department of Justice and the Pentagon, continued to lie and kept me in court for 16 years, wasting taxpayers' money and ruining my life.

It is sadly ironic and unjust that I, the victim's daughter, was treated as if I were the criminal, an impediment to just government rather than a solution.

I believe that in my father's case individuals in government broke their moral, and I think fiduciary, contract with my father and his family when they actively pursued him against his will and killed him.

Thirteen, this apology from the President should be accompanied by a refund of all taxes paid by my father, his wife, and his children, with a recognition that taxes should never be paid by his children. This is to show that the Government recognizes that taxes paid incur an obligation of service for those taxes.

I have not filed a tax return since I was told of my father's death. I am very afraid the Government will use this to put me in jail and keep me quiet.

I challenge this representative body to make a difference and help me be a catalyst for change so I can some day hold my head high when our national anthem is played, not lower it, as I have done for years, in shame.

Thank you.

Mr. CONYERS. I didn't know what you were going to say because you had not submitted a statement. I appreciate very much the additional responsibility and the view that you have so particularly expressed here today. It makes me feel more ashamed than ever for what you and your family have gone through, and maybe other people who will never be able to come before the committee or articulate their experiences. So I can only commit to you that this is the first of an inquiry that is so very, very important. We all know that you could have very easily declined or sent in a statement, but I think it is very significant that you are here today and made this magnificent statement.

As a member, additionally, of the Judiciary Committee, I am pleased to hear of the many legal recommendations that you made, and I want to sort them out. We will continue to do everything possible. There are some things that you have said that I don't think

we need to spend a lot of time determining whether we agree with them or not.

You know, nothing would make me feel better about this than to have the present President of the United States know that both of you were witnesses here in the Congress today, and that he take this matter under his personal advisement.

We in the Congress have a lot to do. But what you two have done to spur and energize those of us who are committed to a true participatory democracy can never be fully measured. We can't thank you enough, both of you.

I would like to recognize Mr. Al McCandless now.

Mr. MCCANDLESS. Thank you, Mr. Chairman.

I want to thank both of you for taking the time to come before the committee. We will take what you gave us in the way of suggestions and review those relative to the future legislative process.

You and others in the audience may say, you can't do all of that between now and October 7 or October 14 or whenever it is that the 103d Congress recesses. But what the purpose of this hearing is all about is to build a record upon which then, in the 104th Congress, this and other committees which have become involved will take this and proceed in a direction that will hopefully solve the problems that become apparent as a result of reviewing records that are developed such as we are here today.

And thank you both for your attendance and your participation.

Ms. BARRETT. Could I make one more comment? I want to say if all this information is revealed and nothing is done about it, you increase the cynicism and the despair. It makes it worse.

I have been offered several opportunities to do a television or movie docu-drama, and I have refused, because the end result would be to make people feel worse, would be to make people feel more despair. Then they would be less likely to fight city hall. We need to show that it is possible to make things better.

And I think the despair in this country now and the cynicism, every place that we go, it just—oh, they will never do anything about it, don't worry it, they have their own agenda. That is why I think our country is falling apart. There is no standard set at the top for responsibility.

So if the President or the Congress or—they don't care, why should we care?

Mr. MCCANDLESS. I understand where you are coming from. I am in accord. What I was trying to diagram out for you is that you made a number of points—I think there were something like 13 or 14—all of which had a direct bearing upon your experience in the legal system as it relates to your case.

Not being a lawyer, I am not in a position to be able to comment yes or no, other than that many of these suggestions would go beyond the parameter of what it is we are here talking about today, if applied to other circumstances. So they need to be addressed in terms of how could we adjust and provide the protection and what is necessary in the way of justice to those who have experienced, such as you, and yet not turn the legal system completely upside down in order to address a particular issue, which then would open the door for other things which had nothing to do with the subject matter that we are talking about here today.

I think you probably have been working with lawyers long enough that you have an idea of what I am talking about.

Ms. BARRETT. The lawyers I have had have almost universally said to me, Elizabeth, we hate working with you because you are too logical, because whatever you are saying absolutely should be the case, and unfortunately it is not. To just shrug and say, "Gee, that is the way it is," seems to me the way down the path of total disaster. You have to say, "If this is a problem here, yes, it probably has a lot of ramifications, and if it turns the justice system upside down, maybe that is what the justice system needs." I don't know that there is a lot of people out there that really have a great deal of faith in the justice system.

Mr. MCCANDLESS. I couldn't agree with you more. I am sharing with you maybe some nostalgia here. After completing 12 years here in the Congress, I have closets full of frustration, and have been told by those who are experts that, well, your ideas are good, what you want to do is fine, but do you realize the ramifications beyond that area in which you are concentrating. And I was just trying to share with you that thought.

Thank you both for coming.

Mr. CONYERS. The Chair recognizes the gentleman from California, subcommittee Chair, Gary Condit.

Mr. CONDIT. Mr. Chairman, I came in late and didn't have the privilege to hear all the testimony. I apologize for that.

I just want to commend you for holding this hearing. I think this is an excellent opportunity for us to get to the truth. And there is no reason for us not to have this information available so that we can make some decisions on how we proceed from here. I want to commend you and the witnesses for being here today.

Mr. CONYERS. We all want to thank you.

There are some questions that we will want to raise with you, but I think your statements are so profound that they will become a part of our history. If we can turn this thing around, if we can make good on the promise of what really makes a system a democracy, this will be an important point at which we started to do that.

Ms. BARRETT. I hope you let us continue to help you.

Mr. CONYERS. You have already helped us immeasurably. I know you can continue to be of great assistance to us. Again, on behalf of the whole committee, we thank you both very, very much.

I would now like to call the Deputy Under Secretary, the Deputy Assistant Secretary, the Director of Environment and Life Sciences, Executive Director of the U.S. Army, Chemical and Biological Defense Command, Ms. Jeanne Fites, Dr. Gordon Soper, Dr. Joseph Osterman, Mr. Michael A. Parker.

Lady and gentlemen, we thank you for joining us today. We have your prepared statements. Dr. Gordon Soper, would you begin, please.

STATEMENT OF GORDON K. SOPER, Ph.D., PRINCIPAL DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR ATOMIC ENERGY

Dr. SOPER. Mr. Chairman, members of the subcommittee, I am Gordon Soper, representing along with my colleagues the Department of Defense. I am the Principal Deputy to the Assistant to the

Secretary of Defense for Atomic Energy. We are happy to be here to support this committee's investigation.

My testimony will focus on radiation experiments. However, I first would like to introduce the other members of our panel. You have our prepared statement, which we have submitted for the record. If you would permit us, we would all like to provide a short opening statement, after which we would be prepared to take your questions.

Mr. CONYERS. Quite all right. All of your statements will be entered into the record in their entirety and reproduced.

Dr. SOPER. Thank you, sir.

On my left is Ms. Jeanne Fites. She is the Deputy Under Secretary of Defense for Requirements and Resources. She will represent the department's efforts to identify individuals involved in chemical and biological testing.

On my right is Mr. Michael Parker, the Executive Director of the U.S. Army Chemical Biological Defense Command at the Aberdeen Proving Ground in Maryland. He is prepared to address your questions about the chemical and biological experiments that have come up, drug testing, and the question you specifically asked in your letter to Secretary Perry, regarding the operational coverage.

Finally, Dr. Joe Osterman, Director of Environmental and Life Sciences in the Office of the Director, Defense Research and Engineering in the Pentagon. He is prepared to discuss with you, in whatever detail you would like, the present rules and regulations for human use research, particularly the issue of informed consent.

You spoke——

Mr. CONYERS. We can make this go smoother and faster if those questions, Dr. Soper and Ms. Fites, Mr. Parker, Dr. Osterman, that you know we are going to ask, if you would just be forthcoming rather than to make a courtesy statement, and then we go into the cross-examination. So let's lay everything on the table that you can. There is nothing complicated about what we want to know, namely everything that it is proposed by DOD and relevant to the inquiry.

Dr. SOPER. I certainly agree. There was no intent at all not to provide the committee with all the information we have on this issue. I am certainly prepared, and I hope you don't think these statements are merely courtesy statements. They are statements we thought about carefully. We read your letter carefully. We are trying to respond as best we can to your questions. If that is agreeable, I will proceed.

You have made mention of the extensive effort that the administration is pursuing in regard to searching for records of human radiation experimentation following Mrs. O'Leary's comments on this subject early this year. The DOD, along with other Cabinet agencies, are full partners in the effort to be forthcoming with records associated with the past radiation testing.

I want to tell you of the extensive effort that the Department of Defense is conducting in order to respond to that challenge. So far literally hundreds of people have spent 65 or so thousand manhours searching for these records in order to understand the dynamics of these past experiments.

I don't know whether you have ever been involved in this kind of activity, but I will really tell you it is a box-by-box, paper-by-

paper, page-by-page endeavor. We are making progress, but we have a long way to go.

Following your suggestion, I would like to briefly turn to your specific questions and give you a top line view of where we are. The Department decided to institute a requirement to err on the side of inclusion in our record search; that is, to include every document that could possibly be related to radiation experiments on humans. The Department of Defense so far has identified over 2,000 possible DOD-sponsored radiation experiments with over 50,000 participants.

I would like to tell you, sir, that these numbers do not include what the GAO representative mentioned earlier and what you have in your press release. Specifically, soldiers that were involved in the U.S. Atmospheric Nuclear Testing Program. We would be happy to answer your questions on that, but I am specifically here to address the Department of Defense's involvement in ionizing radiation experiments on human subjects.

I would like to add a footnote to the numbers I just gave you. It appears that most of these experiments were either therapeutic diagnostic, or they were tracer studies where the radioactive materials or procedures were used to assist the experimentation but the effects of the irradiation were not a central part of research.

But let me point out, that the Department of Defense has chosen not to make a judgment regarding the purpose or intent of the possible experiment. So what we have done is this; in every record where we find three key ingredients—human beings, ionizing radiation, and experimentation—we call that a record, and we include that in our data base.

We are assembling those records. Every one of those records is given to the Advisory Committee on Human Radiation Experiments that you mentioned, for their study and their review.

Now, I would like to respond to your question about what we have done to notify the people who have participated in the human radiation experiments. All inquiries come into our command center. As you might imagine, the Department of Defense established a command center headed by a Senior Executive Service civilian. Inquiries come into the command center by several means: the radiation experiment's national help line sponsored by the Department of Energy; referrals from other agencies, such as Veterans Affairs, on Health and Human Services; from Congress—we have had some from your office, I believe, sir; the White House; and direct inquiries from the public.

To date, the command center has been in touch with over 6,000 individuals through letters. We have provided many of them with questionnaires. We have also been in contact with some of them personally, through telephone calls.

When the records research process in which we are presently engaged has progressed sufficiently, we expect to undertake a comprehensive effort to notify all of the participants in the DOD-sponsored human radiation experiments. After the independent Advisory Committee has issued its first report the executive branch can work closely with the legislative branch to establish any compensation or medical care programs that are necessary.

I would like then to close my brief opening remarks by emphasizing that the Department of Defense is committed, from Secretary Perry on down, to a full public accounting of our involvement in human radiation experimentation, and I would like to also say we are equally committed to ensuring that any experiments today, involving human subjects are conducted in accordance with established medical research protocols and the highest ethical standards.

Thank you for this opportunity to briefly tell you a little bit about our story. I would like to now turn it over to Mike Parker from the Aberdeen Proving Ground.

[The prepared statement of Dr. Soper follows:]

TESTIMONY FOR DR. SOPER
BEFORE THE COMMITTEE ON GOVERNMENT OPERATIONS
SUBCOMMITTEE ON LEGISLATION AND NATIONAL SECURITY
28 SEPTEMBER 1994

Good Morning, Mr. Chairman and Members of the Subcommittee. I am Gordon K. Soper, the Principal Deputy in the Office of the Assistant to the Secretary of Defense for Atomic Energy. I am here to support your request of August 12th to conduct oversight hearings on Cold War era human subject experimentation. My testimony will focus on radiation experiments.

With me today to assist in giving you insight into this matter are Mrs. Jeanne Fites, Deputy Under Secretary of Defense (Requirements & Resources) within the Office of the Assistant Secretary of Defense (Personnel & Readiness); Mr. Michael Parker, Executive Director, U.S. Army Chemical Biological Defense Command (CBDCOM), Aberdeen Proving Ground, Maryland; and Dr. Joseph Osterman, Director of Environmental and Life Sciences in the Office of the Director, Defense Research and Engineering. Mrs. Fites will address your questions about the Department's efforts to identify individuals involved in chemical and biological testing. Mr. Parker will address your questions about chemical and biological experiments, drug testing and "Operation Large Area Coverage." Finally, Dr. Osterman will address the questions you have raised relative to informed consent.

Before I address the specific questions you asked in your letter of August 12th, I would

like to provide you with some background information that will help put our answers into proper context. The use of human volunteers in biomedical research programs in the Armed Forces dates back to the early 1800s. With the advent of the nuclear age and the following Cold War, this research began to include human radiation experiments. There has been Congressional oversight on this topic. For example, in 1972, Senator Edward Kennedy and Senator Mike Gravel held hearings on the Department of Defense involvement in radiation experiments at the University of Cincinnati, and in 1986, Representative Edward Markey published a critical report on 31 of 35 Government-sponsored human radiation studies involving 695 individuals.

This issue was given renewed emphasis in December of 1993, when Secretary of Energy Hazel O'Leary provided to the public some amplifying information about the Government's participation in human radiation experimentation during the Cold War era. Secretary O'Leary's statements are a reflection of the Clinton Administration's desire to govern in a more open manner. In a further demonstration of the Administration's desire to provide a full accounting of the Government's past role in this area, President Clinton instructed the Federal Agencies to conduct a comprehensive search for all available records related to Government-sponsored human radiation experimentation and the public release of the pertinent information in those records. Of note, in compliance with the Privacy Act, great care is being taken to ensure the privacy of the individuals identified in such records.

In order to facilitate this systematic record search and comprehensive review, the President established two major activities: an Interagency Working Group on Human Radiation

Experiments and the Independent Advisory Committee on Human Radiation Experiments. These two groups are working closely together and have provided guidance to Agencies on conducting the Government-wide search.

The first organization, the Government-wide Interagency Working Group, includes key representatives from the Department of Defense, the Department of Energy, the Central Intelligence Agency, the Department of Veterans Affairs, the Department of Health and Human Services, the National Aeronautics and Space Administration, the Department of Justice, and the Office of Management and Budget. This group is responsible for coordinating and overseeing the Government's search for records of human radiation experimentation. The strategy for the Agencies involved in the search process is straightforward and all-inclusive. Radiation experiments are defined as those:

(1) Experiments on individuals involving intentional exposure to ionizing radiation. This category does not include common and routine clinical practices, such as established diagnosis and treatment methods, involving incidental exposures to ionizing radiation.

(2) Experiments involving intentional environmental releases of radiation that (A) were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation.

The second activity established by the President, the Independent Advisory Committee, is an independent group composed of pre-eminent scientists, physicians, legal experts, medical ethicists, and others. Its purpose is to advise the Interagency Working Group on matters pertaining to the ethical and scientific standards that were applied in government-sponsored or conducted research which involved the intentional exposure of humans to ionizing radiation. Specifically, as stated in the Executive Order issued by President Clinton in January: "The Advisory Committee shall consider whether (A) there was a clear medical or scientific purpose for the experiments; (B) appropriate medical follow-up was conducted; and (C) the experiments' design and administration adequately met the ethical and scientific standards, including standards of informed consent, that prevailed at the time of the experiments and that exist today.

Within the Department of Defense, we took further steps to ensure that DoD responded to the executive order issued by the President. Then-Secretary of Defense, Les Aspin, appointed the Assistant to the Secretary of Defense (Atomic Energy), Dr. Harold P. Smith, Jr. as the official responsible for this important initiative. Second, to focus the Department's efforts, we set up a command center structure, initially led by a Flag Officer and now led by a Senior Executive Service civilian, that serves as the central repository for all documents retrieved as a result of our record search. The command center is also responsible for reviewing and analyzing documents found during the search and for responding to public inquiries related to human subject participation in radiation experiments.

Third, DoD established strict records review procedures for all DoD components to

ensure a comprehensive record search. Within these procedures, the need to "err on the side of inclusion" when searching for records was emphasized to assure the public that the Government was being open and forthcoming on this issue. We also established guidelines to allow for the expeditious declassification of documents located during the record search.

Five straightforward principles guide the Department's efforts. First, we want the search to be thorough. Second, the search will be done as quickly as possible. Third, all due care is to be exercised to preserve records related to human radiation experiments. Fourth, the integrity of the process must be preserved to ensure that it retains its credibility in the long term. Fifth, the process must result in open accounting of the Department's past action in human radiation experiments.

In keeping with these principles, the Department's response to this issue consists of two phases. Phase I, which has been completed, identified DoD organizations that conducted or sponsored human radiation experiments, identified the archives or records center where records concerning such experiments are stored, and documented the process by which the search was conducted. Phase II, which is still in progress, will identify each human radiation experiment, provide details of the experiment, and locate the relevant records. Phase II of the search process is expected to be completed by April 1995.

The Department has also focused its efforts to respond to requests for records and information from the Independent Advisory Committee. The Department has provided

information related to Departmental informed consent procedures since the mid-1940's; records on the development of ethics policies since 1944; and policy directives related to the establishment and operation of pertinent research and development bodies; and other data.

The DoD record search has been a massive undertaking and is still in progress. It is truly a box-by-box, page-by-page endeavor. Hundreds of people throughout DoD expended considerable effort on this research task. Some of the locations where records have been located include: National Archives, Washington, D.C. and Suitland, Maryland; Washington National Records Center, Suitland, Maryland; Federal Personnel Records Center, St. Louis, Missouri; Naval Medical Research Institute, Bethesda, Maryland; Naval Hospital, San Diego, California; Dugway Proving Ground, Utah; the Army Training and Doctrine Command, Fort Monroe, Virginia; and Armstrong Laboratory, Brooks Air Force Base, Texas and Wright-Patterson Air Force Base, Ohio. Since January, we have spent approximately 65,000 man hours on this process. We are making progress, but we still have a long way to go.

Now I would like to address your specific questions. First, concerning DoD-sponsored programs involving human subject ionizing radiation experiments during the 1950s, 1960s and 1970s, the Department has categorized these experiments into four categories: therapeutic/diagnostic, intentional atmospheric releases, total body irradiation, and tracer studies. To give you the flavor of what I am talking about, the following are examples of experiments from each category: **Therapeutic/diagnostic** studies include "The Use of Radioisotopes in Diagnostic Hematologic Procedures (Simultaneous Cr-51 and Fe-59 Studies)" and "The

Significance of Positive Ipsilateral Nodes in Resections of Lung"; **intentional atmospheric** releases include "The Green Run Test" conducted in Washington and radiological warfare tests conducted at Dugway Proving Grounds, Utah from 1949-1952; **total body irradiation** research includes the "Metabolic Changes in Humans Following Total Body Irradiation" experiments conducted at the University of Cincinnati and "Systemic and Clinical Effects Induced in 263 Cancer Patients by Whole-Body X-Irradiation with Nominal Air Doses of 15 to 200 Rads"; and **tracer** studies include "The Total Exchangeable Potassium and Chloride and Total Body Water in Healthy Men of Varying Water and Fat Content" and "Assessment of Platelet Function in Patients with Coronary Artery Disease."

Most of the experiments identified to date fall into the therapeutic/diagnostic or tracer study categories, in which radioactive materials or procedures were used to assist the experimentation, but effects of the irradiation were not a central part of the research. Based on the present requirements to "err on the side of inclusion," we have identified over 2,000 possible human radiation experiments with over 52,000 participants that were conducted or sponsored by DoD. When we locate a record containing three key phrases, *viz.* ionizing radiation, humans and experiments, we include it in our data base of possible experiments and will submit it to the Independent Advisory Committee for review and study. Additional experiments are expected to be identified before Phase II of the search process is completed.

I will now address your question concerning the potential effects of such ionizing radiation experiments upon human subjects. This is a key focus of the investigation's being conducted by

the Independent Advisory Committee, the Interagency Working Group, and the Department of Defense. Since its creation in February 1994, the DoD command center has been compiling information about human radiation experimentation. A detailed questionnaire has been developed and distributed to all individuals under DoD's purview who contact or are referred to the command center. This questionnaire includes a section concerning medical problems experienced by these individuals. Responses to these questions are helping to identify individuals who may have been affected by radiation experiments. This information will ultimately be helpful in any notification and compensation initiatives. Determining the potential effect of exposure to ionizing radiation will have to be done on a case-by-case basis. Many factors will influence the answer, such as the subject's age and the type, duration and frequency of exposure.

Let me now respond to your question about what efforts DoD has made to notify the subjects of these experiments. As I mentioned earlier, one of the responsibilities of the DoD command center is to respond to public inquiries related to human subjects participation in radiation experiments. Inquiries come to the command center by several means: the Radiation Experiments National Helpline, referrals from other agencies, Congressional referrals, White House referrals, or direct contact. To date, the command center has been in contact with more than 4,000 individuals. When the records search process has progressed sufficiently, we expect to undertake a comprehensive effort to notify all participants in DoD-sponsored human radiation experiments.

You have also inquired about the efforts DoD has made to provide medical care or

compensation for the subjects of these experiments. At this time, I believe it is premature to discuss any remedy the Government should apply in this matter until our research is completed and the report of the Independent Advisory Committee has been evaluated.

Furthermore, the provision of medical care to veterans as a result of exposure to ionizing radiation is governed by Public Law 97-72, the "Veterans' Health Care and Small Business Loan Act of 1981," as amended (now codified at 38 USC 1710 (e)(i)(B)), which authorized the Department of Veterans Affairs to provide hospital and nursing home care and limited outpatient services to "veterans who were exposed while serving on active duty to ionizing radiation from the detonation of a nuclear device in connection with each veteran's participation in the test of such a device, or with the American occupation of Hiroshima and Nagasaki during the period beginning September 11, 1945 and ending July 1, 1946." This law provides for medical care related to radiogenic diseases, but does not authorize care for conditions that are found by the Department of Veterans Affairs to have resulted from other than the exposure to ionizing radiation.

As you are aware, Congress has not passed legislation to direct the Government to provide compensation or medical services to the subjects of human radiation experiments. Several bills are currently before Congress related to compensation and medical care for radiation experiment subjects, including HR 4292, "Radiation Experimentation Victims Act of 1994" introduced by Representative Edward Markey; HR 3743 "Radiation Experimentation Compensation Act of 1994" introduced by Representative Martin Frost. Congress, in concert

with the Executive branch, will need to examine and determine whether there is a need to establish specific compensation and medical care programs for individual participants in radiation experiments.

As concerns your question regarding informed consent, formal DoD policy for the protection of human subjects in research dates back to at least 1953. At that time, a TOP SECRET Memorandum (declassified August 1975) was sent to the Secretaries of the Services from Secretary of Defense C.E. Wilson, titled "Use of Human Volunteers in Experimental Research". This memorandum authorized the voluntary participation of military personnel and civilian employees in DoD conducted research for atomic, biological and chemical warfare defense and established specific standards, based on guidelines from the Nuremberg Code for informed consent and minimization of risk of harm to subjects.

Over the years, more detailed procedures have been established, including incorporation in 1991 of the 1974 Department of Health and Human Services regulations for the Protection of human subjects, 45 Code of Federal Regulation (CFR) Part 46.

Today, DoD-sponsored research is governed by the so-called "Common Rule"--the Federal Policy for the Protection of Human Subjects--which is part of DoD regulations at Title 32, CFR, Part 219. A copy of this regulation is attached to my statement. DoD is a full partner in the government's commitment to this standard and has further defined its human use regulation in DoD Directive 3216.2, "Protection of Human Subjects in DoD Supported Research," January 7,

1983 and Department of Defense Guidance for Assurance of Compliance with the Federal Policy for the Protection of Human Subjects, June 10, 1993.

In closing, I would like to reemphasize that the Department of Defense is committed to a full accounting in this matter and is equally committed to ensuring that any experiments involving human subjects are conducted in accordance with established medical research protocols and the highest ethical standards. I will be happy to answer any questions you might have on this issue.

Mr. CONYERS. Thank you. What is that hotline number?

Dr. SOPER. I have it. The DOE radiation experiments hotline is 1–800–493–2998. I have other help-line numbers I will provide you for the record. But that is the national radiation help-line number.

[The information follows:]

DOD RADIATION EXPERIMENTS COMMAND CENTER

TELEPHONE NUMBERS AND ADDRESSES OF RELATED AGENCIES

1. **Nuclear Test Personnel Review (NTPR)**
   6801 Telegraph Road
   Alexandria, VA 22310-3398
   1-800-462-3683

2. **VA Hotline**
   (For referral from NTPR - connects caller to VA regional office in home state)
   1-800-827-1000

3. **VA Hotline** (General)
   ATTN. Mr. Adamczeck
   1-800-827-0365

4. **DOE Radiation Experiments Helpline**
   1-800-493-2998

5. **Lawrence Livermore Laboratory (DOE)**
   510-424-6565

6. **Los Alamos (DOE)**
   Human Studies Project
   505-667-1948

7. **Sandia**
   Historical Task Force in Human Studies
   ATTN. Julie Kesti
   Librarian
   505-845-8044

Mr. CONYERS. Thank you very much. Who heads the team?

Dr. SOPER. In the Department of Defense, my boss, Dr. Harold P. Smith, the Assistant to the Secretary of Defense for Atomic Energy, is the single Department of Defense point of contact. And I am his Principal Deputy.

Mr. CONYERS. All right. He, of course, is not working exclusively on this matter. He has many other responsibilities?

Dr. SOPER. Implementation of Nunn-Lugar activities, the development of a counter proliferation acquisition strategy and nuclear stockpiles maintenance, for example.

Mr. CONYERS. And so do you.

Dr. SOPER. Yes, sir.

Mr. CONYERS. All right.

Mr. Parker, welcome to these hearings.

STATEMENT OF MICHAEL A. PARKER, EXECUTIVE DIRECTOR, U.S. ARMY CHEMICAL AND BIOLOGICAL DEFENSE COMMAND, ABERDEEN PROVING GROUND

Mr. PARKER. Good morning. Thank you, Mr. Chairman, members of the subcommittee.

I am Michael Parker, U.S. Army Chemical and Biological Defense Command. It is a relatively new command formed out of the Chemical Research Development and Engineering Center.

I would like to open with an endorsement of Dr. Soper's comment on the Department being committed to providing full disclosure of all information related to the individual exposure so that the affected parties can deal appropriately with the VA and Department of Labor in identifying appropriate compensation.

As was discussed earlier, the historical roots of the chemical and biological defense efforts resulted in heavy classification. That was the common practice up until 1977, at which point, after the Church hearings, which I believe the chairman referenced earlier, caused the Department of Defense to relook the basis of classification. Since that time, many documents have been declassified in an effort to provide information on individuals, to assist them in prosecuting their claims with the appropriate bodies.

Specific comments on the large area of coverage, experiments or other tests that were referenced earlier, that whole test series is going through a declassification review that should be completed in about the next 30 to 45 days. I might advise that some aspects of the test appear to specifically address performance of some of the dissemination systems and vulnerabilities that are still an issue for national security such that certain elements of the report may have to remain classified.

However, the information on exposure of the general population and the nature of the material, the areas covered and all the pertinent information from a health effects standpoint will be sanitized and released.

I might also note that the Department of Defense did outreach beyond the Department in seeking assistance from the Department of Health and Human Services, specifically the Center for Disease Control, to do an independent assessment of the health effects of the so-called large area coverage test using zinc cadmium sulfide.

The Center for Disease Control in their independent judgment determined the health risk to be negligible.

I might also point out that the statement that zinc cadmium sulfide is a radiation product or an ionization source is incorrect. It is a nonradiative-type material, a complex of metals with a sulfur component. It is in no way a radiation type of material, nor is it classified as a poison, as described earlier.

The health effects are somewhat documented as a potential carcinogen based on the cadmium content. But the acute effects are fairly well-known and it is a relatively benign material in that regard.

Mr. CONYERS. OK. You told me what it isn't. What is it?

Mr. PARKER. It is a complex of zinc metal, cadmium metal, and sulfur. It is a commercial dye product that has a strong fluorescence characteristic, which is why it was used in these particular tests, when exposed to ultraviolet.

I might note as a common component of a child's chemistry set that you buy in a toy store. That is the type of material that was used, and it was believed at the time and still believed to be fairly innocuous in the concentration and at the exposures that were involved in the test.

Mr. CONYERS. OK. It is potentially carcinogenic. What is your background?

Mr. PARKER. I am a mechanical engineer by academic training.

Mr. CONYERS. What is your understanding of the use of that term?

Mr. PARKER. A potential carcinogen is a material that one would suspect on chronic exposure or acute exposure to produce carcinogenic effects in excess of those of the normal background.

Mr. CONYERS. It could be cancer causing.

Mr. PARKER. It could be, yes.

Mr. CONYERS. Well, let me ask you, and I include the study that you mentioned that came from Atlanta, do you have other sources that lead you to an opinion of what the carcinogenic potential is in terms of the experiments that were conducted?

Mr. PARKER. Given the concentration, using these standard available health safety data sheets as kind of the source document and then a literature search of what is known of the material, in the concentrations and the exposure period associated with the test, both the Army Environmental Health Agency and the Center for Disease Control assessed it as negligible risk.

Mr. CONYERS. It is a negligible risk?

Mr. PARKER. That was the judgment of the CDC.

Mr. CONYERS. But I was talking about, have you found anybody else besides them? I concede that that is what they found in Atlanta.

Mr. PARKER. No, sir. I am not aware of any other. As was briefed earlier, the effort and the look by the National Academy of Sciences, which is the preeminent body to do this work, should answer the question definitively.

Mr. CONYERS. OK. Well, then, we don't need the million-dollar appropriation that has been put in the budget to further study this question.

Mr. PARKER. I think that is a judgment the Congress has to make.

Mr. CONYERS. We did. We want to make sure.

Mr. PARKER. I don't think there is any disagreement that the National Academy of Sciences can look at this thing independently and render a true third-party judgment. There is no argument on that.

Mr. CONYERS. You know, it is funny. I don't hear the tobacco industry ever making claims like that.

When they receive third-party judgments, you know what their advertisers put out? "What do they know about that? They are wrong, dead wrong."

We have these disputes raging in the medical community, about what to me are fairly well settled questions as a matter of fact.

So I will accept your view that this ought to be decided, but I think we ought to go ahead with a little further investigation.

Please continue your statement, sir.

Mr. PARKER. One of the specific questions that was raised had to do with the approximate number of people involved, which post-World War II or post-1952 through 1974, in looking across the Department of Defense records, we have been able to determine there were approximately 12,000 individuals who have been involved in chemical agent testing where there was a human exposure.

The testing was terminated in the middle of 1975 by direction of the Secretary of the Army, and subsequently there has been no purposeful exposure of human subjects to chemical warfare agents.

In the area of biological warfare testing conducted between approximately 1950 and 1970, there were the large area tests that were discussed earlier, in which biotracers or simulants were used. There also was a series of tests involving human subjects for the purpose of developing vaccines and antidotes. Approximately 2,000 volunteers participated in the latter, in the development of vaccines and antidotes.

This effort was terminated in I am sorry, the offensive aspects of biological warfare research were terminated in 1969 by Presidential directive, at which time we disposed of our total biological warfare stocks and capability. At this point in time we continue only defensive research.

The biomedical component of the research program, which is clearly the oldest program, has its roots in the 1800's, and it has produced many broadly beneficial products. Two of those in the timeframe in question, the cold war years, of special note were testing and development of treatment for malaria and the experimentation with the psychoactive drugs such as LSD, benzoates, BZ, and related glycolates.

With regard to the medical efforts under the malaria treatment program, in the 30-year period spanning 1945 to 1975, there were approximately 7,000 civilian prisoners involved in that research effort. With regard to the LSD and related psychoactive drug efforts, there were about 700 personnel involved in that.

The thrust of the latter was primarily to determine vulnerabilities and countermeasures that could be taken to protect U.S. forces in the event that psychoactive compounds were used against them.

That concludes my remarks, Mr. Chairman.

I would like to introduce Ms. Jeanne Fites.

Mr. CONYERS. Before you introduce her, on page 4 of your statement, did you mean to say that these were volunteers, or do you disagree with the Army IG that found that these volunteers were not fully informed as required prior to their participation?

Mr. PARKER. The testing involved volunteers in the sense that the individuals knew that they were participating in a voluntary manner. The IG found that in some cases and I think by anybody's definition of informed consent, that the individuals were not necessarily provided all the information that would truly allow them to meet the intent of informed consent. No one was coerced to participate in the experiments.

There were occasions when less than adequate information was provided.

Mr. CONYERS. All right. Thank you.

[The prepared statement of Mr. Parker follows:]

RECORD VERSION

STATEMENT BY

MICHAEL A. PARKER

BEFORE THE

SUBCOMMITTEE

ON LEGISLATION AND NATIONAL SECURITY

COMMITTEE ON GOVERNMENT OPERATIONS

UNITED STATES HOUSE OF REPRESENTATIVES

SECOND SESSION, 103RD CONGRESS

CHEMICAL, BIOLOGICAL, AND DRUG TESTING PROGRAMS

28 SEPTEMBER 1994

NOT FOR PUBLICATION
UNTIL RELEASED
BY THE HOUSE
GOVERNMENT OPERATIONS
COMMITTEE

U.S. ARMY CHEMICAL, BIOLOGICAL AND DRUG TESTING PROGRAMS

BACKGROUND

Over the past seventeen years, Congress and the public have expressed interest and concern about the use of humans for chemical, biological and drug testing. Until recently, most information related to these programs was classified due to its sensitivity and national security implications. In 1977, the Army began the declassification effort for its testing programs. Even though quite old, portions of these documents contain technical information that remains critical to our national security interests. Some information contained in various reports has the potential for misuse by individuals or groups intending harm against the nation and the general public. For this reason, complete declassification of all test programs is not in the best interest of national security. The Department of Army is, however, committed to providing, to the maximum extent possible, complete and accurate information on our testing programs to the American people.

CHEMICAL WARFARE PROGRAM

On June 28, 1918, the President of the United States directed the organization of the Chemical Warfare Service (CWS), under the Secretary of War. In October 1922, the CWS created a Medical Research Division to conduct research directed at providing therapeutic and prophylactic defense measures against chemical agents.

Prior to World War II, volunteer employees of Edgewood Arsenal were used as test subjects in various tests of mustard, phosgene, and other chemical agents. In early 1941, the threat of war caused greater urgency for the development of protective items, and consequently, a larger source of volunteers was needed. The first recorded recruiting arrangement was a request made to all technical and officer personnel at Edgewood Arsenal to participate in various tests.

The documentation from the World War II period does not show who explicitly authorized the use of human volunteers. It is believed, however, that the Acting Secretary of Army, approved the test in principle and granted implied authorization. Large-scale human experimentation was thereafter conducted at Edgewood Arsenal, as well as at field laboratories located at Camp Siebert, Alabama; Bushnell, Florida; Dugway Proving Ground, Utah; and San Jose Island.

The Army's World War II mustard agent test program tested protective clothing, equipment, and antivesicant ointments. In addition, the Army developed and tested offensive chemical weapons and evaluated the effectiveness and persistency of mustard agents in different environments. Test documents show that gas chamber tests and skin tests were conducted at Edgewood Arsenal, Maryland, and that field tests were conducted at Bushnell Field, Florida; Fort Pierce, Florida; Dry Tortugas, Florida Keys; San Jose Island, Panama Canal Zone; Camp Siebert, Alabama; Dugway Proving Grounds, Utah; Camp Polk, Louisiana; Gulfport, Mississippi; El Centro, California; San Carlos, California; Fort Richardson, Alaska; and New Guinea.

The Army's records of mustard agent test activities do not identify by name soldiers who participated in World War II chemical tests. However, a Department of Army report titled, "Medical Research in Chemical Warfare," estimates that the number of participants is in the thousands. Over 1,000 soldiers were commended for their participation in tests. The records do not indicate, however, what types of tests these soldiers participated in. According to the report, 200 and 300 soldiers were available at Edgewood and Dugway Proving Grounds to participate in experiments from December 1944 until the end of the war.

In the early 1950's, the Army Chemical Corps began a classified research program for developing incapacitating agents that continued until 1975. This program involved testing chemicals including nerve agents, nerve agent antidotes, psycho chemicals, irritants, and vesicant agents. Human volunteer nerve agent testing with G-agents was conducted during the early 1950's. In the late 1950s, after approval by the Secretary of the Army, testing with V-agent began. The chemicals were given to volunteer service members at Edgewood Arsenal, Maryland; Dugway Proving Grounds, Utah; and Forts Benning, Bragg, and McClellan.

The Army conducted an extensive chemical testing program with human subjects at Edgewood from 1955 to 1975. Human volunteers were exposed to chemical agents to see how agents might affect humans and how such affected humans might respond to therapy. The program consisted of a wide variety of tests including: chemical agents, treatment drugs for chemical agents, personnel protective equipment, skin penetration, irritant agents, and personnel performance measurements. Approximately 7,000 soldiers took part in this program. The volunteer hours were broken down according to the following experimental categories: incapacitating compound - 29.9%, lethal compounds (anticholinesterases, cylinide) - 14.5%, riot control compounds - 14.2%, protective equipment and clothing (masks and climatic effects) - 13.2%, effects of drugs and environmental stress on human physiological mechanisms - 6.4%,

development evaluation and test procedures (compounds in body fluids, stress condition) - 12.5%, human factors tests (ability of volunteers to follow instructions) - 2.1%, other (visual studies, sleep deprivation, incapacitating compounds effect on rifle team) - 7.2%.

Of the 34,500 compounds studied by the Chemical Corps, approximately 150 chemicals were used in the human volunteer program. Of these, approximately 50 were therapeutic agents approved by the Food and Drug Administration or are well-known solvents and nutrients. The Army's Medical Research and Development Command, Fort Detrick, Maryland, maintains records of the test participants and the chemicals to which they were exposed.

The chemical compounds used in chemical testing program at Edgewood Arsenal from 1955 to 1975 include: Anticholinergic - Scopolamine, BZ, Ditran, "several numbered"; Barbiturates - Amytal, Nembutal, Phenobarbital, Seconal; Diagnostic - Antipyrine, Sulfobromphthaleim, Indocardio green, Sodium Aminohippurate; Anticholinesterase Agents - DFP, Physostigmine, Prostigmine, GD, Malathion, GA, GF, VX, GB, G-V; Antidotes - Atropine, Benactyzine, Homatropine, Sodium Nitrite, Vasoxyl, Methscopolamine, BOL, metatropine, THA, BTA; Oximes - Protopam chloride, P2S, TMB4, Toxogonin; Irritants - DMHP, DEP, "several numbered"; Miscellaneous - Adrenalin, Alcohol, Amyl Nitrite, Artane, Ammonium Chloride, Benadryl, Caffeine, Compazine, Cogentin, Curare, Dapsone, Dexedrine, Dilantin, Dibenzyline, Heparin, Inderal, Isuprel, Lanoxin, Lidocaine, Maisilid, Mecholyl Chloride, Meprobamate, Mylaxin, PABA, Propylene glycol, Prolixin, Pryibenzamine, Reserpine, Ritalin, Sodium Bicarbonate, Thiamin, Thorazine, Urecholin, Valium, ACTH, Nitrogen Dioxide, Sernyl, LSD, 5HTP, Mustard, and N-Octylamine.

In addition to the testing previously discussed, field testing was also conducted on small military units to examine the effects of psycho chemical agents on military operations. These tests were conducted at Forts Benning, Bragg and McClellan and Dugway Proving Ground. The Army also conducted field testing in the late 1950's and early 1960's using a wide range of chemical compounds at Dugway Proving Ground, Utah; Edgewood Arsenal, Maryland; England; Hawaii; Horn Island, Mississippi; Marshall Islands; Maryland; San Jose Island, Panama; Arctic Test Center, Fort Greely, Alaska; Water Island, Virgin Islands; and Yuma Proving Ground, Arizona. Since that time, limited field testing without human test subjects has been done at Dugway Proving Ground.

A 1975 Department of the Army Inspector General report states that, "the evidence clearly reflected that every possible medical consideration was observed by the professional investigators at the Medical Research Laboratories." The report, however, concludes that, "...(the) volunteers were not fully informed, as required, prior to their participation; and the methods of procuring their services, in many cases, appeared not to have been in accord with the intent of (the) Department of the Army policies governing (the) use of volunteers in research."

On July 28, 1975, Acting Secretary of the Army Norman R. Augustine suspended testing of chemical compounds on human volunteers at Edgewood Arsenal. To date, the Department of Defense has identified approximately 12,000 individuals who may have been exposed to chemical weapons agents as part of defense research during and after World War II.

BIOLOGICAL TESTING PROGRAM

The United States began a Biological Warfare Program in 1942 that included both offensive and defensive testing programs. The offensive aspects of the program were stopped by Presidential Directive in 1969 and by 1973 the U.S. had destroyed all of its BW stockpiles. Today, only defensive testing work continues.

The policy of the United States regarding biological warfare between 1941 and 1969 was to first deter its use against the United States and its forces, and secondly, to retaliate if deterrence failed. Fundamental to the development of a deterrent strategy was the need for a thorough study and analysis of our vulnerability to both overt and covert attacks, and an examination of the potential range of retaliatory options. From its inception, the program was characterized by continuing in-depth review and participation by the most eminent scientists, medical consultants, industrial experts, and government officials.

Prior to 1977, the BW program was classified up to top secret. In 1977, most aspects of the program were declassified. A congressional hearing was held on this subject on 8 March 1977, and concurrent with the hearing, the Army released an unclassified report titled, "U.S. Army Activity in the U.S. Biological Warfare Programs." The report contains extensive information on the dates and locations of tests, types of simulants used, and rationale for the U.S. biological program.

BW testing was conducted to provide information on several issues such as: the agents likely to be used; the best means of disseminating agents; the sizes of areas that could be attacked; the environmental effects of agents; and the obstructive effects of buildings and terrain of agents. Tests were also done to identify areas of the U.S. and forces most vulnerable to attack, and to devise physical and mathematical models to be used as substitutes for live, open air testing.

The BW testing program was concerned principally with anti-personnel and anti-crop agents and associated delivery capabilities, and to a lesser degree anti-animal agents. Biological testing was conducted in laboratories, closed chambers, and open air field (large scale), and used both simulants and pathogens. The biological testing program also included human volunteers under a codename "Operation Whitecoat."

Anti-personnel agent research covered a wide range of highly infectious pathogenic bacteria, rickettsial, viruses, and fungi, and extremely toxic products of biological origin (toxins). Research efforts were directed toward selecting and preserving the most virulent strains, establishing human dosages, enhancing storability, and survival when released as an aerosol. Technology for large scale production of the most promising agents was developed. Efforts were expended to obtain improved simulants to assist production, development, and testing efforts.

The Department of Defense conducted anti-crop research using BW agents and CW agents (i.e., chemical herbicides and defoliants). Research on BW agents included strain selection, evaluation of nutritional requirements, development of optimal growth conditions and harvesting techniques, and preparation in a form suitable for dissemination. Extensive field testing was done to assess the effectiveness of agents on crops. Many candidate anti-crop BW agents were screened resulting in five standardized BW anti-crop agents that included various stem rust of wheat and rye, and rice blast.

The Department of Defense began conducting open air tests using BW simulants and certain selected inorganic materials such as fluorescent particles in the 1950s to obtain aerosol dissemination data. The two most commonly used biological simulants were Serratia marcescens (SM) and Bacillus subtillis varian niger, normally referred to as Bacillus globigii (BG), and Aspergillus Fumigatus (AF). The most commonly used fluorescent particle (FP) was an inorganic complex, zinc cadmium sulfide.

Bacillus globigii is considered ubiquitous in nature. It can be readily cultured from hay, dust, milk, and water. It was considered by medical authorities to be harmless to man. SM is

commonly found in water, food and sewage and sometimes can be isolated from feces and sputum of apparently healthy people. It was used as a bacterial marker with little risk because of its avirulant nature. In 1969 it was recognized as having limited pathogenic capability and was not used for study of experimental infection in man because of the assumed role as the opportunist, producing disease if man is exposed to large doses or when the body's defenses were weakened for other reasons.

The AF was a fungus simulant used on four occasions from 1950-1953 and abandoned when antifungal agents were removed from the BW program. AF is ubiquitous in nature and is considered an opportunist causing aspergillosis in debilitated persons.

The Department of Defense conducted numerous open air tests using zinc cadmium sulfide in the 1950s and 1960s. This testing, referred to as Fluorescent Particle Atmospheric Tracer Technique, employed accepted meteorological practices using zinc cadmium sulfide to determine the possible effectiveness of an adversary dispersing a BW agent over populated areas of the U.S. The compound is found naturally in the earth's crust and is in numerous products still in use today. Cadmium can be a carcinogen at high levels.

The U.S. Army Center for Health Promotion and Preventive Medicine (formerly the Army Environmental Health Agency) recently completed three Health Risk Assessments for cities involved with the FP aerosol testing. In all cases, the assessments concluded that the level of risk experienced by inhabitants in the test areas was below the 1994 Occupational Safety and Health Administration (OSHA) standards. Additionally, the assessment concluded that the risk of exposed individuals developing cancer is below the accepted level of risk established by the U.S. Environmental Protection Agency for the general population. In August 1994, the Center for Disease Control and Prevention, in an independent study, concluded that zinc cadmium sulfide tests posed negligible health threats to residents of the test areas.

Human Volunteer Testing. It was determined in 1952 that while tests with simulants had demonstrated the vulnerability of the U.S. to biological attack, no scientific data was available to assess human vulnerability to biological agents. The program included several thousand volunteers and examined the vulnerability of man to biological agents, prevention and treatment of BW casualties, and identification of biological agents.

The major human testing program, Project Whitecoat, originated in 1954 following a series of meetings between representatives of the General Conference of the Seventh Day

Adventist Church and the Surgeon General of the Army. It continued at Fort Detrick, Maryland until the end of the draft in 1973. Project Whitecoat was originally established to determine the vulnerability of man to attack with biological weapons using Q fever as a prototype.

Personnel for Project Whitecoat were recruited from military personnel with a 1-A-O (conscientious objector) classification undergoing Basic and Advanced Individual Training at the Medical Training Center, Fort Sam Houston. These personnel were given a complete and comprehensive explanation of the program including discussion of the risks involved. The following day, they were interviewed individually and offered an additional opportunity to ask questions and indicate their desire to participate or not. Many more individuals volunteered than could be accepted.

After administrative processing, these volunteers were assigned to various noncombatant duties at Fort Detrick. Volunteers were again briefed on each individual project and allowed to reject participation. Those who chose to volunteer signed consent forms. Multiple vaccine and antibiotic studies were conducted on a wide variety of infectious diseases. The entire program was initially monitored by the Commission of Epidemiological Survey of the Armed Forces Epidemiology Board. Project Whitecoat involved 2,200 soldiers between 1954 and 1973.

Information obtained for the BW testing program has proven to be of great value to public health, agriculture, industry, and the fundamental sciences. Today's defensive program continues to seek and develop effective warning and detection devices, protective clothing and equipment, and continues to assess the vulnerability of the U.S. and its force to enemy BW threat.

DRUG, DISEASE AND RESEARCH TESTING PROGRAM

Biomedical research programs are the oldest research programs in the Armed Forces with their beginnings the early 1800s. From the 1800s leading up to the 1950s, the military was involved in many programs testing drugs and vaccines in human subjects. These tests have made a number of valuable contributions to medicine. For example, the military studied and participated in the development of a safe Venezuelan Equine Encephalitis vaccine and Sulfamylon, an antibacterial cream for the treatment of pseudomonas infections in burn patients. In the late 60s and earlier 70s, studies validated the use of gamma globulin for prevention of hepatitis.

In 1976, military tests validated use of the drug acetazolamide for Acute Mountain Sickness. During the 1970s, multiple other clinical investigations took place with the rise of antibiotics (carbenicillin, tetracycline, etc.) and other drugs (antacids and cimetidine for Curling's ulcer). While there were other drug testing programs, two major cold war drug testing programs conducted by the Department of Defense deserve discussion:

Malaria

The U.S. government sponsored malaria research involving prisoners from 1945 through 1975. The Committee on Medical Research of the Office of Scientific Research and Development, National Research Council, organized and sponsored the initial malaria drug development program. The U.S. Army was one of several cooperating federal agencies.

During World War II and the later 1940s, several sites were involved in testing new compounds. The U.S. Army was primarily involved with Stateville Penitentiary, Illinois. From the onset, the use of prison volunteers was open to public scrutiny as evidenced by an editorial in the new England Journal of Medicine in March 1945 and other public observation of the program. The volunteers were white male inmates, 21 to 45 years of age and in good physical and mental health. They were cognizant of the nature of the experiments and were able to remain under observation for 18 months. This testing succeeded in the discovery of chloroquine, a drug with rapid and unsurpassed anti-malarial activity.

In the 1960s, chloroquine-resistant malaria surfaced in Southeast Asia, and subsequently initiated the need for new effective anti-malarial drugs. In 1963 to 1964, studies were initiated under government contract at Kansas City Jail, University of Missouri and Maryland House of Correction, University of Maryland.

Two additional facilities were used briefly in the early 1970s, Oklahoma State Prison at McAlester, Oklahoma, and the Florida Correctional Institution, University of Florida College of Medicine. The U.S. Army Investigational Drug Review Board approved each study and ensured that the potential volunteers were informed as to the nature and hazards of their participation in the studies. They were allowed the right to withdraw from participation without prejudice. All of the U.S. Army prison programs were stopped in 1975. Alternative procedures for continuing anti-malarial drug testing in free living volunteers were subsequently developed by the Walter Reed Army Institute of Research and are active today. The U.S. Army worked with approximately 7,000 prisoners in the malaria drug testing program during the period 1945 to 1975.

LSD, Benzilate and Scopolamine Studies.

The remarkable hallucinogenic properties of lysergic acid diethyl amide (LSD) were discovered in 1943. In the 1950s, LSD was thought to possess many properties desirable in chemical warfare. It was known to be effective in incredibly small amounts and conveniently colorless, odorless, and tasteless. Because of these properties, the U.S. Army Chemical Corps and the U.S. Army Intelligence Corps decided to conduct a series of experiments with LSD. These tests began in 1955 and continued through 1967. Volunteer research subjects were solicited from the Army in general and from the Chemical Corps.

In some cases, subjects were volunteering for research but were not told they were in drug research. If they did know they were in drug research, they may not have been told what drugs they were taking. In most cases, LSD-exposed subjects voluntarily participated in the chemical warfare testing and were informed ahead of time they would be receiving a psychoactive agent.

Strict medical supervision was provided during the testing and prior to the actual receipt of the drugs. Almost all subjects received some degree of psychological screening, and 30 to 50 percent of the Army volunteers were turned down during the screening process. The bulk of the testing was carried out at Edgewood Arsenal, Maryland, although other sites such as Dugway Proving Ground and Forts Benning, Bragg and McClellan were occasionally used. Projects were designed to obtain information, not only about the possible usefulness of LSD in operations against an enemy force, but also about means that might be taken to defend against the use of LSD to disrupt U.S. forces. By 1967, further LSD research was discontinued. The civilian community over these same years has tested LSD on a much larger scale. In 1975, Secretary of the Army Norman R. Augustine suspended testing of chemical compounds on human volunteers at Edgewood Arsenal.

There are 54 contracts or reports of contracts with universities and chemical companies from 1950-1971. Twenty-five were awarded for incapacitating agent research. The agent/drugs used were physical incapacitants such as morphine, demerol, seconal, scopolamine, chlorpromazine, and secobarbital. Mental incapacitant studies included LSD, mescaline, atropine, psilocybin, BZ and glycolate compounds.

Several LSD follow-up medical evaluation studies took place in the 1970s, beginning with Project 33 in 1974-75. In the meantime, public and congressional interest in chemical warfare

testing was stimulated by, among other things, the disclosure of the tragic suicide in 1953 of an Army mathematician shortly after surreptitiously being given LSD by non-military experimenters. In 1975, congressional investigators requested that measures be taken to locate and evaluate for possible long-term adverse effects all former participants in Army chemical warfare research with LSD. Project 28 and Project 50/50 followed with the number indicating the number of participants in the follow-up study. In 1978, a follow-up office was established. It proceeded to contact all individuals from a comprehensive roster of 686 individuals believed to have received LSD. Of those, 320 (47%) individuals electing to participate were provided travel at government expense to selected Army medical centers for evaluation. A 158 page summary report of this medical follow-up program was prepared in 1980.

As a group, the LSD testing subjects appeared to be relatively stable socially, unusually well educated and economically successful. The medical and psychiatric findings for those 220 subjects examined directly, as well as that obtained from the additional 100 subjects examined by questionnaire, generally appeared to parallel in type and frequency findings that could be expected in a comparable segment of the general population.

Mr. CONYERS. Ms. Fites.

STATEMENT OF JEANNE FITES, DEPUTY UNDER SECRETARY OF DEFENSE FOR REQUIREMENTS AND RESOURCES

Ms. FITES. Thank you.

As the General Accounting Office stated, the Department has been less aggressive getting information on people who were subjects of chemical or biological weapons experiments. We started in March 1993. We have not had the resources put against it that have been put against, for example, the radiation. A lot of the same people are working on the same things.

We found about 500 sites that are not all test sites. There were 16 test sites for chemicals that we found so far, and the 500 sites include transport points and everything else. So far we have identified 12,000 names. Locating these people isn't going to be easy.

We don't have full names in most cases. We don't have serial numbers, Social Security numbers. We have people literally sitting and going through old dusty boxes to find these names and to find what experiments were conducted and to collect the information on the experiments.

We have had people contact us, and to the extent we can, we are matching them up with records on experiments when they can identify where they thought the experiment occurred, where we have found any records for that experiment. We have put the individuals in contact with the VA or the Department of Labor as appropriate.

Last week we got additional names, both from the office of Congressman Goss and from Mr. Nat Schrerman, who is a victim of mustard gas testing who has testified several times before the Congress. He has been compiling lists of names. We are in the process of trying to contact these people, get more information, and help them find records that would help them prove their cases.

I would be pleased to try to answer any questions you have.

And right now, Dr. Osterman will address the Department's compliance with the Nuremberg Code, et cetera.

[The prepared statement of Ms. Fites follows:]

TESTIMONY OF JEANNE B. FITES

DEPUTY UNDER SECRETARY OF DEFENSE

(REQUIREMENTS AND RESOURCES)

BEFORE THE HOUSE GOVERNMENT OPERATIONS COMMITTEE

SUBCOMMITTEE ON LEGISLATION AND NATIONAL SECURITY

SEPTEMBER 28, 1994

Not for Publication

Until Released by the Committee

Thank you for the opportunity to tell you what the Department of Defense is doing to identify and support military or civilian personnel who were exposed to chemical weapons agents as part of Defense research programs during and after World War II.

On March 9, 1993, Dr. Perry directed the Department to take immediate steps to determine the extent of the potential human exposure to chemical weapons agents through our testing program and to identify the individuals exposed. He immediately declassified all relevant information concerning chemical weapons testing programs that were conducted prior to 1968, and directed the Department to begin the declassification process for all programs since 1968. He also released any individuals who participated in testing, production, transportation, or storage associated with any chemical weapons research from any oaths of secrecy or non-disclosure restrictions concerning their participation in such testing.

Our first efforts focused on two things: first, a definition of the kinds of data we were seeking on the testing programs and on the individuals exposed; and second, identification of places where such information would be found. Unfortunately, there is no central repository for information concerning historical data on our chemical weapons testing programs. We worked with representatives from Veterans Affairs to ensure that we would collect information that would support their efforts to appropriately identify and compensate veterans exposed.

In addition to the National Archives in Suitland and St. Louis, we have identified five major DoD records holding sites and one University site where large volumes of records are stored. They are: Edgewood Arsenal, in Maryland; the Naval Research Laboratory, in Maryland; Dugway Proving Ground, in Utah; the Army Chemical School Library, in Alabama; Rocky Mountain Arsenal, in Colorado; and the University of

Chicago. We also believe that additional records may be stored at other contractor facilities and universities that we have not identified.

In general, these records are not indexed or sorted. They consist of thousands of linear feet of paper in filing cabinets or boxes, and thousands of sets of microfiche. They are in historical library collections, warehouse holding areas, and technical libraries. The files also contain weapons schematics, technical drawings, and operational directions as well as scientific formulae. Personnel information can sometimes be extracted from scientific notebooks, operational orders and plans, administrative correspondence, technical reports, personnel rosters, or medical records. Because of national security, foreign diplomacy, and personal privacy issues, review of this information can only be completed by personnel with appropriate security clearances and technical background, as well as knowledge of personnel issues. Each piece of paper in every collection must be reviewed page by page.

The records at the contractor-operated Chemical and Biological Information Analysis Center at Edgewood are completely automated. We contracted with them to perform a key words search on their records. The resulting report contains over 2,000 entries for about 500 sites. The sites include locations where chemical and biological agents were tested, produced, stored, or shipped. We are currently enhancing this report with additional information from on-site manual searches using contractor and DoD personnel.

One of our sources of information is correspondence from veterans and others who participated in or know something about the tests. We follow up on individual claims forwarded to us from Veterans Affairs and on phone conversations and letters. These contacts have resulted in identification of additional storage and testing sites.

We now have about 12,000 names of individuals who may have been exposed, including 504 from the Bari Harbor incident. We do not have complete information on all of them and not all of them are confirmed exposures.

The Department is committed to supporting these individuals, and we will continue to pursue review of records and follow-up on letters from veterans and personal conversations with veterans and former DoD employees.

Mr. CONYERS. Welcome, doctor.

STATEMENT OF JOSEPH OSTERMAN, Ph.D., DIRECTOR, ENVIRONMENTAL AND LIFE SCIENCES, OFFICE OF THE DIRECTOR, DEFENSE RESEARCH AND ENGINEERING

Dr. OSTERMAN. Thank you, Mr. Chairman.

As mentioned, I am Dr. Osterman, the Director of Environmental and Life Sciences in the Office of the Director of Defense Research and Engineering. I will provide an overview of the measures currently in place to ensure the protection of human subjects in Department of Defense research and development.

The Federal policy for human subjects protection is promulgated in title 32, part 219, Code of Federal Regulations. This Federal policy is designed to make uniform the human subjects protection system in all applicable Federal agencies and departments, including the Department of Defense, and hence its reference as the Federal policy or common rule for human subjects protection.

The basic protections contained in the Federal policy for human subjects protection govern the role of the human subjects review board, or Institutional Review Board, the informed consent document, and the reporting chain of command for overseeing the human subject protection regulations.

These three concepts are interlinked and serve to ensure the protection of human subjects throughout the Federal Government. The informed consent document is a voluntary agreement of the subject to participate in a research study protocol that is based on a plain language explanation of the test purpose and all known risks and benefits associated with participation in the study protocol.

The informed consent document contains a description and explanation of the procedures to be employed, a description of risks and discomforts associated with study protocol participation, a description of the benefits that are expected from such participation, a disclosure of alternative procedures if the research is a clinical, therapeutic trial conducted in a hospital, an offer to answer inquiries about the procedure, and a clear understanding that the individual is free to withdraw consent and discontinue participation in the study protocol at any time.

Informed consent requires the participation be free of coercion. The second key to ensuring human subjects' protection is the Institutional Review Board, IRB, or human use committee. The IRB membership serves as reviewers of the study protocol and acts as human subject advocates to ensure the adequacy of the informed consent document and the safety of human subject participation.

Formal IRB meetings are regularly scheduled, usually on a monthly basis, to review new protocol submissions and to conduct an annual review of existing ongoing protocols. The IRB and informed consent documents are parts of the overall program to ensure the protection of the rights and well-being of human subject participants in research protocols.

Also key to the program is active oversight participation by individual facility commanders through a formal submission of assurance statements. The facility commanders and major military components state their awareness and intent to protect the rights of subjects in research under the Federal policy for protection of

human subjects and to establish formal chains of command for accountability in execution of the human subjects' research program.

Within the various Service components or agencies, human subjects' protection is conducted at biomedical research and development facilities and research programs at various medical treatment facilities. In general, both facets of this program are under the review of the Service Surgeon General.

There are no significant differences in oversight of extramural and intramural human subjects' research programs. The Federal common rule applies to both areas of research activity with regard to human subjects' protection.

In accordance with the common Federal rule, extramural protocols require the facility performing the research to maintain a current National Institutes of Health assurance number issued by the Office for Protection from Research Risk or a Department of Defense assurance number issued by a military service or agency.

In general, a notice of Federal requirements with regard to human use experimentation is often included in the broad agency announcement soliciting research proposals from the private sector.

A contractor or grantee must undergo an Institutional Review Board review and approval of research protocols and informed consent documents prior to the award of any funds from the Department of Defense.

Additional protections for vulnerable classes of individuals, fetuses, pregnant women, children and prisoners can be found in title 45, Code of Federal Regulations, part 46, subparts B, C and D. The Department of Defense has adopted these additional guidance policies for vulnerable classes of individuals.

Let me conclude, sir, by saying the Department views the protection of the human subject as a major responsibility.

This concludes my statement, Mr. Chairman. I would be pleased to answer any questions from you or other members of the committee.

[The prepared statement of Dr. Osterman follows:]

DRAFT TESTIMONY FOR DR. OSTERMAN

BEFORE THE COMMITTEE ON GOVERNMENT OPERATIONS

SUBCOMMITTEE ON LEGISLATION AND NATIONAL SECURITY

28 SEPTEMBER 1994

Good morning, Mr. Chairman. I am Dr. Joseph Osterman, Director of Environmental and Life Sciences in the office of the Director, Defense Research and Engineering. I will provide an overview of the measures currently in place to ensure the protection of human subjects in DoD research and development. I will specifically address the manner in which informed consent is secured from volunteers.

The Federal Policy for Human Subjects Protection is promulgated in Title 32 Part 219 Code of Federal Regulations (32 CFR 219). This federal policy is designed to make uniform the human subjects protection system in all applicable federal agencies and departments, including the Department of Defense, and hence its reference as the Federal Policy or Common Rule for Human Subjects Protection. In addition, the Department adheres to other federal regulations governing human subjects. These include: the vulnerable classes of human subjects protected under 45 CFR 16, and FDA regulations codified in Title 21 of the Code of Federal Regulations. These latter regulations include Parts 50 (requirements for informed consent), 56 (provisions for Institutional Review Boards), and 812 (investigational device exemptions).

The basic protections contained in the Federal Policy for Human Subjects Protection

govern the role of the human subjects review board or institutional review board, the informed consent document, and the reporting chain of command for overseeing the human subject protection regulations. These three concepts are interlinked and serve to ensure the protection of human subjects.

The informed consent document is a voluntary agreement of the subject to participate in a research study protocol that is based on a plain language explanation of the test purpose and all known risks and benefits associated with participation in the study protocol. The informed consent document contains a description and explanation of the procedures to be employed; a description of risks and discomforts associated with study protocol participation; a description of the benefits that are expected from such participation; a disclosure of alternative procedures if the research is a clinical therapeutic trial conducted in a hospital; an offer to answer inquiries about the procedure; and a clear understanding that the individual is free to withdraw consent and discontinue participation in the study protocol at any time. Informed consent requires that participation be free of any coercion. Also a clear delineation of any limitations on compensation for any adverse event resulting from such participation must be described.

The second key to ensuring human subjects protection is the institutional review board (IRB) or Human Use Committee. The IRB membership serves as reviewers of the study protocol and act as human subject advocates to ensure the adequacy of the informed consent document and the safety of human subject participation. Within each service or agency, the oversight of human subjects protection is an ongoing process conducted daily. Formal IRB meetings are regularly

scheduled, usually on a monthly basis, to review new protocol submissions and to conduct annual reviews of existing protocols.

The IRB and informed consent document are parts of the overall program to ensure the protection of the rights and well-being of human subject participants in research protocols. Key to the program is active oversight participation by the individual facility commanders. Through a formal submission of an assurance statement, the facility commanders and major military components state their awareness and intent to protect the rights of subjects in research under the Federal Policy for Protection of Human Subjects and to establish formal chains of command for accountability in execution of the human subjects research program.

Within the Department of Defense, human subjects protection oversight resides with the Director, Defense Research and Engineering. Operational oversight has been delegated to the individual Services or Defense Agencies. Within the various Service Components or Agencies, human subjects protection is conducted at biomedical research and development facilities and clinical investigations programs at various medical treatment facilities. In general, both facets of this program are under the review of the Service's Surgeons General.

CLINICAL INVESTIGATIONS PROGRAMS

The primary responsibility for oversight of human medical research resides with each hospital commander whose facility sponsors a clinical investigation program. This oversight is

exercised at each major teaching medical treatment facility primarily through the Chief of the Department of Clinical Investigation. These medical treatment facilities also enjoy the deliberations and contributions of human-use committees and clinical investigation committees. Medical monitors are appointed for each study not conducted by a physician, and that involves more than minimal risk, to assure the ongoing protection of each subject. Review by the human-use committee is required at least annually in order for studies to continue. A central office is established within each Service to provide human subjects protection, coordination and quality assurance among medical treatment facilities performing human subjects research.

ARMY: Clinical Investigation Regulatory Office (CIRO). CIRO also hosts an annual training conference on human use and animal use oversight for Army, Navy, and Air Force investigators and administrators.

NAVY: Health Sciences Education and Training Command.

AIR FORCE: Headquarters Air Force Medical Operations Agency, Office of the Surgeon General.

BIOMEDICAL RESEARCH AND DEVELOPMENT PROGRAMS

The Commanding Officers of the military medical research laboratories or institutes are ultimately responsible for local institutional oversight. Commanders utilize several review

committees to exercise their responsibilities regarding scientific integrity and protection of human subjects. The principal committees for protocol reviews are the Scientific Review and the Human Use Committees. Commanders cannot overrule the Human Use Committee and approve a protocol which the Human Use Committee does not recommend for approval. Monitoring also is provided by a locally assigned physician who serves as a medical monitor for each protocol determined to be greater than minimal risk. This determination is made by a duly convened Human Use Committee.

Oversight review of intramural and extramural human-use protocols is accomplished by the following Service offices:

Army: Human Use Review and Regulatory Affairs Division of the Office of the Deputy Chief of Staff for Regulatory Compliance and Quality, U.S. Army Medical Research and Material Command.

Navy: Committee for the Protection of Human Subjects, Navy Medical Research and Development Command. The Office of Naval Research also support contracted research activities, and under the authority of the Chief of Naval Research, the Head, Personnel Optimization and Biomolecular Science and Technology Department, is responsible for human subjects protection oversight.

Air Force: Headquarters Air Force Medical Operations Agency, Office of the Surgeon General.

The functions of these various offices are conducted in accordance with requirements delineated in Title 32 Code of Federal Regulations Part 219 (32 CFR 219), *Federal Policy for the Protection of Human Subjects*, which is the Department of Defense "Federal Common Rule" document. Headquarters level oversight involves continuous monitoring and audit reviews of the programs under their cognizance. The various oversight offices described maintain records of all research protocols (including study design), investigator credentials, approved informed consent forms, compliance and assurance documentation, progress reports, and minutes of IRB transactions. In addition, the oversight offices serve as central locations for access to Federal regulations, and directives and policies pertaining to research involving human subjects. Furthermore, these offices offer legal consultation and guidance on issues related to regulations.

There are no significant differences in oversight of extramural and intramural human subjects research programs. The Federal Common Rule applies to both areas of research activity with regard to human subjects protection. All protocols involving the use of human subjects are handled with the same level of oversight by the local IRB. In accordance with the "Common Federal Rule," extramural protocols require the facility performing the research to maintain a current National Institute of Health assurance number issued by the Office for Protection from Research Risk, or a Department of Defense assurance number issued by a Military Service or Agency. In general, a notice of federal requirements with regard to human use experimentation is often included in the Broad Agency Announcement soliciting research proposals. A contractor or grantee must undergo IRB review and approval of research protocols and informed consent documents prior to the award of any funds. Furthermore, noncompliance by a contractor or

grantee could result in a termination of the contract or grant.

The authority for oversight of human subjects protection within DoD is established within the military reporting chain of command. Title 32, Code of Regulations, Part 219, *Federal Policy for the Protection of Human Subjects* and Title 10 United States Code, Section 980 establish the fundamental regulatory requirements for human subjects protection. Execution of these regulations and written standards for performance are found in the Service's directives and instructions:

DoD Directive 3216.2, "Protection of Human Subjects in DoD Supported Research"

DoD Directive 6000.8, "Funding and Administration of Clinical Investigation Programs"

Army Regulation 40-7, "Use of Investigational Drugs and Devices in Humans and the Use of Schedule I Controlled Drug Substances."

Army Regulation 70-38, "Clinical Investigation Program."

Army Regulation 70-25, "Use of Volunteers as Subjects of Research."

Secretary of the Navy Instruction 3900.39B, "Protection of Human Subjects."

HSETC Instruction 6000.41A, "Clinical Investigation Program"

Air Force Policy Directive 40-4, "Clinical Investigation and Human Use in Medical Research."

Air Force Instruction 40-403, "Clinical Investigations in Medical Research, Guidance and Procedures."

Air Force Instruction 40-402, "Using Human Subjects in Research, Development, Test, and Evaluation."

Additional protections for vulnerable classes of individuals, fetuses, pregnant women, prisoners, and children can be found in Title 45, Code of Federal Regulations Part 46, Subparts B, C, and D. The Department of Defense has adopted these additional guidance policies for vulnerable classes of individuals. The requirement in those studies using vulnerable populations (children, prisoners, handicapped persons) is to have an individual knowledgeable about and experienced in working with these subjects. DoD views the protection of the human subject as a major responsibility.

This concludes my prepared statement, Mr. Chairman, and I would be pleased to answer any questions from you or other members of the Committee.

Mr. CONYERS. Thank you.

Mr. McCandless.

Mr. MCCANDLESS. Mr. Chairman, we are in a very technical area, and I would like an opportunity with the unanimous consent of the committee to submit to the panel questions that we would have on more specific parts of their disciplines as it relates to the subject matter here in the hearing.

I want to ask one general question of the panel. I believe you were all present during the previous testimony, in the audience, if I remember correctly. I was quite taken aback by the number of comments about the services and/or the Federal Government participating in experiments without the knowledge and consent of those who are involved, be they individuals or communities.

And I would pose that question to the panel. To your knowledge, are you as people in your disciplines involved in any of this kind of activity at the present time, or have you been in the recent past?

Dr. SOPER. Perhaps I will speak first, and then let everyone else——

Mr. MCCANDLESS. However you would like.

Dr. SOPER. Thank you, sir. We have been very careful in the radiation review to make sure that the record that we find is as complete as possible, including all of the information—or not, if it is not there—all of the information associated with ethical medical research, including statements of the consent, et cetera.

If those aren't there, that needs to be reported as well.

Mr. MCCANDLESS. I understand what you are saying, and I am not trying to quarrel with you. But my question is a very simple one. You used the term "with consent." That would imply the person was aware of what you were doing.

Dr. SOPER. Yes.

Mr. MCCANDLESS. So that would not be an issue. The issue would be, well, let's take the next 12 people coming into sick call, I mean theoretically, for the purposes of our discussion, and try this on to see if it is going to help us with the common cold. And they don't know what they are getting. They came in because they have got a cold and they can't function, so you give them something and they walk away and you have conducted an experiment without their knowledge or consent.

I am reaching probably for an example, but is any of that going on?

Dr. OSTERMAN. Mr. McCandless, sir, if you don't mind, I will respond to that. There is absolutely no chance of that happening under our current regulations. There is a triad, as I mentioned earlier, of events which fully protect the individual in the circumstance that you described.

No. 1, no experimentation could be performed on that individual appearing at sick call without a protocol that had been approved by an institutional review board.

That individual could not be administered experimental drugs or vaccines without his written informed consent.

And third, it would have to be done with the knowledge and approval of the commanding officer of that installation.

So I feel certain in telling you that the scenario you laid out would not happen in today's world.

Mr. MCCANDLESS. Thank you.

In the chemical field, Mr. Parker, are we conducting anything in the way of activities that would be synonymous with what we were hearing about previously that had been done at urban, rural, or suburban areas without the knowledge or consent of those who were involved?

Mr. PARKER. Absolutely not. Any form of testing, and we do continue to do development and evaluation of chemical and biological defensive equipment, and I am speaking at the equipment level, where our procedures are in line with what Dr. Osterman outlined.

When we do even physiological evaluation of, say, a protective mask, we write a protocol, even though there is no chemical exposure, because we are using human subjects, we write a protocol, have an independent review panel that is independent of the primary researchers, subject to review by the Surgeon General, the IG of the Army, and recently the GAO visit us to review what we do along these lines.

I might note that the GAO had no findings or recommendations, and the exit interview indicated we were in full compliance with the most recent 1991 guidance out of HHS.

In the area of any kind of open air testing, most of that would be done at Dugway Proving Ground. There is a full environmental disclosure of all activities at Dugway Proving Ground. There is a citizens advisory board appointed by the Governor of Utah that oversees all of the activities, and prior to any kind of testing there is separate environmental documentation prepared and published in the local newspapers, and a response period for any concerned citizen to comment.

So that there is a full disclosure and a full and aggressive effort to make sure everybody who is potentially impacted is informed.

Mr. MCCANDLESS. Ms. Fites and Dr. Soper, would you agree with those comments from your point of view in your area of responsibility?

Dr. SOPER. From my area of responsibility, I agree with those comments.

Ms. FITES. Absolutely.

Mr. MCCANDLESS. Thank you. Again, I will be submitting questions, with your approval, Mr. Chairman, more of a technical nature.

Thank you.

Mr. CONYERS. Lady and gentlemen, the difficulty that we have is this. We have statements that came in from you, starting from 2 days ago, with Dr. Osterman's, to Mr. Parker's, who came in this morning. None of you have been interviewed by our staff, nor have we had any opportunity for interchange before so I propose that after we have had an appropriate time to analyze the materials you submitted, we meet to discuss these matters—not a second hearing, but a discussion that will be built upon the documents, the statements, and the interchanges that we have had here today. Would that meet with all of your agreement?

Dr. SOPER. Of course.

Mr. CONYERS. Thank you very much.

Mr. MCCANDLESS. If the chairman would yield, obviously these documents which are their statements are a matter of public record.

Mr. CONYERS. The next thing I would like to do is to ask each of you outside of Dr. Soper to identify the chains of command under which you operate.

Ms. FITES. I work for the Under Secretary of Defense for Personnel and Readiness, Edwin Dorn.

Mr. CONYERS. And you say you work for him.

Ms. FITES. Right.

Mr. CONYERS. At what level?

Ms. FITES. I am a Deputy Under Secretary.

Mr. CONYERS. So you have a special assignment of duties that are separate from his, since he is over that entire area?

Ms. FITES. No. It is not separate. I perform the integrative function across the three assistant Secretaries that work for him: Force Management Reserve Affairs, and Health Affairs. I do the programming, budgeting, and congressional testimony integration, and I do any of the projects that are too hard, like support to the Olympics, like these drug-testing programs when they came up.

I worked on Persian Gulf mystery illness for a while. So I am kind of a Jack-of-all-trades.

Mr. CONYERS. Thank you very much.

Mr. Parker, where does your responsibilities fit in?

Mr. PARKER. I am the Deputy to the Commander of the Chemical and Biological Defense Command, an element of the Army Material Command. The Army Material Command answers to the Secretary and the Chief of Staff of the Army.

Mr. CONYERS. And what is the name of your immediate superior?

Mr. PARKER. My immediate boss is Maj. Gen. George Freely.

Mr. CONYERS. Dr. Osterman.

Dr. OSTERMAN. Yes, sir. I am the Director of Environmental and Life Sciences. In the latter capacity of life sciences, I have responsibility for both human use and animal use experimentation within the Department of Defense. I report to Dr. Anita Jones, the Director of Defense Research and Engineering, who in turn reports to the Under Secretary of Defense for Acquisition and Technology.

Mr. CONYERS. Thank you. Thank you all very much.

The final thing I wanted to find out is if anyone has anything to add on the most recent information about the Air Force sponsored LSD tests at several universities. Do any of you have any information on that at this point? If you would include that somewhere in your response for the record, because that information was just made known to us today, and we would like to get a little bit more on it.

Mr. PARKER. Yes, Mr. Conyers, we will take that for the record to try to get some amplification.

[The information follows:]

INSERT FOR THE RECORD									
	HOUSE	APPROPRIATIONS COMMITTEE		HOUSE	ARMED SERVICES COMMITTEE	X	HOUSE	OTHER	Committee on
	SENATE			SENATE			SENATE		Government Operations
HEARING DATE		TRANSCRIPT PAGE NO.		LINE NO.		INSERT NO.			
6 Oct 94				2435		2448			

Human Use Exp During Cold War Era

Unclassified

(The information follows:)

From the late 1950s to the early 1970s, the Air Force contracted five studies at civilian universities that involved lysergic acid diethylamide (LSD). These were: "Investigation of the Effects and Mode of Action of the Psycho-chemicals" on Human State of Consciousness" conducted by Baylor University Mental Center between April 1956 and April 1961; "Psychophysiological Correlates of Human Information Processing" conducted by Houston State Psychiatric Institute (Baylor University College of Medicine) between July 1964 and July 1968; "Psychophysiological Mechanisms of Stress Responsivity" conducted by Duke University Medial Center between April 1958 and July 1966; "Chemical Changes in Learning" conducted by the University of Minnesota between October 1964 and September 1969; and "Aerospace Stress and Human Reliability" conducted by the University of Missouri between July 1969 and May 1971. The actual reports may be obtained directly from the Air Force Office of Scientific Research (AFOSR), Bolling AFB, DC 29332.

Mr. CONYERS. I thank you very much for your cooperation. Any further statements we need to discuss this afternoon?

Dr. SOPER. No. We are looking forward to following up our written testimonies and discussions with you and your staff.

Mr. CONYERS. Thank you very much.

I would like to now call the director for the Center for the Study of Society and Medicine, the professor of political science at Rutgers University, the professor of history of medicine and preventive medicine and family medicine, University of Wisconsin, and the senior associate of the Office of Technology and Assessment—Drs. David Rothman, Leonard Cole, Vanessa Gamble, and Robyn Nishimi.

We want to thank all of you for your patience. We have your statements and they will be included in their entirety in the record. We would invite your discussion, which we hope will include any comments about anything that may have come to your attention during the course of these hearings this morning.

I want to thank you very much for your helpfulness. Unlike some hearings where the last witnesses are something that was tagged on at the end, in this instance the last witnesses are very, very seminal to the work that we are trying to accomplish. So I want you to know we will be carefully listening to the comments that you give this committee. I thank you again for your cooperation.

Dr. Rothman, would you please begin.

STATEMENT OF DAVID J. ROTHMAN, Ph.D., DIRECTOR, CENTER FOR THE STUDY OF SOCIETY AND MEDICINE, COLLEGE OF PHYSICIANS AND SURGEONS, COLUMBIA UNIVERSITY

Dr. ROTHMAN. First, Mr. Chairman, let me just thank you for the opportunity to appear before you.

Even before I came down this morning, I was well aware of the work that the committee had begun in this area, and I must say, listening this morning, having the chance to speak with you briefly before the session, I am just delighted and enthusiastic about your readiness to take on these issues. They are very, very important.

I will try to make a couple of brief points from my testimony. But your readiness to take on these issues strikes me as absolutely exemplary.

The first point that my testimony covers, and I can do it quite briefly, is to try to respond to probably what is the most frequently heard line of defense that is often made toward the materials that we have been dealing with today, and that is that whatever went wrong in terms of consent or whatever went amiss in terms of violations of citizens' rights during the 1940's, 1950's and 1960's, really reflects upon the fact that the standards of consent that we would apply now were not viable and were not being recognized in that earlier period.

Those who take this argument forward would make it seem as though consent was an absolutely new kind of idea born in the 1980's and really had no impact on the earlier period, and we should not hold up investigators of the earlier period to that standard.

I myself think that that position is altogether incorrect, that the standards of consent in human experimentation had been very well

established, and my testimony, as submitted to you in writing, will take you through some 12 pages, briefly and succinctly presented. With time and more space, I could go on at much greater length.

So that if at some point as your own work continues you come up against this notion that we are kind of playing Monday morning quarterback, at least from my perspective, rest assured that that is not the case, and that the standards were well entrenched and violated often, yes, but not because the standards themselves were not particularly clear.

I don't want to go on at length about it, just a couple of little capsule quotes. I can take you back to 1865, the very famous French physiologist, Claude Bernard. "It is immoral to make an experiment on man when it is dangerous to him, even though the result may be useful to others."

Andrew Ivy, bringing it into the United States, coming off the Nuremberg trials. This being written in 1948. "It is a matter of common understanding that an individual may consent to undergo medical or surgical treatment or other experiments for the good of his own body, but you must have the consent of the human subject. All subjects have been volunteers in the absence of any coercion. Before volunteering, the subjects have been informed of the hazards, if any, of the experiment."

And the material you are uncovering from the 1950's and 1960's I think, in a very obvious way, violates those standards.

If you went through the scholarly literature, you would find it again and again, basic ethical principles for the conduct of human experimentation, written by the dean of Western Missouri Medical School in 1950; "The voluntary consent of the human subject must be obtained. The human subject should be at liberty to terminate the experiment at any time."

Again, I don't want to keep repeating them. The record is clear, and I think should be fully understood. Indeed, you can find such statements as well from within the Armed Forces, memorandums by Secretary of Defense Wilson, in 1953, making the same points again.

"The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent, should be so situated as to be able to exercise free power of choice, should be able in this sense to be able to make an understanding and enlightened decision."

The research you heard about this morning violates all of these dictums and I think your sense that something was amiss and it was not in the existence of the standard, is most important.

If the ethics of experimentation were so clearly established, why did American investigators so frequently violate them? Well, I think the essence of the answer is the war effort, first in 1940 to 1945, then the cold war effort after 1945, fostered what we might call highly utilitarian judgments.

Investigators made the calculus that the national interest outweighed individual rights, that the exigencies of the cold war justified violations of known ethical practices. For the sake of national security, investigators wanted to know more about the effects of mind-altering drugs or the ways that biological material is spread

through the atmosphere, whether they were through airports or through cities.

These investigators like so many others might well have minimized the risks of the procedures they carried out. It is not at all unusual for investigators to maximize the potential benefits of proposed research even as they underestimate the dangers involved.

But again, the self-serving quality of the calculus reflected a belief in the importance of the research in the national interest and allowed them, I believe, to ignore the existing precepts.

It is only by appreciating this mind set that we can understand how the distinction between medical experimentation for therapeutic purposes became indistinguishable from experiments with no therapeutic benefited to the subjects themselves, and then slid over into what was essentially weapons research.

What the American record demonstrates over the period from the early 1940's through the 1960's is a steady progression from wartime research into such disease as malaria and dysentery, using backward, mentally disabled patients for subjects, to mind-altering drugs on unknowing soldiers, to weapons testing, releasing various compounds and bacteria into the atmosphere, into public gathering places, and into public transportation systems.

Indeed, the goal of this research apparently was not only defensive, how to protect against an enemy agent performing this kind of activity, but offensive, how could the knowledge gained through this weapons research enable the United States to use these techniques in foreign countries.

The historical record, I think, does have immediate relevance to what the committee ought to be looking at in terms of where we go from here. First, I think it is absolutely essential that the full public record on human experimentation be fully known.

I am pleased, as I know that you are, that radiation has become the focus of investigation. But I think that the other activities that went on within the CIA, within the Defense Department, within all aspects of government, must be explored.

In no other ways can victims be identified and appropriately compensated. But even more than that, in no other ways will I think we understand how to adopt fully corrective measures.

I was most impressed this morning with the questioning that went on about the chain of command. Who was it that allowed or finally passed off on the experiment? How did it work its way through? Was it simply, well, that is a fine idea, let's go out and do it? Was there anything approximate meriting chain of command? Was there anything approximating signoff?

We do not know the answers to those questions. And if we are going to set up various kinds of corrective measures, I think that knowledge is absolutely essential.

Second, I think the committee must spend time thinking, revising, and strengthening the system of research oversight focusing on the institutional review board. We just heard read to us what are essentially the regulations of the IRB that the Defense Department signed onto later, after the IRBs, I believe, were already in existence elsewhere.

But to read us the regs is not to tell us how they are functioning. We need to know who is sitting on those IRBs in defense, what is

the nature of outside review, who is auditing the auditors. And to simply come before us and read the regulations I think does not take us far enough into the dynamics of the process.

It may well be. I have no way of knowing that Defense Department IRBs at this moment are functioning very well. I can only tell you that the Office of Protection from Research Risks is very understaffed—maybe one, two full-time employees able to check into the composition of the IRBs. In essence, the regs are very clear but we know have you little about how these regs are actually being carried out.

There are certainly difficulties and problems, they occur in the press periodically with university based IRBs. What is going on in the intercity cease of various agencies of the Federal Government I think is even more shrouded.

And so to accept a reading of the regs is fine, but I think we are duty bound to try to find out much more about the actual implementation of these regs. And my suspicion at the moment is that we may well find shortfalls in administration.

Are we recapitulating the 1950's? I would certainly hope not. But the exposes of the 1950's I believe should become the occasion for us to make certain administratively and in terms of oversight that those kinds of experiments could not be repeated.

I think medical investigators cannot be allowed to select at will those who will be martyrs for mankind in terms of conquering disease. And I think weapons researchers cannot be allowed to select those who will be martyrs to a sense of national interest or patriotism.

In the end, as the Nuremberg Code makes clear, the ethics of human experimentation cannot be violated because of a State's readiness to advance its own military capability.

Thank you.

[The prepared statement of Dr. Rothman follows:]

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Testimony before The Legislation and National Security Subcommittee of the Committee on Government Operations

September 28, 1994 at 10:00 am

David J. Rothman, Ph.D.

Bernard Schoenberg Professor of Social Medicine

Professor of History

Director, Center for the Study of Society and Medicine

Although the recent disclosures of the practices of the American medical research community over the 1950s and '60s have brought to light new examples of human research performed without patient consent, the additional information does not alter the essential ethical context in which these practices should be understood. Over this period, the ethical principle that experimentation should not be conducted without the explicit and informed consent of the subject was well established; the fact that the principle was frequently violated (perhaps even more frequently than has been recognized before 1993) reflects not on the weakness of the principles but on the readiness of investigators to violate them. The idea that the "standard of the times was different" is not correct. The ethical precepts were clearly formulated and well understood. What is now the more clearly established is that investigators transgressed the standards not out of ignorance but out of a commitment to advancing scientific knowledge and Cold War strategies. In effect, they were prepared to transgress the principles to serve these other ends.

Given the frequency with which it is claimed that notions of informed consent are a 1970s creation, it is worthwhile to review, however briefly, the abundance of evidence that suggests a much earlier recognition and appreciation of the doctrine.

It is not inappropriate to begin with Hippocrates, for the precept that the physician must first do no harm to the patient remains a bedrock principle of medicine and is the correct starting point for an ethical analysis of human experimentation. The administration of experimental mind-altering drugs and psychiatric

procedures in the 1950s (such as "psychic driving") clearly transgressed this ethic. But beyond the general maxims of Hippocrates, there is an abundant and much more specific literature that addresses experimentation directly. And in tone and substance it makes evident that whatever the practice in post-World War Two research laboratories, the ethical imperative to inform the human subject and obtain his or her consent was indisputable.

Perhaps the most explicit 19th century statement of the ethic was provided by the French physician and investigator, Claude Bernard. In his famous 1865 treatise, An Introduction to the Study of Experimental Medicine, Bernard declared:

> The principle of medical and surgical morality, therefore, consists in never performing on man an experiment which might be harmful to him to any extent, even though the result might be highly advantageous to science, i.e., to the health of others.... If it is immoral, then, to make an experiment on man when it is dangerous to him, even though the result may be useful to others...

Bernard's views on experimentation were derived from the work of still others. Thomas Percival, for example, in his widely read early 19th Century treatise on medical ethics declared: "Every rash experiment ... is in the eye of conscience, a crime both against God and man" (C.D. Leake (ed.), Percival's Medical Ethics, 132, Williams & Wilkie Co., Baltimore: 1927). And one could also add to this roster the practices of such physicians as William Beaumont,

who drew up a formal agreement with his subject before carrying out his research with him.

There can be no disagreement, I believe, about the fact that by the 1950s, the voluntary consent requirement was a well-established medico-legal obligation of physicians. Again, a number of examples establish the point. As stated by Hubert W. Smith of the Harvard Law and Medical Schools in 1942, ethical and legal principles required "full disclosure of material facts" and the securing of the "enlightened consent" of the human subject:

> Here the patient is made an involuntary and unwitting guinea pig for some new and experimental treatment not yet recognized by the profession as proven for general use ... subjecting a patient to experimental remedies without disclosure and consent is contrary to the customs of surgeons and thus negligent.... The surgeon should make a full disclosure of material facts to the patient, including risks and alternative treatments, and obtain his enlightened consent before applying any novel or experimental treatment.... (Antecedent Grounds of Liability in the Practice of Surgery, 14 Rocky Mt. L. Rev. 233, 263-65.)

These positions were formally enunciated in medical codes. In 1946, for example, the Judicial Council of the American Medical Association adopted the following ethical code recognizing the voluntary consent requirement in research:

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> In order to conform to the ethics of the American Medical Association, three requirements must be satisfied: (1) the voluntary consent of the person on whom the experiment is to be performed; (2) the danger of each experiment must be previously investigated by animal experimentation, and (3) the experiment must be performed under proper medical protection and management. [132 AMA Jour. 1090, December 28, 1946].

Indeed, were the principles of consent not well embedded in an ethic of human experimentation, the code set forth at Nuremberg would be little more than an ex post facto condemnation of Nazi doctors. When the world learned of the experimental atrocities that they had committed during World War II, the legal and medical communities joined to seek justice at the Nuremberg War Crimes Trials on the basis of the fact that a requirement for voluntary consent existed in an uncodified form by the medical community long before the Nuremberg trials.

Although the Nuremberg Code was not cited with great frequency in the American medical literature before the mid-1960s, there can be no doubt that the substantive requirements of the Code were themselves well known. By the late 1940s and early 1950s, the ethical standards stated in the Nuremberg Code, including the voluntary consent requirement, were the principles applicable to medical experimentation. This was the view expressed by Dr. Andrew

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C. Ivy, whose testimony had been pivotal at the Nuremberg medical trials:

> It is a matter of common understanding that an individual may consent to undergo medical or surgical treatment, or other experimentation, for the good of his own body .... [medical experiments] have been conducted according to certain ethical principles in all countries of the world which have contributed to the prevention, cure, and control of disease and suffering. These principles, which have been in force by common understanding and practice, may be summarized as follows: (I) Consent of the human subject has been obtained. All subjects have been volunteers in the absence of any coercion in any form. Before volunteering, the subjects have been informed of the hazards, if any. [The history and ethics of the Use of Human Subject in Medical Experiments, 108 Science 3-4, July 2, 1948].

Moreover, the Nuremberg principles were overtly recognized by a special advisory committee appointed by Illinois Governor Dwight H. Green in its 1948 report published in the AMA Journal:

> The ethical principles most pertinent to the present consideration are (1) that all subjects should be volunteers in the absence of coercion in any form; (2) before volunteering, they be adequately informed of the hazards, if any, and (3) that the choice of

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> volunteers be made on the basis of established criteria. [Ethics Governing the Service of Prisoners as Subjects in Medical Experiments: Report of the Committee Appointed by Governor Dwight H. Green, 136 AMA Jour. 457 , 458]

The ethical requirements for obtaining consent prior to experimentation were also widely recognized in scholarly publications. For example, Louis John Reagan, in the 1949 edition of Doctor and Patient and the Law, emphasized the obligation of a physician to obtain a signed consent before initiating experimental procedures (at 398):

> The physician must keep abreast of medical progress, but he is responsible if he goes beyond the usual and standard procedures to the point of experimentation. If such treatment is considered indicated, it should not be undertaken until consultation has been had and until the patient has signed a paper acknowledging and assuming the risk.

And more detailed requirements for the provision of information to patients were also announced in professional journals during the early 1950s. Carl J. Wiggers, Dean of Western Reserve Medical School, published the following Basic Ethical Principles for the Conduct of Human Experimentation in 1950:

> The voluntary consent of the human subject must be obtained.... All unnecessary physical and mental suffering should be avoided.... The human subject

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should be at liberty to terminate the experiment at any time. [1950 Alumni Bulletin, School of Medicine, Western Reserve University, 60-65, quoted in Beecher, Research and the Individual: Human Studies, 238-39]

Were all this not persuasive enough, the need for obtaining consent was also discussed at professional medical associations during the early 1950s. Thus, in his November 1951 presidential address to the Central Society for Clinical Research in Chicago, William Bennett Bean warned that "[in] clinical research we must do experiments on our fellow man, but they are justifiable only with freely granted permission, and we must forego them when they conflict with the interests and rights of our patients" (39 Jour. Lab. & Clin. Med. 3, 9, January 1952)

The AMA itself frequently and explicitly brought these points to the attention of physicians. In 1957, it warned physicians of their responsibility to "be certain, too, that the patient understands fully the content of the written consent he is signing" and stated that if "the patient is being asked to take a calculated risk in submitting to a recommended procedure, the patient is entitled to know what those risks are so that he will be able to form an intelligent judgement about the matter." Indeed, it elaborated on the consent and responsible experimentation requirements, stating unequivocally: "In the treatment of a patient, experimentation should be done only with the knowledge and consent of the patient or those responsible for him, and then only

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if the treatment does not vary too radically from the accepted method of practice" (J. Sadusk, AMA Law Department, "Hazardous Fields of Medicine in Relation to Professional Liability," 163 AMA Jour. 953, 956 (March 16, 1957)). Its Law Department advised physicians of their responsibility to obtain informed consents for experimental procedures in no less certain terms. (AMA Law Department, "Consent to Operations and Other Procedures," 165 AMA Jour. 65 (Sept. 7, 1957)). Treatment involving an element of experimentation may properly be administered only with the full knowledge and consent of the patient or those legally responsible for him, and then only if the treatment does not vary too radically from the accepted methods of medical practice."

The AMA Judicial Council in 1957 set forth these principles to cover all new drugs or procedures:

> In order to conform to the Principles of Medical Ethics of the American Medical Association, three requirements must be satisfied:
>
> (1) The voluntary consent of the person on whom the experiment is to be performed must be obtained;
>
> (2) The danger of each experiment must have been investigated previously by means of animal experimentation; and
>
> (3) The experiment must be performed under proper medical protection and management. [AMA Jour. (March 30, 1957)].

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Critical evidence of the recognition of the importance of consent is also apparent in the 1953 Memorandum by the Secretary of Defense Wilson to the Secretaries of the Army, Navy and Air Force Regarding Use of Human Volunteers in Experimental Research. As summarized by the Inspector General of the Department of the Army, in a March 1976 Report on the Use of Volunteers in Chemical Agent Research (33, 61):

> The matter of the use of human volunteers was under deliberate consideration by the Armed Forces Medical Policy Council during the first two years of the 1950s. In the fall of 1952, following extensive study, the Council reported to the Secretary of Defense that researchers had reached the point beyond which essential data could not be obtained unless human volunteers were utilized. Thus, they recommended that the Nuremberg Code of 1947 be cited as the principal guidance to the services. [T]he Armed Forces Medical Policy Council established the rules of the Nuremberg Code as an essential part of future medical research involving the use of human subjects when in 1952 they recommended that the Secretary of Defense permit the use of humans in medical research.

Based thus expressly on the Nuremberg Code, the 1953 Wilson Memorandum provided:

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> The voluntary consent of the human subject is absolutely essential.... This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The Wilson Memorandum was supplemented by Chief of Staff Memorandum 385, Use of Volunteers in Research, issued on June 30 1953, and Principles, Policies and Rules of the Office of the Surgeon General governing Use of Human Volunteers in Medical Research issued in March 1954. All of these U.S. Government policy statements provided that the human subject "should have sufficient

knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision" (see 1976 Army I.G. Rep. 82). Together, these official policy statements confirm that the "absolute essentiality of voluntary consent has been the stated policy of the Department of Defense and the Department of the Army since the inception of authority to conduct experimental research with human subjects" (id. at 77).

The acceptance by the United States Government of the principles of responsible medical experimentation and informed consent codified at Nuremberg is confirmed by the adoption in 1958 of a Covenant on Civil and Political Rights by the Third Committee of the General Assembly of the United Nations, which included both Canada and the United States. That Covenant provided:

> No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation. [See Beecher Research and the Individual: Human Studies, 247-51].

Finally, there was a recognized obligation on the part of entities financing, sponsoring or conducting medical experimentation to adopt ethical standards on human research, particularly the informed consent requirement; and to make inquiry and to ascertain the competence and prudence in dealing with research subjects of those conducting medical experiments on their

behalf. These obligations flowed from the language of the Nuremberg Code:

> The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

If the ethics of experimentation were so clearly established, why did American investigators so frequently transgress them? For one, the war effort, first in 1940-1945, and then in the Cold War era after 1948, fostered utilitarian judgments. Investigators made the calculus that the national interest outweighed individual rights, that the exigencies of the Cold War justified violations of standard ethical practices. For the sake of national security, investigators had to know more about the effects of mind-altering drugs or the ways that biological materials spread through the atmosphere or through airports, or through cities. These investigators, like so many others, may well have minimized the risks of the procedures that they carried out; it is not unusual for investigators to maximize the potential benefits of proposed research even as they underestimate the dangers involved. But again, the self-serving quality of the calculus reflected a belief in the importance of the research to the national interest.

It is only by appreciating this mind-set that we can understand how the distinction between medical experimentation for therapeutic purposes became indistinguishable from experiments with no therapeutic benefit to the subjects and then, most notably, with what was essentially weapons research. What the American record demonstrates over the period from the early 1940s through the 1960s is a steady progression from wartime research (1942-44) into cures for such militarily important diseases as malaria and dysentery (using backward mentally disabled patients for subjects), to testing mind-altering drugs on unknowing soldiers, to weapons testing, by releasing various compounds and bacteria into the atmosphere, into public gathering places, and into public transportation systems. Indeed, the goal of this research apparently was not only defensive (how to protect against an enemy agent performing this kind of activity) but offensive: how could the knowledge gained through this weapons research enable the United States to use these techniques on foreign countries.

The lessons that ought to be drawn from this record include:

First, to make certain that the public record on human experimentation is fully known. The focus on radiation is certainly important but it should not be an exclusive focus. It is vital that the activities of other Departments over the period 1945-1970 be fully explored. In no other ways can victims be identified and appropriately compensated. In no other way, can the lessons to be learned be altogher understood and necessary corrective measures adopted.

Second, to explore the best methods for revising and strengthening the systems of oversight of research, focusing on the Institutional Review Board. This need is clear for IRBs in university and commerical settings; it is even more important that the IRB operation within governmental agencies be overhauled. The scrutiny over government departmental research must be increased so that ethical norms do not fall victim to utilitarian calculations. Just as medical investigators cannot be allowed to select at will those who will be martyrs to mankind, weapons researchers cannot be allowed to select those who will be martyrs to a sense of national interest or patriotism. In the end, as the Nuremberg Code makes clear, the ethics of human experimentation cannot be violated because of a state's readiness to advance its own military capability.

Mr. CONYERS. Thank you very much.

I must say that for a person who has written so extensively on these and other related subject matters, your comments were very lucid and really quite brief. I believe you when you said you could have gone on and on, because in looking at one of your books, I know you are an author of at least a half dozen more. We welcome your collaboration in this operation, and I know that all the panelists regard this as a beginning.

This is not a one-time flashy hearing to titillate the American people, and off to the next whatever it is next week. This is going to take a long time. We are going to need to marshal the services of many like yourselves here today as we begin what could be one of the most important inquiries into the kind of activity and conduct that so appalls the Nation. So I am grateful to you for your testimony.

I am now pleased to recognize Dr. Leonard Cole from Rutgers, who himself has written extensively, particularly one book, "Clouds of Secrecy: The Army's Germ Warfare Experiments Over Populated Areas." That makes you very key to share your views with us this afternoon. Welcome to the committee.

STATEMENT OF LEONARD A. COLE, Ph.D., PROFESSOR OF POLITICAL SCIENCE, RUTGERS UNIVERSITY

Dr. COLE. Thank you, Congressman Conyers.

May I say that I think you capsulized in one sentence earlier on what I think is the essence of what we are after today: The relationship of an individual to his or her government and the government's relationship to that person, and the responsibilities we have to each other. I thank you for that summary, too.

Well, as you suggested, my expertise is in the area of the open air biological warfare testing program during the 1950's and 1960's, although I am in the middle of another enterprise now that goes beyond that. I am looking at the general question of biological weapons defense and how we might as a Nation benefit and as a world benefit from avoiding the use of these weapons ever.

The Army began a program in 1949, as you heard, to assess the Nation's vulnerability to attack with biological and chemical weapons. During the next 20 years, biological and chemical agents were released over hundreds of populated areas around the country. And some of the areas that were mentioned earlier, and beyond, included Hawaii, Alaska, San Francisco, St. Louis, Minneapolis, many, many other cities.

And some tests, as you heard as well, were narrowly focused, as when bacteria were released in the New York City subway system and in Washington National Airport, and in the Greyhound terminal in Washington in the early 1950's. The purpose of these tests was to see how bacteria spread and survived as people went about their normal activities.

The Pentagon always maintained that the bacteria and chemicals used in these tests were harmless. They were described as simulants, intended to mimic more lethal bacteria and chemicals that might be used in an actual warfare situation.

But, and this I emphasize, increases in infections among people in some of the testing areas were reported as early as 1950, immediately after the testing program began.

In September of that year, San Francisco was blanketed with bacteria called Serratia marcescens. The bacteria were sprayed from a boat offshore. Within days, patients at Stanford University Hospital, then located in San Francisco, began to develop heart and urinary tract infections caused by Serratia marcescens. One patient, Edward Nevin, died as a consequence.

When the Army learned about the epidemic of Serratia infections, it secretly convened a panel to assess the situation. Although infections from these bacteria had never before been reported at the hospital, and Stanford University Hospital is one of the preeminent institutions in the world, the panel concluded that the relationship between the test and infections appeared coincidental. It recommended that the spraying of these bacteria be continued, "even over populated areas when such studies are necessary for the advancement of the biological warfare program."

Since the Army never monitored the health of the people exposed during its experiments, no one knows how many may have suffered illness or death as a result.

The public first became aware of the biological testing program in late 1976. A newspaper story revealed that a few experiments in cities had been conducted years earlier. But at Senate hearings in 1977, Army witnesses acknowledged that 239 tests over populated areas had been conducted between 1949 and 1969.

The breadth of the program to me seemed remarkable. And I might say for a moment that while we are talking about thousands and perhaps even hundreds of thousands of people who had been affected by some of these other tests, particularly the radiology tests or nuclear tests, when you discuss the biological test program, we are dealing with millions of people who have been subjects.

Based on my own interest and intrigue with the situation, I began to develop more information about it through interviews, through previously classified reports, and from a legal suit against the government by the family of Edward Nevin, the person who had died after the 1950 San Francisco test.

The Nevin trial went to Federal court in 1981, 30 years to after the fact, and one of the witnesses was retired Gen. William Creasy, formerly the commander of the testing program. His rationale for testing in cities was that biological agents are, and I quote from his testimony, "designed to work against people. You have to test them in the kind of place where people live and work."

On the ethics of the program, he testified: "I would feel it completely impossible to conduct such a test trying to obtain informed consent. I could only conduct such a test without informing the citizens it was being conducted."

The general recognized that the citizens under some circumstances deserved the right of informed consent before being exposed to these materials, although he was obviously willing to circumvent that understanding.

A document obtained this year through the Freedom of Information Act confirms that the Army then was literally using the country as an experimental laboratory.

In 1957 and 1958, a cargo plane criss-crossed the country releasing tons of zinc cadmium sulfide, the chemical you have heard referred to many times today.

Mr. CONYERS. You say tons.

Dr. COLE. Tons. During that period they would take 5,000 pounds of this material and over a long, slow flight, disperse the material. In fact, again according to the Army summary of the experiment, "the test area covered the United States from the Rockies to the Atlantic, from Canada to the Gulf of Mexico."

And I think you mentioned, Congressman Conyers, in your opening remarks, that there was a path that was described in the report that ran from Detroit to Springfield, Illinois, then west to Goodland, Kansas.

Millions and millions of Americans were unwittingly exposed to the chemical during this series of tests. Unnoted in the Army document is the fact that the chemical, especially the cadmium component, is toxic and a potential carcinogen. We have heard that discussed a good deal today.

This I think is important for the record as well. As far back as 1932, a scientific study concluded that——

Mr. CONYERS. Excuse me, Dr. Cole. But didn't Mr. Parker dispute whether it was toxic or not?

Dr. COLE. Well, I heard him dispute it. I would say that, first, if I may give this quotation to you from this 1932 study, then I would make a comment on his remarks.

The comment—this statement that I shall read to you, which is a quote from a report in the Journal of Industrial Hygiene, May 1932, was based on studies of cadmium sulfide, part of the ingredient of the zinc cadmium sulfide composition, which led the scientists doing the work on animals to conclude that "cadmium, no matter how small the amount taken into the lungs, causes pathologic changes, and that there is, therefore, no permissible amount of cadmium."

I have looked at the scientific literature, not all of it, but a good deal of it having to do with cadmium toxicity, and I can assure you there is a mixed review about this. It is true that some would suggest that at very, very low concentration, cadmium might not offer the toxicity that is suggested by this earlier report. But it seems to me that when you are going to be spreading that material around millions of people, it would be prudent to err on the side of caution. One should anticipate the worst possibilities rather than hope that only the best of the findings might be seen.

Although experiments in heavily populated areas presumably are no longer taking place, as you have heard this morning, unhappy consequences of the earlier program persist. Just this year, just a few months ago, Minneapolis residents learned about tests with zinc cadmium sulfide in their city during 1953. Again, you have heard about several former students in an elementary school targeted during that period who believe they have suffered health problems as a result.

I understand, as you have heard this morning, that Congressman Martin Sabo and Senator Paul Wellstone have introduced provisions in the 1995 defense appropriations bill for a study of the

health effects of that test. I think that is an absolutely welcome and desirable result of their efforts.

Biological warfare testing has caused anguish to many citizens who are put at risk and to their families, and of course you heard not just about biological testing but several resulting heart-rending stories. There was a ripple effect, that it is not just the individual who happens to be in the exposed area or who has been victimized individually in one of these tests, but the effects on certainly several people in the family and perhaps dozens when you count the extended family and friends who are victims in their own way.

This hearing is in my judgment a very valuable step toward addressing the question not only of the health effects on these individuals. Another very important ingredient which has not been touched upon very much today is the terrible legacy of distrust in government that these kinds of tests have caused.

While this hearing cannot undo injuries that people may have suffered, I think by seeking full disclosure it should help the aggrieved parties in their quest for information and for justice. Equally important, informing the American public about these experiments makes less likely the chance that such activities will take place again.

And in conclusion I note the Army has not considered people in testing areas, in these large-scale testing areas, to be research subjects, and that therefore the requirement of informed consent does not apply.

I suggest enactment of legislation to remedy this, that anyone in a test area be treated as an experimental subject with the right to informed consent. No one should ever have to worry while in a subway, an air terminal, or a school that he or she might be an unwitting target in a biological or chemical warfare test.

[The prepared statement of Dr. Cole follows:]

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Testimony before the Legislation and National Security Subcommittee of the Committee on Government Operations

U.S. House of Representatives, September 28, 1994

Biological Warfare Testing "Where People Live and Work"

Leonard A. Cole, Ph.D.

Thank you, Congressman Conyers, for inviting me to discuss the army's biological warfare tests during the Cold War. While I teach science and public policy at Rutgers University in Newark, I have a particular interest in the subject. As noted in your letter of invitation, I am the author of Clouds of Secrecy: The Army's Germ Warfare Tests over Populated Areas.

The army began a program in 1949 to assess the nation's vulnerability to attack with biological weapons. During the next 20 years, biological and chemical agents were released over hundreds of populated areas around the country. Tests were conducted in Hawaii and Alaska, San Francisco, St. Louis, Minneapolis, and many other cities. Some tests were narrowly focused, as when bacteria were released in the New York City subway system and in Washington National Airport. The purpose was to see how the bacteria spread and survived as people went about normal activities.

The Pentagon maintained that the bacteria and chemicals used in these tests were harmless. Described as simulants, they were intended to mimic more lethal bacteria and chemicals that might be used in actual warfare. Yet increases in infections among people in some of the testing areas were reported from the outset. As early as 1950, there were indications that the experiments might be causing harm. In September of that year, San Francisco was blanketed with bacteria called Serratia marcescens. The bacteria were sprayed from a boat offshore. Within days, patients at Stanford University Hospital, then

located in San Francisco, began to develop heart and urinary-tract infections caused by Serratia marcescens. One patient, Edward Nevin, died as a consequence.

When the army learned about the epidemic of serratia infections, it secretly convened a panel to assess the situation. Although infections from these bacteria had never before been reported at the hospital, the panel concluded that the relationship between the test and the infections appeared coincidental. It recommended that spraying of Serratia marcescens be continued "even over populated areas, when such studies are necessary for the advancement of the biological warfare program." Since the army never monitored the health of the people exposed during its experiments, no one knows how many may have suffered illness or death as a result.

The public first became aware of the biological testing program in late 1976. A newspaper story revealed that a few experiments in cities had been conducted years earlier. At Senate hearings in 1977, army witnesses acknowledged that 239 tests over populated areas had been conducted between 1949 and 1969. The breadth of the program seemed remarkable. I began to develop more information about it through interviews, previously classified reports, and from a suit against the government by the family of Edward Nevin.

The Nevin trial was held in 1981, and one of the witnesses was retired General William Creasy, formerly the commander of the testing program. His rationale for testing in cities was that biological agents are "designed to work against people. You have to test them in the kind of place where people live and work." On the ethics of the program he testified: "I would feel it completely impossible to conduct such a test trying to obtain informed consent. I could only conduct such a test without informing the citizens it was being conducted."

A document obtained this year through the Freedom of Information Act confirms that the army was literally using the country as an experimental laboratory. In 1957 and 1958, a cargo plane criss-crossed the country releasing tons of a chemical called zinc cadmium sulfide. According to an army summary of the experiment, "the test area covered the United States from the Rockies to the Atlantic, from Canada to the Gulf of Mexico." I think, Congressman Conyers, you would be especially interested in one of the flight paths, which ran "from Detroit to Springfield, Illinois, then west to Goodland, Kansas."

Millions of Americans were unwittingly exposed to the chemical during this series of tests. Unnoted in the army document is the fact that the chemical, especially the cadmium component, is toxic and a potential carcinogen. As far back as 1932, a scientific study concluded that "cadmium, no matter how

small the amount taken into the lungs causes pathologic changes, and that there is, therefore, no permissible amount of cadmium" (Leon Prodan, "Cadmium Poisoning," The Journal of Industrial Hygiene, Vol. 14 [May 1932], 192).

Although experiments in heavily populated areas presumably are no longer taking place, unhappy consequences of the earlier program persist. Just this year, Minneapolis residents learned about tests with zinc cadmium sulfide in their city during the 1950s. Several former students of a targeted elementary school believe they may have suffered health problems as a result. They have identified hundreds of classmates who now are seeking information about the risks posed by the tests. I understand that Congressman Martin Sabo and Senator Paul Wellstone have introduced provisions in the 1995 Department of Defense appropriations bill for a health effects study of the test.

Biological warfare testing has caused anguish to many citizens who were put at risk, and to their families. Beyond the health risks, the tests have left a terrible legacy of distrust in government. This hearing is, in my judgment, a valuable step toward addressing both matters. It cannot undo injuries that people may have suffered, but by seeking full disclosure it should help aggrieved parties in their quest for information and justice. Equally important, informing the American public about these experiments makes less likely the chance that such activities will take place again.

This concludes my prepared remarks, but I would be pleased to answer any questions from the committee.

Mr. CONYERS. Excellent suggestion. I appreciate very deeply your testimony, and the career of work that has led to your being able to come here and speak with such authority.

I note also that Ms. Elizabeth Barrett joined with you in finding that there is the question of one's relationship with their government, and that in terms of these secret experiments, the question goes beyond merely the legal relationship of citizens to their country—it contributes to the cynicism that almost seems to be continuing, even raging, in certain quarters of our country. It is very important that our work help turn this around rather than further contribute to it by having a brief exposure to this problem, and then we turn away to the next sensational item that will surely soon come along. So I appreciate your observations in that respect, Dr. Cole.

We are delighted now to call on Dr. Gamble of the University of Wisconsin, who works in many areas, medicine, preventive medicine, family medicine, and the history of medicine. We are pleased you could join us today, Dr. Gamble. Welcome to our hearings.

STATEMENT OF VANESSA NORTHINGTON GAMBLE, M.D., Ph.D., PROFESSOR OF THE HISTORY OF MEDICINE, PREVENTIVE MEDICINE, AND FAMILY MEDICINE, UNIVERSITY OF WISCONSIN SCHOOL OF MEDICINE

Dr. GAMBLE. Thank you thank you for inviting me, Chairman Conyers.

I have been asked here to testify about the use of vulnerable populations in cold war experiments. At the outset, I should state that at present many of the specifics about the use of such populations in the experiments cannot be answered because the necessary documents have only recently become declassified. Others remain classified and must be made available if the questions regarding the nature of the government's activities in cold war era experimentation are to be answered. So I would like to add my voice to the voices of other people here today who have urged for the opening of records.

The other thing that I would like to say at this point is that there were a couple of comments made this morning that I think need to be commented upon, and that is that there are some complaints that this is going to take a page-by-page, box-by-box approach. It will. And that there are some of us who spend our lives doing work and have the technical expertise of doing page-by-page and box-by-box work. And so I want you not to be swayed by that argument, that this is going to take a lot of work. It will.

My area of expertise is the history of race in medicine, specifically African-Americans. Subsequently, most of my remarks will be directed toward this group.

After the revelations of the radiation experiments came out, I think a comment that a patient of mine said to me capsulized the ideas of many African-Americans when he said, "If they were doing all that to white folks, you can imagine what they were doing to us."

In my comments in terms of African-Americans, I don't mean to say that other groups have not been affected. But that focusing on African-Americans, we see how vulnerable populations have been

exploited. We also learn about the ramifications of government policies and also the legacy of government policies.

With respect to human experimentation, vulnerable populations are those who are more likely to be used as subjects of experimentation because they belong to groups who are less valued and respected by society, or those who may find themselves in situations in which the voluntariness of their informed consent should be questioned, or those who are unable or not given the chance to give their informed consent.

Examples of vulnerable populations include members of racial and ethnic minorities, the poor, prisoners, the mentally ill, and the mentally retarded. However, they also include members of the military who might cooperate with an experiment because they fear they have no choice.

These populations require special scrutiny, and illustrate why the concept of informed consent must not be examined in isolation, but within a sociopolitical context.

I also would like to add my voice to the call to examine the implementation of IRBs and also look at—when we look at the informed consent, what do we actually mean.

It is important to note that the designation of vulnerable population, does not carry with it homogeneity. These are many different groups, and safeguards must be established that protect the particular needs of each group.

Historians, as I said, have not yet had access to the documents that will fully reveal the government's role in morally questionable research. Even with the limited records that have been released and analyzed so far, we already know that members of vulnerable populations were often singled out. Two examples illustrate how African-Americans, especially those who are poor and uneducated, have been exploited.

I want to give a few remarks on the Tuskegee syphilis study, even though this is not a cold war experiment, because you see a pattern here. In the whole issue of the relationship of African-Americans to the government, Tuskegee is often used. Let me briefly talk about the study.

The study was conducted between 1932 and 1972 by the U.S. Public Health Service to investigate the consequences of untreated syphilis. The subjects of the investigation were 400 poor black sharecroppers from Macon County, AL, with latent syphilis, and 200 men without the disease who served as controls.

As part of the project, however, government doctors deliberately denied treatment to the men who had syphilis, and went to extreme lengths to ensure that they would not receive any.

They also used incentives such as free meals, free burial insurance, and free medical examinations to ensure the participation of the men. Published medical reports have estimated that between 28 and 100 men died as a result of their syphilis.

I should state that despite historical evidence, many African-Americans to this day believe that the men were injected with syphilis, that it was a biological warfare experiment.

Another experiment, this one at the University of Cincinnati College of Medicine further illustrates the abuse of vulnerable populations and government-sponsored research. From 1960 to 1972,

with funding from the Department of Defense and the Public Health Service, investigators exposed 88 cancer patients to full and whole body radiation. The patients, ranging in age from 9 to 84, were poor. They were recipients of charity care at Cincinnati General Hospital. They were uneducated. They were predominantly members of minority groups. Sixty percent of the patients were African-Americans.

The patients were exposed to radiation, not for therapeutic purposes. At the time, whole body radiation had been largely discounted for all but a few cancers. They were exposed to radiation for national security purposes.

The objective of the experiment was to study the influence of whole body radiations on the combat effectiveness of troops. For example, they sought to ascertain, in the event of a nuclear explosion, how much radiation a soldier could withstand before becoming disabled.

Patients drafted in the study suffered from several side effects, including nausea, vomiting, mental confusion, and abdominal pain. It is not yet clear how many patients died as a result of their underlying disease or as a direct result of their participation in the experiment. There is no evidence that the investigators obtained consent of the patients in the study.

Even if they had, the issue remains whether poor patients who were receiving free care from the hospital thought that they had any choice but to submit to the researchers' investigation, or whether black patients, especially elderly ones, thought that they could refuse a solicitation from a white researcher. Which brings up the point that informed consent has to be looked at in terms of social context.

The consequences of these experiments go beyond the unwitting subjects and their families. They have contributed to a legacy of distrust of many Americans, including African-Americans, toward many institutions of our society, including the government and medicine.

As a physician, I see this firsthand with respect to the attitudes that African-Americans hold toward AIDS. Many believe that AIDS resulted from government-sponsored biological warfare intended to destroy gay and black populations.

Given the government's disregard for the lives of many of its citizens as evidenced by the experiments that we have heard about today, it is very difficult to dislodge such rumors and obtain African-American participation in research trials and in HIV/AIDS prevention programs.

As this committee proceeds with its investigation, it is imperative that it concern itself with the members of vulnerable populations, who so very often do not have access to the resources that allow their stories to be told.

Thank you very much.

[The prepared statement of Dr. Gamble follows:]

Testimony
Legislation and National Security Subcommittee
House of Representatives
Committee on Government Operations
28 September 1994

My name is Vanessa Northington Gamble. I am an associate professor in the Departments of the History of Medicine and Family Medicine at the University of Wisconsin School of Medicine. I am trained both as a physician and as an historian of medicine. My area of expertise is the history of race and American medicine, specifically the experiences of African Americans. Consequently, most of my remarks will be directed toward this group. I have been asked here today to testify about the use of vulunerable populations in Cold War experiments. At the outset, I should state that at present many of the specifics about the use of such populations in the experiments cannot be answered because the necessary documents have only recently been declassified. Others remain classifed and must be made available if the questions regarding the nature of the government's activities in Cold War era human experimentation are to be answered.

With respect to human experimentation, vulnerable populations are those who are more likely to be used as subjects of experimentation because they belong to groups who are less valued and respected by society or those who may find themselves in situations in which the voluntariness of their informed consent should be questioned or those who are unable to give their informed consent. Examples of vulnerable populations

include members of racial and ethnic minorities, the poor, prisoners, the mentally ill and the mentally retarded. However, they also include members of the military who might cooperate with an experiment because they fear for their jobs. It is important to note that the designation, vulnerable population, does not carry with it homogeneity. Safeguards must be established that protect the particular needs of each group.

Historians have not yet had access to the documents that will fully reveal the government's role in morally questionable research. Even with the limited records that have been released and analyzed so far, we already know that members of vulnerable populations were often singled out. Two examples illustrate how African Americans, especially those who are poor and uneducated have been exploited.

The foremost example is the Tuskegee Syphilis Study, the study conducted between 1932 and 1972 by the United States Public Health Service to investigate the consequences of untreated syphilis. The subjects of the investigation were 400 poor black sharecroppers from Macon County, Alabama with latent syphilis and 200 men without the disease who served as controls. As part of the project, however, government doctors deliberately denied treatment to the men who had syphilis and went to extreme lengths to ensure that they would not receive any. They also used incentives such as free meals, free medical examinations, and burial insurance to ensure the participation of the men. Published medical reports have estimated that between 28 and 100

men died as a result of their syphilis.

Another experiment this one at the University of Cincinnati College of Medicine further illustrates the abuse of vulnerable patients in government-sponsored research. From 1960 to 1972, with funding from the Department of Defense and the Public Health Service, investigators exposed 88 cancer patients to full and whole body radiation. The patients, ranging in age from 9 to 84, were poor - they were recipients of charity care at Cincinnati General Hospital. They were uneducated - their average length of education was six years. And they were predominantly members of minority groups - 60 percent of them were African Americans. The patients were exposed to radiation, not for therapeutic purposes - at the time, whole body radiation had been largely discounted for all but a few cancers. They were exposed to radiation for national security purposes - the objective of the experiment was to study the influence of whole-body radiation on the combat effectiveness of troops. For example, it sought to ascertain in the event of a nuclear explosion how much radiation a soldier could withstand before becoming disabled. Patients drafted in the study suffered from several side effects, including nausea, vomiting, abdominal pain, and mental confusion. It is not yet clear how many patients died as a result of their underlying disease or as a direct result of their participation in the experiment. There is no evidence that the investigators obtained the consent of the patients in this study. Even if they had, the issue remains whether poor patients who were receiving

free care from the hospital thought that they had any choice but to submit to the researchers' invitation. Or whether black patients, especially elderly ones, thought that they could refuse a solicitation from a white researcher.

The consequences of these experiments go extend beyond the unwitting subjects and their families. They have contributed to a legacy of distrust of African Americans toward many institutions of our society. As a physician, I see this first hand with respect to the attitudes that African Americans hold towards AIDS. Many believe that AIDS resulted from government-sponsored biological warfare intended to destroy gay and black populations. Given the goverment's disregard for the lives of many of its citizens - as evidenced by the experiments that I have discussed today - it is very difficult to dislodge such rumors and obtain African American participation in research trials and in HIV/AIDS prevention programs

As this committee proceeds with its investigation it is imperative that they not forget members of vulnerable populations, who so very often do not have access to the resources that allow their stories to be told.

A Legacy of Distrust: African Americans and Medical Research

Vanessa Northington Gamble, MD, PhD

After the abuses of the Tuskegee Syphilis Study were revealed, the federal government strengthened regulations to protect the subjects of human experimentation. These increased safeguards, however, have not erased many African Americans' fear that they will be abused in the name of medical research. The tenacity of this conviction is understandable if one examines the broader history of race and American medicine. The goals of this short essay are twofold: (1) to place the Tuskegee Syphilis Study within its historical context and (2) to examine how race and racism influence contemporary biomedical research.

A historical analysis of racism and American medicine illuminates the ways in which the profession has been used to support racist social institutions and has, in turn, been influenced by them. Examination of this history demonstrates why so many African Americans mistrust the medical profession and its institutions. As efforts begin to include more African Americans in clinical trials and to develop community-collaborative research programs, this legacy of distrust must be addressed, not dismissed as paranoia or hypersensitivity. The challenge is to understand and confront the historically based realities behind these sentiments.

An understanding of the Tuskegee Syphilis Study and its impact on African Americans is imperative for medical researchers. Although the study is not the only case in which black people have been exploited in the name of medicine, it has come to symbolize such abuse. The history of the study is often used to demonstrate why African Americans should not cooperate with medical researchers. Most recently, its specter has been raised in connection with human immunodeficiency virus prevention programs.

Law professor Patricia A. King warns that the Tuskegee Syphilis Study should serve as a caveat to medical researchers when they analyze racial differences between whites and blacks. She writes that "in a racist society that incorporates beliefs about the inherent inferiority of African Americans in contrast to the superior status of whites, any attention to the question of difference that may exist is likely to be pursued in a manner that burdens rather than benefits African Americans."[1] The premise underlying King's comments is that medicine is not a value-free discipline. Rather, it has reflected and reinforced the beliefs, values, and power dynamics of the wider society. Accordingly, it has been influenced by issues of race and racism. History shows numerous examples of the use of medical beliefs to support the alleged inferiority of black people.

Medical theories, for example, were used to justify the enslavement of Africans. Antebellum physicians contended that black people possessed peculiar physiological and anatomical features that justified their enslavement. This medical distinctiveness, they argued, made Africans not only inferior but inherently suited for slavery. For example, the physicians theorized that Africans had thicker skins, which allowed them to tolerate better the rays of the sun. They also observed, in this case accurately, that black people seemed to be less susceptible than white people to some diseases, such as yellow fever and malaria. Plantation owners took note of these observations and, without qualms, worked slaves in environments such as mosquito-ridden swamps, which they believed detrimental to white people.[2]

Medical theories influenced societal attitudes that held that black people were inferior and inhuman. Such attitudes underscored the use of slaves and free black people as subjects for medical experimentation and demonstration in the antebellum South.[3,4] Although poor whites were also used as subjects, blacks were used far more often. Harriet Martineau, after an 1834 trip to Baltimore, commented that "the bodies of coloured people exclusively are taken for dissection, 'because the whites do not like it, and the coloured people cannot resist.'"[3,4] In 1839 abolitionist Theodore Dwight Weld asserted, "'Public opinion' would tolerate surgical experiments, operations, processes, performed upon [slaves], which it would execrate if performed upon their master or other whites."[5]

Two antebellum experiments, one carried out in Georgia, the other in Alabama, confirm Weld's charge. In the first, Georgia physician Dr. Thomas Hamilton conducted a series of brutal experiments on a slave to test remedies for heatstroke. The sub-

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ject of these investigations was Fed, who had been loaned to Hamilton as repayment for his owner's debt. Fed was forced to strip and sit on a stool on a platform placed in a pit that had been heated to a high temperature. Only his head was above ground. Over a period of two or three weeks, the man was placed in the pit five or six times and given different medications to determine which enabled him best to withstand the heat. Each ordeal ended when Fed fainted and had to be revived. But note that Fed was not the only victim in this experiment; its whole purpose was to make it possible for masters to force slaves to work still longer hours on the hottest of days."

In the second experiment, Dr. J. Marion Sims, the so-called father of modern gynecology, used three Alabama slave women to develop an operation to repair vesico-vaginal fistulas. Between 1845 and 1849, the three slave women on whom Sims operated each underwent up to thirty painful operations. The physician himself described the agony associated with some of the experiments.[8] He wrote, "The first patient I operated on was Lucy. . . . That was before the days of anaesthetics, and the poor girl, on her knees, bore the operation with great heroism and bravery." This operation was not successful, and Sims later attempted to repair the defect by placing a sponge in the bladder. This experiment, too, ended in failure. He noted, "The whole urethra and the neck of the bladder were in a high state of inflammation, which came from the foreign substance. It had to come away, and there was nothing to do but to pull it away by main force. Lucy's agony was extreme. She was much prostrated, and I thought that she was going to die; but by irrigating the parts of the bladder she recovered with great rapidity. . . . " Sims finally did perfect his technique and ultimately repaired the fistulas. Only after his experimentation with the slave women proved successful did the physician attempt the procedure on white women volunteers. He found, however, that they could not, or more accurately, would not, withstand the pain and discomfort that the procedure entailed. The black women had no choice but to endure. They, like Fed, were forced to submit because the state considered them property and denied them the legal right to refuse to participate. This history of medical experimentation on slaves profoundly influenced African-American attitudes toward the medical profession even after the Civil War. In the 1920s, for example, many black people believed that they would be experimented upon if they entered hospitals.[9] Thus, the legacy of distrust preceded the 1932 initiation of the Tuskegee Syphilis Study.

The influence of racism on medicine did not end at Appomattox. The medical and public health journals of the late nineteenth and early twentieth centuries contain many articles that discuss the health problems of African Americans. Many of the discussions focused on syphilis. White physicians maintained that intrinsic racial characteristics such as excessive sexual desire, immorality, and overindulgence caused black people to have high rates of syphilis. As Dr. Thomas W. Murrell noted in 1910, "Morality among these people is almost a joke and only assumed as a matter of convenience or when there is a lack of desire and opportunity for indulgence, and venereal diseases are well-nigh universal."[10] Dr. H. H. Hazen echoed this sentiment: "The negro springs from a southern race, and as such his sexual appetite is strong; all of his environments stimulate this appetite, and as a general rule his emotional type of religion certainly does not decrease it."[11] Physicians also pointed to alleged anatomical differences—large penises and small brains—to explain the disease rates.[12]

White physicians, in the early twentieth century, believed that syphilis was difficult to treat in black patients because they could not be convinced to come in for treatment or, if they did, to follow the treatment regimen. In the words of Dr. Eugene Corson, "this absolute indifference [to treatment] is a characteristic of the negro, not only as regards syphilis, but of all diseases. He is simply concerned with the present moment of suffering, and not always concerned then."[13]

Historian Allan Brandt has argued that these assumptions regarding black people and venereal disease influenced the physicians who initiated the Tuskegee Syphilis Study. He writes: "The premise that blacks, promiscuous and lustful, would not seek or continue treatment, shaped the study. A test of untreated syphilis seemed 'natural' because the USPHS presumed the men would never be treated; the Tuskegee Study made that a self-fulfilling prophecy."[14] The Tuskegee Syphilis Study thus did not occur in a vacuum. It represented the continuing influence of racist thought not only on medical theory but on physicians' perceptions of a group of people and consequently on the treatment, or lack of treatment, individuals would receive.

The United States Public Health Service (USPHS) initiated the study in 1932 to document the natural history of syphilis.[15] The subjects of the investigation were 400 poor black sharecroppers from Macon County, Alabama, with latent syphilis and 200 men without the disease who served as controls. The physicians conducting the study deceived the men, telling them they were being treated for "bad blood." The men, for example, were informed that lumbar punctures were therapeutic, not diagnostic.

As part of the project, however, the USPHS deliberately denied treatment to the men who had syphilis and went to extreme lengths to ensure that they would not receive any. When the Tuskegee Syphilis Study began, the standard therapy for syphilis consisted of painful injections of heavy metal compounds, such as arsenic and bismuth, which had to be administered for up to two years. Although this therapy was less effective than penicillin would later prove to be, in the 1930s every major textbook on syphilis recommended it for the treatment of the disease at all stages. Published medical reports have estimated that between 28 and 100 men died as a result of their syphilis. In exchange for their participation, the men received free meals, free medical examinations, and burial insurance.

The Tuskegee Syphilis Study continued until 1972. Throughout its 40-year history, accounts of the study appeared in prominent medical journals. Thus, the experiment was widely known in medical circles. As late as 1969, a committee from the Centers for Disease Control examined the study and decided to continue it. Three years later, a USPHS worker, who was not a physician, leaked details about it to the press. Media disclosure and the subsequent public outrage led to the termination of the study and ultimately to the National Research Act of 1974. This act, established to protect subjects in human experimentation, mandates institutional review board approval of all federally funded projects with human subjects.

After the study had been exposed, many black people charged that it represented "nothing less than an official, premeditated policy of genocide."[15] This was neither the first nor the last time that the issue of genocide has been raised with

regard to the relationship of African Americans and medical research. It has been associated with the development of birth control programs and with the sickle cell anemia screening programs of the 1970s.[16–18]

Most recently, both genocide and Tuskegee have come up in connection with acquired immunodeficiency virus (AIDS). In September 1990, an article entitled "Is it Genocide?" appeared in *Essence*, a black woman's magazine. The author noted: "As an increasing number of African-Americans continue to sicken and die and as no cure for AIDS has been found some of us are beginning to think the unthinkable: Could AIDS be a virus that was manufactured to erase large numbers of us? Are they trying to kill us with this disease?"[19] In other words, some members of the black community see AIDS as part of a deliberate plot to exterminate African Americans. The views of James Small, a black studies instructor at City College of New York exemplify this position. "Our whole *relationship* to [whites] has been of [their] practicing genocidal conspiratorial behavior on us, from the whole slave encounter up to the Tuskegee Study," Small contends. "People make it sound nice, by saying the Tuskegee 'study', but do you know how many thousands and thousands of our people *died* because of that?"[19]

It would be a mistake to dismiss such ideas as those of a paranoid extremist. In 1990 a survey conducted by the Southern Christian Leadership Conference found that 35% of the 1,056 black church members who responded believed that AIDS was a form of genocide.[20] The legacy of Tuskegee has also influenced the wariness that many African Americans maintain toward needle exchange programs.[21,22]

The Tuskegee Syphilis Study symbolizes for many African Americans the racism that pervades American institutions, including the medical profession. A lasting legacy of the study is African Americans' distrust of medical researchers. Dr. Stephen B. Thomas, director of the Minority Health Research Laboratory at the University of Maryland—College Park, laments, "Although everyone may not know the *specifics* of the Tuskegee experiment, they have enough residual knowledge of it so that they mistrust government-sponsored programs, and this results in a lack of participation in [AIDS] risk-reduction efforts."[19] Alpha Thomas, a Dallas health educator, University Hospital, often confronts the legacy of Tuskegee. She notes that "so many African American people that I work with do not trust hospitals or any of the other community health care service providers because of that Tuskegee Experiment. It is like . . . if they did it then they will do it again."[20]

The strengthening of safeguards and the reforms in research standards that followed the public disclosure of the abuses of the Tuskegee Syphilis Study have been insufficient to change African Americans' historically based fears of medical research. These apprehensions contribute to the low enrollment rate of African Americans in clinical trials.[23] A 1989 study conducted by pharmacologist Craig K. Svensson demonstrated the underrepresentation of African Americans in clinical trials. He reviewed 50 clinical trials for new drugs that had been published in *Clinical Pharmacology and Therapeutics* for the three-year period 1984–1986. He discovered that the percentage of black subjects was less than their percentage in the cities in which the research was conducted and less than their percentage in the general population of the United States. More recent studies confirm this underrepresentation of African Americans in clinical trials for AIDS drugs.[24,25]

Why this underrepresentation of black people? As one physician has put it, "We're battling centuries of mistrust based on historical actions of the very institutions involved."[26] The attitudes and practices of medical researchers towards African Americans also cannot be discounted. Once at a job interview, I was told that black people are not included in clinical studies because "it is a well-known fact that they are noncompliant." Furthermore, in the past, most clinical researchers have used white men as the standard or norm from which to extrapolate data to the rest of the population. Young white men were presumed to be a homogenous population that had fewer confounding factors. Members of minority groups and women were frequently excluded from clinical studies. However, federal guidelines now call for the inclusion of these groups in studies unless a compelling reason exists for their exclusion.

Does it matter that African Americans have been excluded from therapeutic drug trials? In the case of the Tuskegee Syphilis Study, clearly the inclusion of the men in a nontherapeutic experiment was detrimental to their health; today, however, exclusion from a therapeutic one may be harmful. For example, recent studies suggest that there are racial and gender differences in the therapeutic efficacy of some drugs.[25,27,28] In addition, it is crucial to have African Americans participate in clinical and public health studies that examine diseases and conditions that disproportionately affect them.

The researchers associated with the innovative research strategy to examine preterm delivery in African-American women recognize that a historically-based mistrust still influences African Americans' perceptions of biomedical research. They understand that these attitudes represent a significant research obstacle. These researchers have chosen not to cavalierly dismiss this legacy of distrust but to confront it. They have acknowledged that the voices and experiences of African-American women are crucial for the project's success. In a radical departure from traditional scientific studies, the investigators have actively solicited advice about the study from the African-American lay community. Their goal is to develop a collaborative research study that is conducted *with* African-American people, not *on* them. The efforts of these researchers are a significant step in eroding the legacy of distrust that has so profoundly shaped the relationship of African Americans to medicine.

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Mr. CONYERS. Thank you very much for your contribution, Dr. Gamble. I am sure that as these investigations and hearings go on, the African-American involvement in these tests will be reviewed and that we will learn more about it, particularly in the institutionalized groups and in the military.

Dr. Nishimi is a Senior Associate, Office of Technology Assessment, and we welcome you here as our final witness for the day.

STATEMENT OF ROBYN Y. NISHIMI, Ph.D., SENIOR ASSOCIATE, OFFICE OF TECHNOLOGY ASSESSMENT

Dr. NISHIMI. Thank you, Mr. Chairman.

I would like to first make three brief points about the Federal Government's mechanisms to protect human research subjects, and then summarize possible policy options to address the concerns of human research subjects.

First, while the Department of Health and Human Services has had policies or regulations in place since 1953, it was not until 1991 that a uniform policy based on DHHS's regulations was adopted by the entire Federal Government. Today, 16 Federal agencies adhere to this common set of regulations.

Second, the Federal system is by design, decentralized and diffuse. It depends, and in fact emphasizes, review by local institutional review boards.

Third, the Federal mechanism to protect human research subjects has changed little, structurally and in its decentralized approach, since initially implemented by the then Department of Health, Education and Welfare. The legal authority, however, has shifted to recommended, and then required, guidelines and finally to regulations. No statute, however, governs the general oversight of research involving Americans.

Moreover, the current system, while changing incrementally, has fallen short of implementing, or did not implement at all, recommendations made between 1973 and 1982 by an ad hoc committee of DHEW, a congressional report, and two congressionally mandated commissions.

With respect to policy options, since reports began to accumulate, it has become clear to OTA that a definitive picture of the government's implementation of the regulations is not available, even though the regulations have been in effect since June 1991. Thus, a broad spectrum of issues has surfaced.

Regardless of the type of research, three issues that are mentioned repeatedly are compensation for research injuries, the adequacy of the current Federal system per se, and oversight of privately funded research.

The issue of compensation, not surprisingly, is a volatile matter. Although 12 years old, the 1982 President Commission's report remains the most comprehensive document. It concluded no program be instituted until DHHS conducted a small experiment to determine whether a formal program was needed, and if so, the most fair and efficient means to administer it. No such studies have been undertaken. Compensation remains controversial, one with many opinions, but no data.

Not surprisingly, the renewed interest in Federal protection of human research subjects is perceived as having created a climate

in which some of the bypassed recommendations of the prior bodies might now be implemented.

First, even if no systemic changes are undertaken, it might be appropriate to evaluate whether current Federal resources to ensure compliance are sufficient. Dr. Rothman alluded to the situation at the Office for Protection from Research Risks. Over the past three administrations, NIH has been downsizing the human subjects protection staff despite the significant increases in research funding.

OPRR currently has a backlog of more than 90 complex cases of alleged noncompliance, and this is overseen by two investigators. And you have to keep in mind that OPRR has the most developed office and system of all the Federal entities. Except for DHHS, most agencies have one part-time professional, one part-time secretary, and no specified budget for implementing the current regulations.

To say that no problems exist is disingenuous. Agencies will not be aware of violations unless a rigorous system to monitor compliance is in place. Those departments that are not looking for problems will not find problems.

The second option that might warrant further scrutiny centers on the role bioethics commissions have played in U.S. public policy. For over a decade, the Federal Government has been without an operational, broad-based forum to address these issues. In contrast, the governments of at least 27 nations on six continents have established national bioethics commissions or currently have legislation pending. And in fact the option of establishing a new commission is already being pursued in some quarters. For example, last month the White House Office of Science and Technology Policy published a draft charter for a proposed national bioethics advisory commission.

A third option would involve a dramatic alteration in the Federal approach to protecting human research subjects. A national board could be created to review classes of protocols or even single protocols.

Depending on the nature of such an entity, protocol reviews could significantly shift to the national level, resulting in uniform review. It would, however, represent the philosophical antithesis of the current theory that local review accommodates the prevailing values and ethics of the community in which the research will be conducted.

Additionally, the sheer volume of human research currently conducted, especially compared to 20 years ago when this approach was first contemplated, might make a national IRB-like entity unmanageable.

A fourth option could be less drastic philosophically than a national IRB, but would require legislation to provide statutory force to the current regulations. Such legislation could inject consistency in review and implementation of Federal protection of human research subjects. If Congress pursues this option, it would likely face a decision about whether to create a new independent agency charged with the responsibility of ensuring the protection of all human subjects who participate in federally funded protocols. Currently, each agency polices itself and its own research portfolios, an

approach that OTA has already seen results in uneven implementation compliance and oversight.

In the interests of time, Mr. Chairman, I would just like to conclude that to maintain the public trust it is clear that we must all share a vigorous and unwavering commitment to protect the rights of those who participate in research. These people are our relatives, our neighbors, our friends and our fellow citizens.

Thank you.

[The prepared statement of Dr. Nishimi follows:]

OTA TESTIMONY

Statement of

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Senior Associate
Office of Technology Assessment

Before the

Subcommittee on Legislation and National Security
Committee on Government Operations

U.S. House of Representatives

September 28, 1994

THE FEDERAL ROLE IN PROTECTING HUMAN RESEARCH SUBJECTS

Congress of the United States
Office of Technology Assessment
Washington, DC 20510-8025

Mr. Chairman and members of the Committee, it is a pleasure to appear before you today to discuss issues related to federal oversight of research involving human subjects. There is little doubt that, over the decades, research involving humans has contributed to improvements in the health, safety, and well-being of all Americans. Through the participation of few, all benefit. Safeguarding the interests and well-being of individuals who participate in research is of paramount importance. As you requested, my statement summarizes three broad areas related to the government's experience with the protection of human research subjects:

- the response of the federal government to past reports of "abuses" of human research subjects and whether the approach has evolved,
- the mechanisms employed by the federal government to protect human subjects and the extent to which these have changed over time, and
- possible policy options to address the concerns of human research subjects.

In general, my remarks pertain to the protection of human subjects by the range of federal agencies that conduct research involving humans. For the first issue, however--the historical response of the federal government to reports of unethical treatment of human research subjects--I focus primarily on the Department of Health and Human Services (DHHS) and its predecessors. As the largest funder of research involving human subjects, this agency has played a pivotal role in the development of U.S. policies governing the ethical conduct of research involving humans.

Federal Policies and Human Research Subjects

The U.S. government's policymaking in research ethics lagged behind others' recognition of the importance of formal codes of conduct about the treatment of human research subjects. For example, in the United States, the American Medical Association adopted a code of research ethics in December 1946. This code preceded, but included tenets of, the so-called "Nuremberg Code,"--ten principles that were part of the judgment in the Nuremberg trial of 23 Nazi physicians.

The earliest, publicly acknowledged, federal guidance for the protection of human research subjects can be traced to the 1953 National Institutes of Health (NIH) Clinical Center guidelines. In

1966, the then Department of Health, Education and Welfare (DHEW) enlarged upon this action by issuing a broad policy--with the inauspicious name, "Policy Procedure Order 129"--governing all research supported by the Public Health Service (PHS). Since that time, incremental changes in the federal government's oversight of research involving humans have occurred. Three events, in particular, were catalysts for change: 1972 news reports of the Tuskegee Syphilis Study, congressional hearings in 1973 on an array of controversial experiments involving humans, and a 1981 report by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.

In 1972, front page news reports brought one of the most notorious abuses of human research subjects to an end. From 1932 to 1972, the PHS and several foundations had conducted a study on approximately 600 African American males in Tuskegee, Alabama. When the study was initiated, the Tuskegee area had the highest incidence of syphilis in the nation, and more than 400 of these men had this sexually transmitted disease, for which limited treatment was then available.

The men were lured into participating by the promise of free medical treatment, food, and burials. Initially, they were treated with mercury and arsenic compounds--then standard therapy--when the drugs were available. However, they also endured spinal taps without anesthesia and were denied penicillin long after it became apparent in 1945 that this antibiotic was the preferred therapeutic drug. To prevent participants from receiving treatment by the U.S. Army, PHS also instructed draft boards not to induct them. Under congressional scrutiny, PHS officials offered the excuse that treating the subjects with penicillin would have arrested the disease and made following the long-term effects of syphilis impossible.

Soon after the widespread disclosure of the Tuskegee Syphilis Study, DHEW convened the Tuskegee Syphilis Study Ad Hoc Advisory Committee. This committee's final report in 1973 recommended that Congress "establish a permanent body with the authority to regulate at least all Federally supported research involving human subjects." Such a body, referred to as the National Human Investigation Board, was not created. In the wake of this report, however, came renewed and heightened congressional interest in the protection of human research subjects.

Congress previously had examined the topic of informed consent for participants in clinical trials during 1962 hearings on investigational studies that involved the use of thalidomide by pregnant women and had addressed, in a limited fashion, the issue of informed consent with respect to investigational new drugs and the Food and Drug Administration. It was a series of Senate hearings in 1973, however, that prompted the U.S. government to respond to concerns about the protection of human research subjects. In addition to receiving testimony about the Tuskegee Syphilis Study, witnesses testified about the injection of liver cancer cells into patients at the Jewish Chronic Disease Hospital in Brooklyn, New York; the intentional infection with hepatitis of residents of the Willowbrook State School for the Retarded; and on other "abuses" in behavior control research, research in prisons, and research involving institutionalized individuals.

In response to this information, legislation was proposed to establish a permanent commission that would not only develop and refine existing DHEW policies governing research involving humans, but one that also would oversee and enforce their implementation. Congress also recognized that protecting human research subjects was an issue extending beyond DHEW, and noted "it is important to establish a single standard to be applied by all agencies . . . ."

The ultimate outcome, however, was the establishment in 1974 of a fixed-term advisory commission--the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereinafter referred to as the National Commission); enforcement powers were dropped. Congress directed the National Commission to identify the ethical principles necessary for protecting human subjects involved in research and to use those principles to recommend actions by the federal government. The conference committee report also called for a permanent National Advisory Council to replace the National Commission after its sunset, but no such entity materialized. Nor was the issue of a single standard addressed.

Still, the work of the National Commission had a significant impact on federal protection of human research subjects. From 1974-78, the National Commission issued ten reports and several appendices on the general ethical principles and procedures that should govern research involving humans, as well as reports and recommendations for research on what have been termed "vulnerable

populations"--pregnant women and fetuses, children, prisoners, and "those institutionalized as mentally infirm." Today's regulatory framework for the protection of human research subjects owes its existence in its current form to the work of the National Commission.

I mentioned earlier that my discussion on the evolution of federal policies centers on three events--media focus on the Tuskegee Syphilis Study, congressional scrutiny of research involving humans and its creation of the National Commission, and a report by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (hereinafter referred to as the President's Commission). The President's Commission report, however, differed from the cases just cited. Nevertheless, it bears mentioning because of its impact in standardizing the federal approach to protecting human research subjects.

The President's Commission was established by Congress, but not in response to a specific incident (or set of incidents) involving questions about the protection of human research subjects. Its 1981 report, *Protecting Human Subjects*, systematically documented that 23 federal entities funded research involving human subjects. It found a lack of conformity among component parts of a department or agency, inconsistency in the application of regulations or policies to all types of human research within a single entity, and a lack of uniformity in policy among the 23 federal departments and agencies who fund research involving humans. The President's Commission recommended that all federally-funded research involving humans should conform to a uniform, core set of regulations and that DHHS's regulations should serve as the template for such an effort. Ten years[1] elapsed before 16 federal departments and agencies[2] adopted the so-called "common rule"--the regulatory requirements

[1] And, in fact, 17 years had passed since Congress had recognized the importance of a single standard.

[2] 58 F.R. 28002 for the Department of Agriculture, Department of Energy (DOE), National Aeronautics and Space Administration (NASA), Department of Commerce, Consumer Product Safety Commission, Agency for International Development, Department of Housing and Urban Development, Department of Justice, Department of Defense (DOD), Department of Education, Department of Veterans Affairs (VA), Environmental Protection Agency, Department of Health and Human Services (DHHS), National Science Foundation, and the Department of Transportation. The action also notes that the Central Intelligence Agency (CIA) is required by Executive Order 12333 to conform to the guidelines issued by DHHS.

that detail the mechanisms used by the federal government to protect human research subjects,[3] which is the second area that you requested my testimony address.

Before describing some of the details of these mechanisms, however, I would like to reinforce what are probably obvious points about the government's responses to past reports of real and/or perceived "abuses" of human research subjects. First, in many respects the first two examples I cited--Tuskegee and the series of congressional hearings--represent a "crisis management" model following increased publicity about research "abuses." In the first instance, the executive branch convened an advisory committee; in the second, Congress created an advisory commission. Second, in each case, the recommendations of these bodies--as well as that of another congressionally created commission--advanced federal policies for the protection of human research subjects, but either not to the extent envisioned by the parties involved or not at all.

Not surprisingly, then, when nationwide news reports of Cold War era human radiation experiments surfaced in December 1993 and through the early months of 1994, the government's approach resembled previous responses. Congress and the executive branch again have responded to perceived needs to strengthen federal policies governing the protection of human research subjects.

During the past nine months, Congress has held a series of hearings on the issues surrounding the human radiation experiments. And as this hearing demonstrates, congressional interest is not confined to that set of experiments, but also is concerned with other Cold War era chemical and biological warfare tests, as well as purely biomedical research during that period. And as you know, the General Accounting Office is conducting several investigations related to human subjects protection at your request and at the request of other committees. Additionally, President Clinton chartered the Advisory Committee on Human Radiation Experiments (ACHRE) and appointed a group of experts to provide advice and recommendations on the ethical and scientific standards

[3] The President's Commission issued a second report on human subjects protection in 1983 and reported to Congress that while some progress had been made by Federal agencies in response to recommendations in the 1981 report, the overall progress was "disappointing." The Commission identified numerous deficiencies in agencies' mechanisms to protect human research subjects. It made a series of recommendations to improve Federal oversight, but to date virtually none has been implemented.

applicable to human radiation experiments carried out or sponsored by the U.S. government; ACHRE will deliberate until April 1995. The President also directed all heads of executive departments and agencies to immediately review their present practices to ensure that the current regulatory framework is being "strictly enforced." I will discuss the possible implications of these events for federal human subjects protection policies in the final part of my testimony, which addresses policy options to address the concerns of human subjects.

Federal Mechanisms to Protect Human Research Subjects

Returning to the issue of how the federal government protects human research subjects, regulations adopted in June 1991 mean that 16 federal agencies should employ a common mechanism intended to ensure that research involving humans is conducted ethically. Today, all federally funded research involving human subjects must conform with a series of core regulatory requirements. Each agency is responsible for ensuring compliance at institutions that receive its funds. For instance, NIH's Office for Protection from Research Risks (OPRR) oversees implementation of DHHS human research subjects regulations in all domestic and foreign institutions or sites receiving DHHS funds.

The provisions of the common rule, first promulgated as regulations for DHHS in 1974, set forth the elements, mechanisms, and conditions by which federally funded research involving human subjects shall be conducted. Roughly speaking, there are three key aspects: 1) review of the protocol and informed consent document by a local Institutional Review Board (IRB); 2) the interaction between the volunteer participant and investigator, including the informed consent process; and 3) federal agencies' oversight of institutions through an assurance of compliance process. I will describe these elements in some detail--though by no means exhaustively--because of their importance to possible policy options.

The mechanisms that the federal government employs to protects human research subjects are, by design, decentralized and diffuse. The underlying tenents and basic approach of the current system differ little from those put forth by the 1966 PHS guidelines. Then--and now--the U.S. approach centers on local review, under the belief that a local group of individuals is most desirable because

they are in the best position to know the prevailing values and ethics of the community and proposed research subject population.

Thus, under the regulations, the principal responsibility for ensuring that scientists conduct human subjects research ethically rests with IRBs. The regulations detail minimum IRB membership requirements, how IRBs shall operate, the scope of authority assigned to IRBs, the criteria by which IRBs shall approve research, and the documentation required by the federal funding agency. The regulations also mandate eight specific informed consent requirements:

- "A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the subjects.
- A disclosure of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than "minimal risk,"[4] an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled."

[4] The regulations define minimal risk as meaning "that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

IRBs may alter or exclude some or all consent elements--as well as expedite review of a protocol--if the research exposes subjects to no more than minimal risk. Overall, IRBs are required to review research involving humans according to the following criteria:

- minimization of risk to the subjects,
- reasonable risks in relation to anticipated benefits,
- equitable selection of subjects,
- assurance of informed consent,
- adequate provisions for monitoring data,
- provisions for protecting patient privacy, and
- assurance that decisions to participate in research will not be coerced.

The regulations specifically preclude IRBs from assessing the broad-based societal implications of a protocol--i.e., IRBs may not assess the "long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy)."

Additionally, three special provisions govern research funded by DHHS. Referred to as subparts B, C, and D of 45 CFR 46, the regulations detail additional protections for research involving pregnant women and fetuses, prisoners, and children, respectively--i.e., those populations deemed vulnerable by the National Commission.[5] Thus, DHHS regulations governing human subjects research are more comprehensive than those that pertain to the other 15 signatories to the common rule. Research conducted with funds from an agency other than DHHS is not strictly subject to the additional protections for vulnerable populations, although any IRB may voluntarily employ them.

However, non-DHHS funded research may be governed by the full regulatory system under certain circumstances. As I have mentioned, the mechanisms for the protecting human research subjects include the responsibility of a federal agency to provide assurance that facilities receiving federal funds that support research involving humans are in regulatory compliance. An assurance is a

[5] The DHHS regulations that cover research involving pregnant women and fetuses, children, and prisoners resulted from specific recommendations in reports by the National Commission. The National Commission also issued a report and made recommendations for "those institutionalized as mentally infirm." DHHS, in violation of the law, never promulgated regulations to cover this population.

formal, detailed written commitment by the receiving institution that it shall abide by the human research subject regulations. DHHS has the oldest and most comprehensive architecture in place, and among its procedures is a mechanism referred to as a Multiple Project Assurance of Compliance (MPA).

Because large universities can have tens or hundreds of protocols involving human subjects, case-by-case submission of protocols would be extremely burdensome for both the institution and OPRR. Thus, OPRR may invite an institution to negotiate with OPRR for one or more MPAs--i.e., an umbrella assurance that sets forth an institution's approaches and guarantees to safeguard the interests and welfare of human subjects who participate in DHHS-funded research. Institutions granted an MPA because of their experience and expertise need not submit each case to OPRR for review for a specified period of time, generally five years. About 95 percent of the 420 institutions holding DHHS MPAs pledge that *all* research--not just DHHS-funded research, and including privately funded research--will be conducted in accordance with the full set of DHHS regulations. Hence, research sponsored by the Department of Energy, or other federal departments covered by the common rule, would be subject to the additional protections for special populations if it is undertaken at such institutions. Unless an institution has an MPA with OPRR, responsibility for monitoring and compliance, however, still remains with the funding source--in my example, the Department of Energy would be obligated to ensure compliance of research it funded.

Thus, to briefly summarize the mechanisms employed by the federal government to protect human subjects and the extent to which these have evolved:

- Sixteen federal agencies adhere to a common set of regulations that describe elements of informed consent, requirements for local review of protocols, and the agencies' responsibilities to assure compliance.
- The federal system to protect human research subjects is by design, decentralized and depends on review by local Institutional Review Boards;
- Federal mechanisms to protect human research subjects have changed little--structurally and in approach--since their initial implementation nearly three decades ago, although the legal authority has shifted from informal policies to recommended, then required, guidelines, to federal regulations.

Options to Address Concerns of Human Subjects

Mr. Chairman, as you are well aware, the flurry of news reports documenting questionable research practices involving the exposure of humans to ionizing radiation has evoked a deep and visceral anger in much of the American populace. The public outrage can, in some respects, be divided into two distinct concerns. The first looks back in time and asks: How could this have happened? Why did it happen? What redress is appropriate? And second, a more contemporary and future concern: Is this happening today? Could this happen tomorrow?

About the first type of concern, much is being done. Congressional hearings and investigations contribute to the public debate and remind Americans that Congress is committed to as full an accounting of the human radiation experiments as possible. And, in due course, the Advisory Committee on Human Radiation Experiments will make findings and recommendations in this regard. Currently at its mid-course stage, it already has uncovered documents that are likely to rewrite the early history of the awareness and attentiveness of some federal agencies to principles governing the ethical conduct of research involving human subjects.

The spotlight on human radiation experiments also has provided the opportunity for reflection--as in this hearing--about the adequacy of federal protection of *all* human research subjects in the past, at present, and in the future. Since reports of the human radiation experiments began to accumulate, it has become clear to OTA that a definitive picture of current federal implementation and oversight of existing regulations to protect human research subjects is not available. I do not mean to imply that OTA believes the likelihood of egregiously unethical research practices are anything but remote. Nevertheless, agencies will not be aware of violations of existing regulations unless a rigorous system is in place to monitor compliance. Put agnother way, those Departments and agencies that are not looking for problems will not find any problems.

Currently, information from all agencies on the total number of all research grants or contracts, total funding for all research grants or contracts, total number of research grants involving human subjects, total funding for research and grants involving human subjects, and number of full time

equivalent personnel devoted to assurance and compliance has not been collected in a coordinated or centralized fashion. Nor has information been collected about oversight, including whether unannounced or announced site visits are used to monitor compliance. Similarly, a reporting of compliance *investigations* is unavailable, although investigations are the means by which violations of the regulations are determined. The types of compliance investigations, the results of such investigations, and the corrective actions taken, if any were required based on those investigations, has not been compiled.

For some agencies, information even limited to the number of, funding levels for, and types of research involved for *current* grants or contracts using human subjects could not be reported as recently as March 1994, although the common rule has been effective since June 1991. Without such information, ensuring that proper institutional assurances are in place and then overseeing compliance would appear to be problematic.

Thus, over the past nine months, a broad spectrum of issues related to the U.S. government's role in overseeing research involving humans has surfaced and been discussed by policymakers, researchers, and subjects and their families. These issues cut across types of research, and I would like to briefly discuss three that are mentioned repeatedly: compensation for research injuries, the adequacy of the current Federal system per se, and oversight of privately funded research.

Suffice to say, the issue of compensation is a volatile matter and one with a range of opinions. Current federal regulations make a single reference to this complex issue, requiring that it be addressed as an element of informed consent. That is, the informed consent document must indicate whether there will be any compensation--or no compensation--if injury occurs as a result of the research.

Though twelve years old, the 1982 report of the President's Commission, *Compensating for Research Injuries*, is the most recent, comprehensive examination of the issue. It noted that several federal panels that preceded it had recommended the establishment of a governmental program of compensation for injured research subjects. In contrast, the President's Commission concluded that no

program be instituted until DHHS conducted a small, controlled experiment to determine whether a formal program was needed and, if so, the most fair and efficient means to administer it. It described in detail how such an effort could be conducted, but no such project has been undertaken. Thus, the issue of compensation remains controversial and one with many opinions, but no data. Thus, to address the issue of compensation, Congress could direct that DHHS embark on the experiment recommended by the President's Commission, or it could conclude that the current disclosure requirement suffices.

Not surprisingly, the renewed interest in and attention to federal protection of human research subjects has created a climate--or is perceived as having created a climate--in which some of the bypassed recommendations of the Tuskegee Syphilis Study Committee, National Commission, and President's Commission might be implemented. In other words, a strong sentiment exists among many that not only might past harms and redresses be addressed, but incremental or wholesale changes in current federal oversight of research involving humans, too. As with compensation, a broad range of options have been suggested to modify the overall federal approach to protecting human research subjects, and I will briefly discuss four of these

First, even if no systemic changes are undertaken, an evaluation of whether the current federal *effort* to ensure compliance is sufficient might address the concerns of some. For example, in February 1994, Dr Charles R McCarthy, retired director of OPRR, testified before Congress on what he believes is a decreased commitment across the federal government to oversight of human research subjects regulations--including oversight by DHHS, the agency with the most experience and most developed program.

Dr. McCarthy reported that over the past decade and across three administrations, NIH[6] has been downsizing the human subjects protection staff despite the significant increases in biomedical research funding. OPRR currently has a backlog of more than 90 complex cases of alleged noncompliance that is overseen by two investigators. OPRR does not conduct unannounced, random

[6] Although previously housed at the departmental level (under a different name), OPRR's predecessor was moved to NIH in about 1970.

site visits, in part due to lack of funds. Except for DHHS, most agencies have one part-time professional, one part-time secretary, and no specified budget for implementing current regulations.

The second option that might warrant further scrutiny centers on the role bioethics commissions have played in U.S. public policy, which was reviewed in OTA's recent report, *Biomedical Ethics in U.S. Public Policy*. As I mentioned earlier, 20 years ago Congress created the National Commission to review what were then DHEW policies governing the conduct of research involving humans. Today, however, no body currently is in place to perform such a review because for over a decade the federal government has been without a formal, operational forum that addresses bioethical issues.[7] This absence is especially noticeable when we look abroad: The governments of at least 27 nations on 6 continents have established national bioethics commissions of some type or currently have legislation pending. Moreover, the focus of a significant number of these international commissions is the protection of human research subjects. Thus, two decades after constituting the National Commission, Congress could consider whether a similar effort is again necessary, or it could determine that ad hoc committees convened at the initiative of the executive branch--such as the radiation committee or the Tuskegee committee--are adequate.

In fact, the option of establishing a new commission already has already been adopted by some. Senator Mark Hatfield, one of the requestors of the OTA bioethics report, has introduced legislation to establish a broad-based commission. And, on August 12, 1994, the White House Office of Science and Technology Policy (OSTP) published a draft charter for a National Bioethics Advisory Commission in the *Federal Register*. The OSTP effort would be a term-limited broad-based advisory commission, and under the proposed charter, one study it would address "as a first priority" would be the protection and welfare of research subjects, including current notions of informed consent (e.g., whether multicultural views should be articulated), the adequacy and implementation of Federal

[7] Since the National Commission, three other broad-based bioethics entitities have operated: the President's Commission, as well as the Ethics Advisory Board and the congressional Biomedical Ethics Advisory Committee.

human research subjects mechanisms, and whether the definition of "minimal risk" needs modification.[8]

A third option that could be adopted to address the concerns of human research subjects would involve a dramatic alteration in the Federal approach to protecting human research subjects, but it is an idea that traces its history, in part, to the 1973 report of the Tuskegee Syphilis Study Ad Hoc Advisory Committee. The Tuskegee committee advocated that a board should be created to identify the overarching principles that should govern research involving human subjects; enforce the policies developed from these principles; interpret and refine the principles and policies as cutting edge research demands; review classes of protocols, or even single protocols, if novel issues make such a national review advisable; and investigate and review conflicts that arise between IRBs, subjects, and investigators.

Depending on the nature of such an entity, protocol reviews could significantly shift to the national level, which would represent the philosophical antithesis of the current theory that reliance on local review accommodates the prevailing values and ethics of the community. Others express concern that the sheer volume of human research currently conducted (especially compared to 20 years ago when this approach was first contemplated) makes a national IRB-like entity unworkable and unmanageable. Such an approach would, however, satisfy those who see the current system as failing to adequately protect human subjects because it lacks a single, national mandate and authority.

A fourth option to address the concerns of human subjects could be less drastic than a national IRB, but would require that Congress enact legislation to provide statutory force to the current regulatory requirements that encompass human subjects protection by the 16 common rule agencies. Such legislation could serve to further standardize federal oversight of research involving human subjects and create a formal system of investigation, sanctions, and penalties, while preserving the

[8] The OTA report also identified the issue of vulnerable research populations as an area that might merit inquiry. For example, research involving individuals with dementia and research involving individuals with mental disorders are potential areas for a new commission to explore should one be formed. Additionally, several experts note that individuals who are terminally ill might constitute a vulnerable population worthy of special protections; terminally ill patients might seize any opportunity without regard for weighing risks, no matter how great, against potential benefits, no matter how small.

philosophical principles of local review by IRBs that the regulations embody. If Congress were to pursue this option, however, it likely would face a decision on whether to adopt a decentralized enforcement mechanism or whether a central authority (e.g., a new independent agency or White House office) should be vested with the responsibility of ensuring the protection of all human research subjects who participate in federally funded protocols. Currently, each of the 16 common rule agencies police themselves and their own research portfolios--clearly, as just described, with uneven implementation, compliance, and oversight. On the other hand, the prospect of a statute for the protection of human research subjects raises concerns by many about increased federal intervention and some loss of local review authority, along with the potential loss of flexibility in interpretation that today's system affords, which many view as a positive feature.

Finally, while many questions have been raised (and options advanced) about the current system to protect human subjects involved in federally funded research, of growing interest and concern is privately funded research, which falls wholly outside the purview of federal regulations and the options just discussed. For example, research conducted by private physicians and funded by a pharmaceutical company can be beyond scrutiny of today's system; news reports last month illustrate this issue. A pharmaceutical company was reported to have made research grants to physicians in private practice to do research (a survey) in schools, in order to identify children of short stature. The federal government has no authority to assure protection of human subjects in such research (which in this case involved children, who are considered a vulnerable subject population).

Thus, if Congress considers options to modify current federal mechanisms to protect human research subjects, Congress also could examine the extent (if any) to which privately funded research should or should not be subject to federal oversight.

Prospectus

Mr. Chairman, over the past two decades, Congress has exhibited an enduring interest in ensuring the ethical treatment of human research subjects. In fact, each year Congress explicitly acknowledges this obligation: We continue to pay the ethical and economic costs of not being

sufficiently vigilant about the societal ramifications of human subjects research. As OTA Director Roger Herdman noted last October in his testimony at the release of OTA's report *Biomedical Ethics in U.S. Public Policy:*

> [T]his year, as in years past, Congress will appropriate funds for the ongoing medical care of survivors of the Tuskegee syphilis study . . . . Let no one doubt that the compensation is appropriate; it should also serve as an ever present reminder to us all about the important role of bioethics in [biological and medical research].

Today and in the past, the United States' research enterprise--the envy of the world--unquestionably has yielded extraordinary advances in health, welfare, and safety. And there is no dispute that such advances depend on the participation in research of our relatives, neighbors, friends, and fellow citizens. Their participation has served, and continues to serve, as the cornerstone of an increasing knowledge base that helps us all.

Still, incidents such as the Tuskegee syphilis study and revelations of the human radiation experiments cast a shadow over the U.S. research enterprise, as, perhaps more importantly, do concerns raised about some current protocols research (e.g., research involving people with schizophrenia or the use of tamoxifen for breast cancer prevention). The length of this shadow is testament to the need for continued and unwavering federal oversight of human subjects research. Sound ethical practices must go hand in hand with scientifically valid research involving human subjects. To maintain the public trust, we must all share a vigorous commitment to protect the rights and welfare of those who participate in research protocols that ultimately benefit everyone.

Again, OTA appreciates the invitation to discuss the important issues raised at this hearing, and I will be happy to answer any questions.

Mr. CONYERS. I thank you very much.

Dr. Nishimi, because you are from OTA, I would like to make your statement available to the three persons who are at the witness table with you, because it is going to play a large role in how we organize ourselves to move forward in this matter.

I would like all of you to feel invited to continue in this inquiry. I will be in touch with you, I can assure you.

I just say that this matter is larger than I thought it was. When I talked to Secretary O'Leary when these matters first broke, I thought she had done an excellent job, but I failed to appreciate the fuller ramifications of this. Now today I think I see some of them, and I am sure that there are others that remain to be hooked up. So I am very pleased to have you all here.

I must say that we have received an incredible number of specific recommendations, and that the thoughtfulness of them gives us a very, very large challenge indeed. I will be reading some of your literature, some of your books.

This committee will continue the kind of work that made us realize that this matter had not been gone into far enough. Indeed, if there is anybody in the Congress that is going to follow up on this, it should be the oversight committee of the Congress. That is what we have tried to do.

So on behalf of many of my colleagues, we want to thank you very much, and announce that the committee now stands adjourned.

[Whereupon, at 1:25 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

Volume XIV MAY, 1932 Number 5

THE JOURNAL OF INDUSTRIAL HYGIENE

WITH ABSTRACT OF THE LITERATURE

On the Effects of Prolonged Exposure to Sulphur Dioxide

Cadmium Poisoning: II. Experimental Cadmium Poisoning

The Reactions of the Organism to Repeated Electric Shocks

Published at Mount Royal and Guilford Aves., Baltimore, Md.
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CADMIUM POISONING: II. EXPERIMENTAL CADMIUM POISONING*

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GENERAL CONSIDERATIONS

POISONOUS substances may enter the body through the respiratory system, the gastro-intestinal tract, the mucous surfaces (conjunctivae, nasal mucosa, and buccal mucosa), and the skin (broken or unbroken). The reactions and changes produced are dependent on many factors, the most important of which are the manner of entrance into and excretion from the organism, and the concentration, duration (time of exposure), and physicochemical properties of the poison. The physicochemical properties are especially important and sometimes enable us to foresee the possible changes which may occur in the organism as a result of their action.

Cadmium is classed as a heavy metal and consequently should have the same properties as the heavy metals. Briefly, according to Flury and Zangger (1), the heavy metals have the following pharmacologic characteristics: great atomic weight and consequently great specific gravity or density; a tendency when in contact with organic material to form complex metal albumin compounds; a general toxic action which may lead to inflammation and degeneration of different organs, and frequently cause injury to the capillaries. The soluble metal albumin compounds are more noxious because they have a more profound action, and because they are resorbed more rapidly. As a secondary noxious action we have the elaboration of acids at the moment of formation of metal albumin compounds.

In the consideration of cadmium as an industrial health hazard, we have to deal with a poison which enters the body mainly through the respiratory system, and secondly through the gastro-intestinal tract. Consequently observations on poisoning through the respiratory system are of greater value. In studying any kind of poisoning we are interested not only in the acute and chronic action of the poison, and the sequelae, but also in the fate of the poison after its entrance into the body—resorption, distribution, and elimination. The most common kind of cadmium poisoning is the acute respiratory form resulting from exposure in manufacturing and handling cadmium compounds. Serious acute poisoning through the gastro-intestinal tract is improbable for man

* From a thesis presented to the Harvard School of Public Health as partial fulfilment of the requirements for the Doctorate in Public Health.

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owing to the emetic effect of cadmium; and since cadmium is not absorbed through the unbroken skin, poisoning cannot occur in this manner.

The observations here reported were made on cats poisoned with cadmium oxide fume, cadmium oxide dust, and cadmium sulphide dust. These compounds were chosen because of their frequent use. Cadmium sulphide was especially included because it is believed in some industries to be harmless. In general the experimental animals were killed by bleeding, and after specimens were taken for microscopic study the organs were analyzed for cadmium. The method of cadmium analysis described by Fairhall and Prodan (2) was employed in all the chemical work and proved uniformly satisfactory.

Poisoning by Inhalation

Cadmium Oxide Fume

High Concentrations:

Two cats (Cats 1 and 2), subjected to very highly concentrated fume, were exposed separately for thirty minutes in a wooden box of about 150 liters' capacity. The fume was generated in a pyrex glass tube connected to the box at one end and to an oxygen tank at the other. Small pieces of metallic cadmium were placed in a bulb blown at the middle of the tube; this was heated from below by a Bunsen burner and a gentle stream of oxygen was blown through. The molten cadmium was then ignited by means of a glowing splint and the combustion of the metal proceeded evenly, with the abundant production of cadmium oxide fume. Cat 1 was killed by bleeding five hours after exposure; Cat 2 died about twelve hours after exposure.

Symptoms.—About ten minutes after exposure was started the cats showed an abundant salivation, rather thick in character, and an increased respiration (panting). After they were taken out of the box the salivation continued and they showed great difficulty in respiration, stretching out their forefeet so that the accessory respiratory muscles entered into action.

Autopsy.—The lungs showed congestion with several emphysematous patches at the bases, and were more solid than normally. The mediastinum was edematous, and Cat 1 showed a yellowish pleural effusion. On section the lungs exuded a pink-colored, aerated liquid. The trachea appeared normal; a few of the bronchioles were filled with froth. The liver in both cats had a fatty appearance. The rest of the organs were very congested.

Microscopic Findings.—The lungs (see Fig. 1) of both cats showed extensive acute injury, with the following outstanding changes: edema, injury to the bronchioles and alveolar ducts manifested by desquamation of the epithelium, polymorphonuclear leukocyte infiltration in the walls, and edema of the walls. Acute alveolar emphysema was present and a small amount of fibrin was found in the alveolar spaces.

The liver presented different lesions in the two cats. Cat 1 showed slightly swollen cells with prominent marginal borders, and uniformly vacuolated and granular cytoplasm. Cat 2 showed extensive fatty infiltration (about half of the total liver cells were filled with fat), and polymor-

phonuclear leukocyte infiltration in some areas.

The kidneys in Cat 1 showed marked fatty degeneration, mostly in the convoluted tubules, and badly swollen

Chemical analysis of the organs of Cat 1 showed that the cadmium content was highest in the lungs, next in the liver, and third in the kidneys (see Table 1 and Fig. 2).

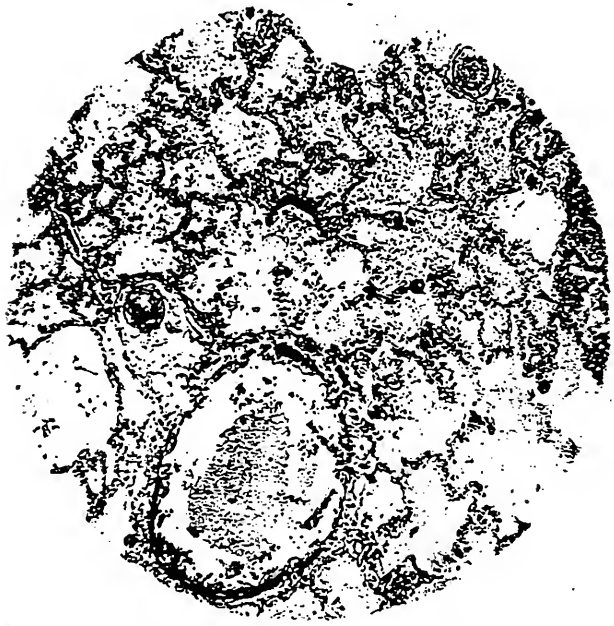

FIG. 1.—Lesions occurring in lungs of cats poisoned with high concentrations of cadmium oxide fume. Showing extensive edema and emphysema, and epithelial desquamation and fibrin precipitate in alveoli and bronchioles. × 300.

cells. Some fat in the form of medium-sized vacuoles, chiefly in the convoluted tubules, was found in Cat 2. The other organs presented no pathologic changes.

Low Concentrations:

After it was observed that high concentrations of cadmium oxide fume were fatal, Cats 3, 4, and 5 were exposed in a gas chamber to less

concentrated cadmium oxide fume for twenty-four hours. Samples of the air in the chamber were taken from time to time in order to determine the exact concentration of cadmium during the experiment. A typical concentration curve (or settling curve) is given in Figure 3. The first sample was

TABLE 1.—CADMIUM CONTENT OF TISSUES OF CAT 1, POISONED WITH HIGHLY CONCENTRATED CADMIUM OXIDE FUME

TISSUE	WEIGHT OF TISSUE	TOTAL CADMIUM FOUND	CADMIUM IN 100 GM. OF TISSUE	PERCENTAGE OF TOTAL CADMIUM FOUND
	gm.	*mg.*	*mg.*	
Blood	127.0	traces	.....	.....
Lungs	69.0	2.50	3.62	46.30
Liver	112.0	1.90	1.70	35.20
Kidneys	54.0	0.60	1.11	11.10
Bile	1.8	0.25	13.90	4.62
Urine	2.5	0.15	6.00	2.78
Total	.....	5.40	.....	100.00

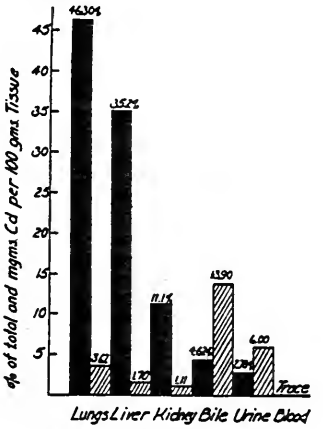

FIG. 2.—Distribution and concentrations of cadmium in tissues of Cat 1.
Solid black columns represent percentages of total cadmium found by analysis in different organs. Cross-hatched columns represent milligrams of cadmium per 100 gm. of fresh tissue.

taken two hours after setting up the fume; the initial concentration was therefore estimated from this concentration curve and was found to be 18 mg. per cubic meter of air. The fume was generated in the same manner as for Cats 1 and 2, by burning cadmium in a pyrex glass tube with oxygen.

Symptoms.—After about twelve hours of exposure the cats began to salivate and showed an increased rate of respiration. They refused to eat or drink and became very depressed. At the end of the exposure all three cats were salivating and showed difficulty in breathing. Cat 3, which had the symptoms in most accentuated form, was killed by bleeding. The blood count before exposure was 7,432,000 for red cells, and 16,500 for white cells; after exposure it was 8,824,000 for red cells, and 29,600 for white cells.

Cats 4 and 5 appeared very sick on the days following exposure. Their respiration was difficult and they refused to eat. Cat 4 was killed by bleeding on the fifth day after exposure, and Cat 5 on the ninth day.

Autopsy.—In Cat 3 the lungs appeared very congested and of dark reddish-brown color, more solid than usual and with emphysematous patches. On section a very little aerated, reddish-brown liquid escaped from them. The trachea was slightly reddened. The liver had a fatty appearance. The rest of the organs were normal, except for congestion.

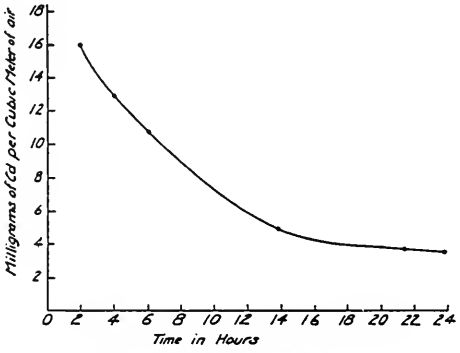

FIG. 3.—Typical settling curve of cadmium oxide fume.

Cat 4 showed changes very similar to those observed in Cat 3. The lungs in Cat 5 were extremely congested and of very dark-brown color, with emphysematous patches. On section, after the blood content had been expressed, they did not collapse.

Microscopic Findings.—Cat 3 showed a moderate thickening of the alveolar walls in the lungs as the most striking change, with interstitial and perivascular edema and early poly-

morphonuclear leukocyte infiltration. Other findings included extensive hemorrhage; atelectatic regions and acute emphysema; desquamation of the epithelium and hemorrhage in the bronchioles; and polymorphonu-

TABLE 2.—CADMIUM CONTENT OF TISSUES OF CAT 4, POISONED WITH LESS CONCENTRATED CADMIUM OXIDE FUME

TISSUE	WEIGHT OF TISSUE	TOTAL CADMIUM FOUND	CADMIUM IN 100 GM. OF TISSUE	PERCENTAGE OF TOTAL CADMIUM FOUND
	gm.	*mg.*	*mg.*	
Blood	36.0	traces	.....	.....
Lungs	27.5	0.39	1.42	21.67
Liver	57.0	0.35	0.61	19.44
Kidneys	12.6	0.20	1.59	11.11
Bile	2.5	0.12	5.00	6.67
Urine	1.0	0.10	10.00	5.56
Heart	10.0	0.15	1.50	8.33
Spleen	3.5	0.07	2.14	3.89
Pancreas	3.5	0.07	2.14	3.89
Feces	10.5	0.35	6.67	19.44
Total	....	1.80	.....	100.00

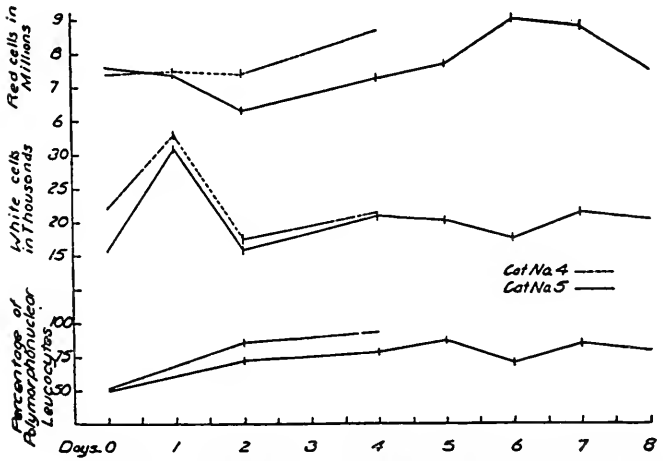

FIG. 4.—Blood variations of Cats 4 and 5. (The first sample was taken before exposure.)

clear leukocytes in the walls of the bronchioles.

The liver showed numerous granular vacuolated cells, especially around the central vein, and here and there the nucleus was destroyed. The architecture was not disturbed and the sinusoids were empty. The cells were slightly swollen and the epithelial border was prominent. The kidneys showed a moderate amount of fat in the tubular epithelium.

The changes in Cat 4 were very similar to those in Cat 3. The most prominent change in the lungs of Cat 5 was the marked thickening of the alveolar walls, which showed extensive hemorrhage, marked fibroblastic proliferation, and a moderate degree of inflammatory cell infiltration. The liver and kidneys showed changes similar to those found in Cats 3 and 4. The other organs were negative.

The chemical analysis of the tissues of Cat 4 is presented in Table 2.

Blood Changes.—The blood changes in Cats 4 and 5 are shown in Figure 4. There we see a tendency toward increase in the red cells; the white cell count increases abruptly on the day immediately following exposure, but drops back on the third day, and subsequently fluctuates around the normal point. The polymorphonuclear leukocytes, however, maintain a definite tendency to increase—in Cat 4 from 51 per cent. to 94 per cent. in four days, and in Cat 5 from 50 per cent. to 80 per cent. in eight days, with slight fluctuations during this period. The microscopic study of the blood smears showed more or less normal appearance with no abnormal cells except in Cat 4 which showed one normoblast in a whole slide on each of the last two days before it was killed.

Discussion:

The problem of how much cadmium was inhaled by the cats and how much was retained in the lungs is most important. Although these questions cannot be answered with accuracy, they may be answered approximately. Saito (3), in his experiments on dogs and on one rabbit, obtained from 4 to 24 per cent. dust (white lead) retention in the lungs. Cecil K. Drinker and his coworkers (4) observed that the natural protection of the lungs of cats, rabbits, and rats against the inhalation of dust was very great and was influenced by different factors, such as quiescence and light breathing. Philip Drinker and his coworkers (5), in a study of the retention of dust and fume by man, found that for zinc oxide powder it averaged 56 per cent. and for zinc oxide fume 57 per cent. Brown (6) points out different factors that influence the dust retention—inspired dust concentration, particulate size, density, wettability, and rate of respiration. He concluded that with a respiration rate over 20 per minute the dust retention is effected only by impingement and is about 40 per cent. for man.

Normal cats breathe about seventy times per minute. In the present research, after about twelve hours of exposure the breathing of the cats increased to approximately 100 times per minute, an unfavorable condition for the retention of fume or dust. The volume of air inspired is known to be about 300 c.c. per minute per kilo of cat. From these figures and from

the concentration curve (Fig. 3) it was possible to calculate the theoretical cadmium content in the inspired air. The percentage retention was calculated from the results of the chemical analysis.

From Table 3 it may be concluded that the cats had inhaled from 6 to 12 mg. of cadmium—the maximum possible amount under the conditions of the experiments. Certainly all the cadmium retained could not be recovered by analysis since some must have been excreted. Even if we assume that 50 per cent. of the inspired cadmium was retained, which represents a very small amount (3 to 6 mg.), this was sufficient to cause considerable damage to important organs in these animals, namely, the lungs, liver, and kidneys.

TABLE 3.—THEORETICAL AMOUNT OF CADMIUM INSPIRED AND PERCENTAGE RETENTION IN CATS POISONED WITH LESS CONCENTRATED CADMIUM OXIDE FUME

CAT NO.	WEIGHT OF CAT	THEORETICAL AMOUNT OF CADMIUM INSPIRED	TOTAL CADMIUM FOUND	PERCENTAGE RETENTION
	kg.	*mg.*	*mg.*	
3	2.45	8.75	1.49	17.03
4	1.70	6.05	1.80	29.75
5	3.55	12.60	2.79	22.14

Cadmium Oxide Dust

For the purpose of poisoning cats with commercial cadmium oxide dust, a modification of the apparatus described by Jötten and Arnoldi (7) was used (see Fig. 5). The cats were put in the lateral branch boxes of this apparatus. The cadmium oxide was placed below in a glass tube, with a sieve at the bottom, and the glass tube connected with a blower interrupted about forty times per minute. This air blast maintained a fairly constant concentration of cadmium oxide dust in the air. Two cats were used for the experiment: Cat 6, which was exposed for twenty minutes and was killed by ether and bleeding one month later; and Cat 7, which was exposed three times—for eleven minutes on the same day as Cat 6, for fifteen minutes one month later, and for thirty minutes on the following day—and was killed by ether and bleeding six hours after the last exposure.

Symptoms.—Cat 6 had abundant salivation when removed from the box, appeared very depressed, refused to eat, and did not react to normal stimuli. Respiration was increased. During the following days the cat was very sick, had noisy respiration, and refused to eat. Seven days after exposure it showed signs of recovery, and on the eighth day began eating. During this period its weight dropped from 4.9 kg. to 2.05 kg. The symptoms shown after this exposure were similar to those following exposure to cadmium oxide fumes; therefore the

cat was left to recover, and on the following days it improved steadily although the rate of respiration continued to be higher than before the exposure. In two weeks there was an increase in weight of 0.6 kg., but this was followed by a loss during the next two weeks, so that one month after exposure, when the cat was killed, it weighed 2.3 kg.

Cat 7 showed very few symptoms following the first exposure—chiefly slight loss of appetite on the day of exposure. On the next day its appearance was absolutely normal. During the following month it gained 0.5 kg. in weight, and at the end of that time was again exposed for fifteen minutes. This second exposure apparently disturbed the cat very little, and on the following day it was again exposed for thirty minutes. After the third exposure there was abundant salivation and vomiting. Respiration was very difficult and the animal was in the same serious condition as the two cats exposed to high concentrations of cadmium oxide fume.

Autopsy.—In Cat 6 the lungs were of a light pink color, with a gray alveolar design. The trachea was normal in appearance. The liver was yellowish brown, friable on section, and had a fatty appearance. The other organs were normal. In Cat 7 the lungs were very congested, and on section exuded an aerated liquid. The trachea and other organs were normal.

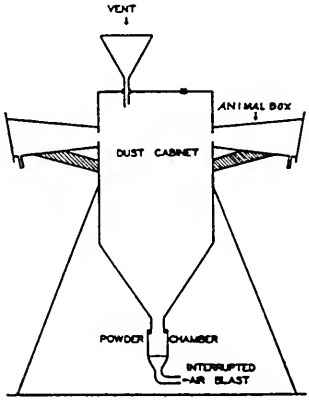

FIG. 5.—Cross section of apparatus used for poisoning cats with cadmium oxide dust and cadmium sulphide dust.

Microscopic Findings.—Cat 6 showed most pronounced changes in the lungs: chronic and subacute interstitial pneumonia, and marked thickening and fibrosis of the alveolar walls. Some hemorrhage, as well as foci of lymphoid cell infiltration, was seen. Scattering of polymorphonu-

clear leukocytes, hyperplastic alveolar epithelium, and emphysematous regions alternating with atelectatic regions were also observed. The liver showed a marked, central fatty infiltration, with an occasional tiny nec-

TABLE 4.—CADMIUM CONTENT OF TISSUES OF CAT 6, EXPOSED TO CADMIUM OXIDE DUST FOR TWENTY MINUTES AND KILLED ONE MONTH LATER

TISSUE	WEIGHT OF TISSUE	TOTAL CADMIUM FOUND	CADMIUM IN 100 GM. OF TISSUE	PERCENTAGE OF TOTAL CADMIUM FOUND
	gm.	*mg.*	*mg.*	
Blood	80.5	0.00	0.00	0.00
Lungs	24.0	0.25	1.04	11.74
Liver	72.0	0.50	0.69	23.47
Kidneys	11.0	0.55	5.00	25.82
Bile	2.0	0.05	2.50	2.35
Urine	4.0	0.06	1.50	2.82
Heart	11.0	0.04	0.36	1.88
Spleen	2.5	0.05	2.00	2.35
Pancreas	6.6	0.08	1.21	3.75
Brain	19.5	0.05	0.26	2.35
Muscle	56.0	0.10	0.18	4.70
Bone (2 femurs)	18.0	0.40	2.21	18.77
Total	....	2.13	....	100.00

TABLE 5.—CADMIUM CONTENT OF TISSUES OF CAT 7, EXPOSED TO CADMIUM OXIDE DUST FOR ELEVEN MINUTES, AND AGAIN FOR FIFTEEN AND THIRTY MINUTES, RESPECTIVELY, ON TWO SUCCESSIVE DAYS ONE MONTH LATER

TISSUE	WEIGHT OF TISSUE	TOTAL CADMIUM FOUND	CADMIUM IN 100 GM. OF TISSUE	PERCENTAGE OF TOTAL CADMIUM FOUND
	gm.	*mg.*	*mg.*	
Blood	73.0	traces	.....	.....
Lungs	23.0	2.00	8.70	47.96
Liver	74.0	0.75	1.11	17.99
Kidneys	20.0	0.50	2.50	11.99
Bile	2.0	0.30	1.50	7.19
Urine	1.5	0.25	16.65	5.99
Heart	8.5	0.10	1.12	2.40
Spleen	4.0	0.12	3.00	2.88
Pancreas	9.0	0.15	1.67	3.60
Total	....	4.17	.....	100.00

rotic area, and some yellow-brown material (bile or blood) in the phagocytic cells. The kidneys showed fatty infiltration, especially in the convoluted tubules. The other organs were negative. The chemical analysis of Cat 6 is given in Table 4.

The lungs of Cat 7 showed acute edema and generalized bronchopneumonia, polymorphonuclear leukocytes in the alveolar walls and alveolar lymphatics, interstitial edema, blood in some of the larger bronchioles, and acute alveolar emphysema. As was stated before, Cat 7 appeared absolutely normal following the first exposure, but lesions were found in the lungs which showed that this first exposure had had a damaging effect. Reparative reaction was found around and in the lining of the alveolar ducts. Here and there were small scars with lymphoid infiltration. The kidneys showed a moderate fatty infiltration in the tubules. The spleen showed abnormal congestion and many polymorphonuclear leukocytes. The liver and other organs were negative. The results of the chemical analysis of this cat are given in Table 5.

Discussion:

From these observations we may conclude that cadmium oxide dust is harmful, and that the toxicity resembles that of cadmium oxide fume.[1] Further, it is apparent that owing to fibrotic process, the pneumonia and bronchopneumonia produced by cadmium oxide (fume or dust) permanently damage the lungs by thickening the alveolar walls. It is important that very small amounts of cadmium oxide were capable of producing scars in the lungs, though the animal was very little disturbed by the exposure. The effect of cadmium oxide dust on the liver and kidneys was similar to that of cadmium oxide fume. One month after exposure there was a large quantity of cadmium in the body, the largest amounts being retained in the kidneys, liver, and bones.

The cadmium oxide dust concentration to which the cats were exposed, was determined and was found to be 0.4 mg. per liter of air (or 400 mg. per cubic meter of air). Taking the quantity of air inspired as 300 c.c. per kilo of cat, we have the results shown in Table 6.

Cadmium Sulphide

The same apparatus was used as for the experiments with cadmium oxide fume. The total number of cats exposed was four: Cat 8, which was exposed for two hours and killed by ether four hours later; Cat 9, which was exposed for one hour and died one week later; Cat 10, which was exposed for two hours and twenty minutes and died on the sixth day after exposure; and Cat 11, exposed for twenty minutes and killed one week later.

Symptoms.—Cat 8 did not show the least disturbance after exposure to cadmium sulphide dust, and immediately started to eat. Cat 9 presented a normal appearance and ate well at the end of exposure and on the day following. On the third day it had

[1] In the case of both cadmium oxide fume and cadmium oxide dust the amounts inhaled were very large, larger probably than would ever be encountered industrially. The experiments show that cadmium is a dangerous substance and that the type of damage to be expected is of such critical nature as to indicate the avoidance of the inhalation or ingestion of even small amounts of cadmium.

small amts. toxic

very little appetite, appeared depressed, and had diarrhea. During the following four days, until its death, it refused to eat and was very sick, showing definite pulmonary symptoms: increased rate of respiration, dyspnea, and noisy respiration. Cat 10 displayed similar symptoms, followed by death on the sixth day. In Cat 11 no symptoms were manifested following exposure. On the next day, however, the animal refused salmon and drank only milk, after which salivation appeared. On the third day salivation continued and vomiting occurred in the afternoon after drinking milk. On the fourth day the cat appeared depressed, was dyspneic, and took only a very little milk and salmon. These conditions continued for several days but the cat was not so seriously sick as Cats 9 and 10.

Autopsy.—The lungs of Cat 8 were normal in appearance except for numerous dark spots denoting areas of atelectasis. The lungs of Cat 11 were nearly normal, having little congestion. Cats 9 and 10 showed considerable congestion. In the rest of the organs nothing abnormal was observed.

Microscopic Findings.—In Cat 8 the lungs showed extensive emphysema, some alveolar edema, extensive interstitial and alveolar hemorrhage, and early pouring out of polymor-

TABLE 6.—THEORETICAL AMOUNT OF CADMIUM INSPIRED AND PERCENTAGE RETENTION IN CATS POISONED WITH CADMIUM OXIDE DUST

CAT NO.	WEIGHT OF CAT	TIME EXPOSED	CADMIUM CONTENT OF AIR	THEORETICAL AMOUNT OF CADMIUM INSPIRED	TOTAL CADMIUM FOUND	PERCENTAGE RETENTION
	kg.	*min.*	*mg./l.*	*mg.*	*mg.*	
6	4.9	20	0.4	11.76	2.13	18.11
7	2.0	11	0.4	2.64		
		15	0.4	3.60	4.17	31.03
		30	0.4	7.20		
				Total 13.44		

TABLE 7.—CADMIUM CONTENT OF LUNGS AND LIVER OF CAT 8, POISONED BY INHALATION OF CADMIUM SULPHIDE

TISSUE	WEIGHT OF TISSUE	TOTAL CADMIUM FOUND	CADMIUM IN 100 GM. OF TISSUE	PERCENTAGE OF TOTAL CADMIUM FOUND
	gm.	*mg.*	*mg.*	
Lungs	16.0	1.95	11.86	92.86
Liver	62.0	0.15	0.32	7.14
Total	....	2.10	.....	100.00

phonuclear leukocytes. The observation gave the impression that the extensive acute emphysema might be due to the obstruction of the small bronchioles and alveolar ducts by the cadmium sulphide dust. Chemical analysis is given in Table 7.

The lungs of Cat 9 showed marked engorgement of the blood vessels and capillaries, with hemorrhage in the interstitial tissue and alveoli. There was extensive emphysema, some atelectasis, but relatively little inflammatory cell infiltration and edema. The liver and kidneys were very little involved.

Examination of the lungs of Cat 11 showed moderate congestion, quite extensive interstitial and alveolar hemorrhage, and early pouring out of the polymorphonuclear leukocytes. There was moderate emphysema and atelectasis.

CdS not harmless

Discussion:

From these observations we may conclude that cadmium sulphide is far from being harmless. Its noxious action is different from that of cadmium oxide. The subjective symptoms, usually appearing from twenty-four to thirty-six hours after exposure, are vomiting and diarrhea, occasionally salivation, dyspnea, and noisy respiration. The pathologic changes referable to cadmium itself take place slowly. The first change in the lungs is an extensive emphysema, which cannot be other than mechanical, resulting from the filling of the small bronchioles and alveolar ducts with cadmium sulphide dust. This effect is of course not specific for cadmium. After thirty-six to forty-eight hours the animals develop generalized pneumonia, and bronchopneumonia with edema, and after about a week they die. Very small amounts of cadmium sulphide are capable of producing congested inflammatory conditions in the lungs, and this can occur without antecedent atelectasis or emphysema. The fact that even one week after exposure to cadmium sulphide dust over 70 per cent. of the total cadmium found was in the lungs, explains why the other organs were affected very little, if at all. The difference in the action of cadmium sulphide and cadmium oxide is due to the difference in physicochemical properties. Cadmium sulphide, being very insoluble, is resorbed slowly; therefore the subjective symptoms are retarded and its distribution in the body is limited. Because of its lower density, it requires a greater volumetric amount than cadmium oxide, and consequently the tendency to emphysema production is greater.

Poisoning by Feeding

Cadmium poisoning through the gastro-intestinal tract, as has already been mentioned, is of no great practical importance for man. The aim was especially to investigate microscopically the pathologic changes which were observed macroscopically in poisoning by feeding, and also to determine the distribution of cadmium in the body.

For this purpose two cadmium compounds were used, namely, cadmium carbonate and cadmium phosphate. We had three groups of cats, with two in each group, for each salt, and two cats as control animals, making a total of fourteen. The cadmium salts were suspended in a 2 per cent. solu-

tion of gum acacia, of which 1 c.c. was equivalent to 10 mg. of metallic cadmium. The cats were fed with salmon and milk to which the cadmium was added in different doses for each group. Feedings were given daily except Sundays for the first month, and every day including Sundays during the second month, with the exception of Christmas day.

Table 8 shows the grouping of the cats according to the amount and the duration of cadmium feeding: Group A, fed 100 mg. daily for one month; Group B, 10 mg. for two months; and Group C, 2 mg. for two months.

TABLE 8.—GROUPING OF CATS FED DIFFERENT AMOUNTS OF CADMIUM CARBONATE AND CADMIUM PHOSPHATE

GROUP	CAT NO.	COMPOUND FED	DOSE DAILY	DURATION OF FEEDING	KILLED AT END OF FEEDING	KILLED 1 MO. AFTER FEEDING DISCONTINUED
			mg.	*mos.*		
A	1	$CdCO_3$	100	1	yes	...
	2	$Cd_3(PO_4)_2$	100	1	yes	...
	3	$CdCO_3$	100	1	...	yes
	4	$Cd_3(PO_4)_2$	100	1	...	yes
B	5	$CdCO_3$	10	2	yes	...
	6	$Cd_3(PO_4)_2$	10	2	yes	...
	7	$CdCO_3$	10	2	...	yes
	8	$Cd_3(PO_4)_2$	10	2	...	yes
C	9	$CdCO_3$	2	2	yes	...
	10	$Cd_3(PO_4)_2$	2	2	yes	...
	11	$CdCO_3$	2	2	...	yes
	12	$Cd_3(PO_4)_2$	2	2	...	yes

The cats were weighed, and blood samples were taken, before the experiment was started and every two weeks afterwards. At the end of the observations the animals were killed by bleeding; specimens were then taken for microscopy, and the body was analyzed for cadmium. The aim was to make the cats eat all the cadmium destined for them, and this was accomplished for the most part except in the case of the highest doses. An estimate was made of the consumed food containing cadmium, but no attempt was made to determine how much was vomited. As there was no difference between the effects of the two cadmium salts, the observations will be described together.

Group A

Of the four cats in this group, two (Cats 1 and 2) were killed by bleeding after one month of cadmium feeding, and two (Cats 3 and 4) were allowed to live for one month following the feeding experiment, during which time they were given only salmon and milk.

Symptoms.—During the entire feeding period there was always vomiting when the cats ate food containing 25 per cent. or more of cadmium. At the beginning of the experiment the vomiting occurred within from two to four

hours after the meal; later it was delayed so that at the end of about a month it occurred from eighteen to twenty-four hours after eating. In these cases of delayed vomiting the food was very little digested, having almost the same appearance as in the period of early vomiting. This is perhaps explained by the toxic effect of the cadmium salts on the gastric ferments. At the beginning of the feeding the vomiting was preceded by abundant salivation, and this still persisted after the vomiting. The cats, as would be expected, lost considerable body weight during the cadmium feeding. This may be explained by the inanition due to vomiting, loss of appetite, and deficient digestion of the retained food, and also to the toxic effect of cadmium. When the cadmium was discontinued the animals ate better and partly regained their lost weight.

Autopsy.—In Cat 1 the kidneys had the aspect of the so-called "big white kidney." The lungs, liver, and other organs were normal in appearance. Cats 3 and 4 showed nothing abnormal, and Cat 2 nothing except possibly a fatty liver and large kidneys.

Microscopic Findings.—Cat 1 showed very slight congestion of the lungs, a few polymorphonuclear cells in the alveolar walls, and some emphysema. The liver was essentially negative. The kidneys showed a varying degree of degeneration of the tubular epithelium, involving principally the proximal convoluted tubules, and to a slight extent the collecting tubules. The glomeruli showed no change. The gastro-intestinal tract, the trachea, and other organs, including the heart,

TABLE 9.—CADMIUM CONTENT OF TISSUES OF CAT 1, FED 100 MG. OF CADMIUM CARBONATE DAILY FOR ONE MONTH AND KILLED AT END OF CADMIUM FEEDING

TISSUE	WEIGHT OF TISSUE	TOTAL CADMIUM FOUND	CADMIUM PER 100 GM. OF TISSUE	PERCENTAGE OF TOTAL CADMIUM FOUND
	gm.	*mg.*	*mg.*	
Blood	97.5	0.00	0.00	0.00
Lungs	21.5	0.10	0.46	0.83
Liver	67.5	6.75	10.00	55.97
Kidneys	44.0	4.00	9.10	33.17
Bile	2.0	0.12	6.00	1.00
Urine	8.0	0.10	1.25	0.83
Heart	14.0	0.10	0.71	0.83
Spleen	7.5	0.05	0.67	0.41
Pancreas	7.0	0.05	0.71	0.41
Brain	22.0	0.07	0.32	0.57
Muscle	67.0	0.12	0.18	1.00
Bone (2 femurs)	28.5	0.60	2.10	4.98
Total	....	12.06	.....	100.00

spleen, pancreas, brain, bone marrow, and muscle, were all negative. The chemical analysis of this cat is given in Table 9. The analysis of 11 gm. of feces (found in the rectum) yielded 60 mg. of cadmium.

The lungs of Cat 2 showed very few polymorphonuclear cells. In the liver there was a general granulation of the cells, which was more prominent in the central areas. The kidneys presented the same tubular fatty degeneration as those of Cat 1, but to a lesser extent.

Blood Changes.—The blood was not affected in this group of feeding experiments.

Group B

The cats in this group were fed 10 mg. of cadmium daily for two months, after which two (Cats 5 and 6) were killed and two (Cats 7 and 8) were put on a plain diet for a month.

Symptoms.—During the first ten or twelve days vomiting occurred from four to six times, accompanied by salivation. During the vomiting period the appetite was decreased. After vomiting ceased, all the cats started to eat well, and continued to do so until about the end of the second month when, with the exception of Cat 5, they all showed a marked decrease in appetite. Cat 5 refused to eat on the forty-second day of the cadmium feeding, and was killed the next day. The variations in body weight were definite only for Cat 5, in which there was a steady decrease.

TABLE 10.—CADMIUM CONTENT OF TISSUES OF CAT 3, FED 100 MG. OF CADMIUM CARBONATE DAILY FOR ONE MONTH AND KILLED ONE MONTH AFTER DISCONTINUANCE OF CADMIUM FEEDING

TISSUE	WEIGHT OF TISSUE	TOTAL CADMIUM FOUND	CADMIUM PER 100 GM. OF TISSUE	PERCENTAGE OF TOTAL CADMIUM FOUND
	gm.	*mg.*	*mg.*	
Blood	117.0	0.00	0.00	0.00
Liver	103.0	4.00	3.88	57.14
Kidneys	38.0	2.00	5.26	28.57
Bile	0.8	0.05	6.25	0.72
Urine	34.0	0.15	0.44	2.14
Bone (1 femur)	16.0	0.80	5.00	11.43
Total	.....	7.00	....	100.00

In Cat 3 the lungs were negative; the liver showed a general granulation of the cells, and large vacuoles of fat. The fat accumulation was not so prominent in the central areas, but seemed to be more generalized. If there was any repair it was very slow. The kidneys showed a pronounced fatty degeneration of the tubules. Chemical analysis of the tissues is given in Table 10.

The changes observed in Cat 4 were much the same as those in the other cats in this group.

Autopsy.—Except for a very fatty

liver in Cat 5, nothing abnormal was found.

Microscopic Findings.—In Cat 5 the liver showed a strikingly profound alteration, so that the central and midzonal areas of lobules stood out prominently as lightly stained vacuolated areas. In the periphery of the lobules of the liver the tissue was relatively normal in all respects. The portal blood vessels and biliary ducts presented no abnormalities. The central veins were engorged. A more detailed study of the central areas mentioned above revealed that practically every liver cell contained many small or single large, clear vacuoles of fat. This fat accumulation caused distortion of the columns of liver cells so that the sinusoidal spaces were difficult to recognize and appeared compressed. Throughout the liver tissue, but especially near the periphery of the lobules, a yellow-brown pigmented material was noticed in the form of droplets and granules, often enclosed within phagocytic cells. Occasional scattered liver cells could be seen which were necrotic and were invaded by polymorphonuclear leukocytes. The kidneys showed a moderate degree of fat in the tubules; the other organs were negative. The chemical analysis of Cat 5 is given in Table 11. The analysis of the feces showed 10 mg. of cadmium in 6 gm. of feces.

TABLE 11.—CADMIUM CONTENT OF TISSUES OF CAT 5, FED 10 MG. OF CADMIUM CARBONATE DAILY FOR TWO MONTHS AND KILLED AT END OF CADMIUM FEEDING

TISSUE	WEIGHT OF TISSUE	TOTAL CADMIUM FOUND	CADMIUM PER 100 GM. OF TISSUE	PERCENTAGE OF TOTAL CADMIUM FOUND
	gm.	*mg.*	*mg.*	
Blood	62.0	0.00	0.00	0.00
Lungs	14.0	0.10	0.79	2.16
Liver	44.5	2.50	5.62	54.11
Kidneys	21.5	1.00	4.65	21.65
Bile	1.5	0.07	4.66	1.52
Urine	11.0	0.15	1.36	3.25
Heart	9.0	0.05	0.56	1.08
Pancreas	5.0	0.04	0.80	0.87
Spleen	4.5	0.05	1.11	1.08
Brain	23.0	0.06	0.26	1.30
Muscle	99.0	0.10	0.10	2.16
Bone (2 femurs)	20.0	0.50	2.50	10.82
Total	....	4.62	....	100.00

The changes observed in the other cats in this group consisted chiefly in granulation of the liver cells and pronounced fatty degeneration of the renal tubules.

Blood Changes.—No marked blood changes were noted except in Cat 5,

which showed an increase in the number of red cells and in the hemoglobin content.

Group C

The experiments in this group, in which cats were fed 2 mg. of cadmium daily for two months, proved to be simple variants of those with large doses, and they will therefore not be considered separately.

Discussion:

Cats fed with large doses (100 mg.) of cadmium vomited during the entire period of cadmium feeding. At the beginning of the period the vomiting occurred within two or three hours after eating, but it became progressively delayed until at the end it occurred from eighteen to twenty-four hours after eating. The cats showed a marked loss of appetite and a progressive loss of weight. The loss of weight was so pronounced in one instance (Cat 1) that the muscles were reduced to a minimum and the cat could hardly walk. The cats which were fed an intermediate dose (10 mg.) vomited only at the beginning of the period. They lost less weight than the animals fed larger doses, and had fairly good appetites except during the vomiting period and at the end of the second month. The vomiting in both groups of cats was accompanied by salivation. The cats fed with small doses (2 mg.) did not vomit, and in general maintained their body weight. Their appetites were good except at the end of the second month, when there was a marked loss of appetite. During the feeding period no other symptoms were observed.

At autopsy, in general no pathologic changes were found except occasionally very marked fatty liver and large kidneys. The urine from these cats gave a typical Gmelin test, and was negative for albumin when tried in a few cases (four in all). Microscopic changes occurred chiefly in the liver and the kidneys, and in such a manner that either one or the other was more affected, and only seldom were both affected profoundly. For the most part, the cats with less appetite, or those that refused more often to eat, had badly affected livers; in those that ate well, the kidneys were more affected. The changes in the liver ranged from general granulation of the liver cells, as the minimum, to a generalized fatty infiltration as the most profound change, predominant in the central areas of liver lobules. The cats which were put on a plain diet for one month after the cadmium feeding was discontinued did not show any sign of repair; if there was any it was very slow. The changes in the liver were accompanied by a biliary stasis. The kidneys presented only one type of lesion, namely, fatty infiltration, which was more predominant in the convoluted tubules and occurred very little in the collecting tubules; the remainder of the kidneys was more or less normal in appearance. No casts were observed in the tubules, such as were described by Severi (8) after intravenous injection of cadmium chloride. Neither was inflammation of the upper respiratory tract observed during the period of cadmium feeding, as described by Schwarz and Otto (9), and the microscopy of the trachea was always negative. The gastrointestinal tract also appeared normal

in all instances, both macroscopically and microscopically.

The cadmium was stored principally in the liver; in the majority of cases the kidneys contained the greatest relative amount (*i.e.*, the quantity per 100 gm. of tissue), and in a few cases the greatest absolute amount. The excretion was effected through the gastro-intestinal tract and the kidneys, and was very slow as is seen from the analysis of the organs of the cats remaining on a plain diet for one month after cadmium feeding was discontinued. The blood did not change in any definite way.

The observations concerning vomiting and distribution of cadmium in the body are in accordance with Schwartze and Alsberg's (10) findings, and the distribution of cadmium is also in accordance with Hessel's (11) work, except that in neither instance (10) (11) was cadmium found in the bones.

Prevention of Poisoning

It has been shown that cadmium poisoning as an industrial hazard occurs through the respiratory tract, and that very small amounts of cadmium oxide fume or dust, as well as of cadmium sulphide, may produce serious damage in the lungs. On the basis of these observations one may conclude that cadmium, no matter how small the amount taken into the lungs, causes pathologic changes, and that there is, therefore, no permissible amount of cadmium.

There are two possible methods for protection against cadmium fume or dust: adequate ventilation at the source of the fume or dust, which is of course the more important; and the provision of masks or respirators for use in emergencies or for short periods of time. The type of ventilation which should be provided will not be discussed here, but the protective value of one type of mask and one type of respirator will be presented, together with suggestions as to when each should be used.

The Burrell dust mask and the Willson bag respirator were tested for cadmium oxide fume and for cadmium chloride fume mixed with hydrochloric acid. The procedure was as follows: Cadmium was burned in an electric furnace in a large dust cabinet. After there was sufficient cadmium oxide fume, samples were taken with two impingers in series (12) for the determination of the cadmium concentration in the cabinet. Air was then extracted from the cabinet through the respirator or the mask, and conducted through the double impinger, in order to determine the cadmium content. Finally, from the cadmium concentration in the cabinet and the quantity of cadmium passed through the mask or the respirator, the percentage efficiency of each device was calculated. For the tests with cadmium chloride fume, cadmium chloride was burned in an electric furnace, and in order to simulate industrial conditions hydrochloric acid vapor was introduced, the concentration of which was not determined since cadmium chloride and hydrochloric acid in varying amounts sometimes occur together in industry. The determination of the cadmium content of the cabinet and the test for the masks were carried out in the same way as for cadmium oxide.

The results of these tests, presented

in Table 12, show that the Burrell dust mask retained a greater percentage of cadmium than the Willson bag respirator. A respirator of the efficiency of the Willson bag seems suitable for protection against low concentrations, while the Burrell mask is advisable when high concentrations are encountered. It should be emphasized again, however, that adequate ventilation is the chief consideration in protective measures. Furthermore, persons who have once been exposed to cadmium in any form and have developed pulmonary symptoms, however mild, should not suffer a second exposure. In the smelting of zinc ores containing cadmium, particular precaution should be taken during the first two hours when cadmium fume in high concentration is given off. The possibility of cadmium poisoning in zinc smelters was asserted by Tracinski (13) and Sigel (14), and more recently by

TABLE 12.—EFFICIENCY OF BURRELL DUST MASK AND WILLSON BAG RESPIRATOR IN CADMIUM OXIDE FUME AND IN CADMIUM CHLORIDE FUME MIXED WITH HYDROCHLORIC ACID

COMPOUND	CADMIUM CONCENTRATION IN CABINET	MASK OR RESPIRATOR TESTED	PERCENTAGE EFFICIENCY
	mg./cu. m.		
Cadmium oxide	134.00	Burrell mask	96.2
	55.00	Willson bag	79.0
	26.00	Willson bag	82.6
Cadmium chloride	19.30	Willson bag	73.3
	11.00	Burrell mask	82.5
	8.84	Willson bag plus soda lime cartridge[1]	87.0

[1] The soda lime cartridge is for protection against the hydrochloric acid vapors.

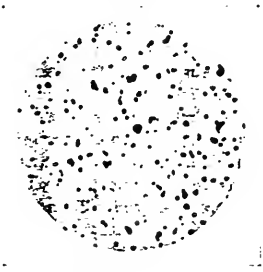

FIG. 6.—Particles of cadmium oxide fume. × 1,285.

Stephens (15). Stephens based his conclusions on chemical analyses made on the livers of persons working in zinc smelting.

The fact that the efficiency of the mask and the respirator is not nearer 100 per cent. is probably explained by the smallness of the cadmium oxide fume particles. A measurement of these particles after the fume had been set up eight hours showed that 83.5 per cent. were under 1 micron. The sample was taken with the electric precipitator, and the floccules were left out of the measurement. The appearance of the cadmium oxide fume is given in Figure 6. The size of particles reported by Legge (16) shows 96 per cent. under 2 microns. The smallness of the particles is an additional argument for adequate ventilation.

Summary and Conclusions

A thorough review of the literature showed that the work done on cadmium was considerably varied, but unsatisfactory from the standpoint of the industrial hygienist (17). Although industrial cadmium poisoning occurs practically entirely through the respiratory system, the least work was done in this direction. Even in feeding experiments the pathologic changes were not precisely determined since they were not verified by microscopic examination. Much has been achieved, therefore, in the present study which presents valuable information for the industrial hygienist.

Poisoning by Inhalation

Cadmium poisoning was produced in cats through the respiratory system with cadmium oxide fume, cadmium oxide dust, and cadmium sulphide dust. From these experiments the following conclusions may be drawn:

Cadmium Oxide Fume and Dust.—Cadmium oxide fume or dust when inhaled produces an increase in the rate of respiration and abundant salivation, which appears during the exposure or immediately after. Later the respiration becomes more dyspneic and noisy. The animals refuse entirely to eat or drink.

In high concentrations cadmium oxide induces the development of edema of the lungs which results in the death of the animals. In smaller amounts it produces generalized pneumonia and bronchopneumonia, emphysema, and atelectasis. The development of the pneumonia is accompanied by a progressive thickening of the alveolar walls constituting a permanent damage due to fibrotic tissue and indicated by the subjective symptom of increased rate of respiration. The emphysema at best is partly mechanical, being formed by filling of the small bronchioles and alveolar ducts with cadmium oxide. In very small amounts cadmium oxide produces scars in the lungs, though there are no subjective symptoms following such exposures.

Cadmium oxide produces changes in the liver varying from a general granulation of the cells, as a minimum lesion, to a pronounced fatty infiltration of the cells from the central areas of the lobules, as a maximum lesion. The kidneys are affected by a fatty infiltration of the cells which is more pronounced in the convoluted tubules. The other organs in general are not affected.

Cadmium is found mainly in the

lungs, liver, and kidneys shortly after the exposure; later it becomes stored up chiefly in the liver, kidneys, and bones.

Cadmium Sulphide Dust.—The animals exposed to cadmium sulphide dust manifested symptoms only after twenty-four to thirty-six hours following the exposure. These consisted in vomiting, diarrhea, occasional salivation, and increased rate of respiration, which was dyspneic and noisy.

Cadmium sulphide causes generalized pneumonia and bronchopneumonia accompanied by edema, and extensive emphysema and atelectasis of a mechanical nature. The lungs are usually the only organs affected.

Cadmium is found mainly in the lungs, with a small percentage in the liver and kidneys. The difference in the distribution of cadmium sulphide and cadmium oxide is explained by the greater insolubility of the former compound.

With both cadmium sulphide and cadmium oxide the excretion is affected very slowly through the kidneys and the gastro-intestinal tract. No definite blood changes are found.

Poisoning by Feeding

Cadmium poisoning was produced by feeding cats cadmium carbonate and cadmium phosphate. Since no difference was noted in the action of these two salts, the same conclusions may be drawn from both groups of experiments:

Cadmium fed in large doses induces vomiting, with salivation and loss of appetite. Vomiting also occurs for a short period following medium doses, but is absent with small doses. The vomiting and loss of appetite are followed by loss of body weight.

Irrespective of the dose of cadmium fed, the liver and kidneys are affected, with more pronounced lesions in one or the other. The liver presents changes varying from a general granulation of the cells to a pronounced fatty infiltration, especially around the central vein. The kidneys show a fatty infiltration, which is more prominent in the convoluted tubules. The other organs are not usually affected.

Cadmium is retained in the liver in greater absolute quantity, and in the kidneys in greater relative quantity. The bones also retain a high percentage.

Cadmium is excreted very slowly through the kidneys and the gastro-intestinal tract.

No definite blood changes are found.

Prevention of Poisoning

One type of mask and one type of respirator were tested against cadmium oxide and against cadmium chloride mixed with hydrochloric acid vapor. The use of the respirator is recommended where the percentage of cadmium contained in the material handled is small. A soda lime cartridge should be attached to the respirator when acid fume is also present in the atmosphere. The mask should be used in all cases where the cadmium content is high. Adequate ventilation is the most important consideration in the prevention of cadmium poisoning.

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FLUORESCENT PARTICLE ATMOSPHERIC TRACER: TOXICITY HAZARD

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Abstract—Fluorescent particle atmospheric tracer (FP) is commonly used in atmospheric diffusion and air pollution studies. FP is a finely powdered mixture of zinc sulfide and cadmium sulfide which fluoresces a characteristic color when exposed to ultra-violet radiation. Cadmium and cadmium compounds are highly toxic and the use of FP in open atmospheric experiments presents a potential human health hazard.

INTRODUCTION

ATMOSPHERIC tracers are distinctive materials released into or formed naturally in the atmosphere which are useful as indicators of atmospheric flow or of the transport and diffusion of materials in the atmosphere. Fluorescent particle atmospheric tracer (FP) has found wide application in atmospheric studies (LEIGHTON, 1964; LEIGHTON *et al.*, 1965). FP is a dry, finely powdered mixture of zinc sulfide and cadmium sulfide which radiates a characteristic ultra-violet-stimulated fluorescence distinct from that of common atmospheric materials.

Cadmium (Cd) and Cd compounds are highly toxic to humans (AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS, 1971; ANON., 1970; ATHANASSIADIS, 1969; BARRETT *et al.*, 1947 a, b; DUNPHY, 1967; FRIBERG, 1959; FRIBERG *et al.*, 1971; KENDREY *et al.*, 1969; PRODAN, 1932 a, b; SAX, 1963). Cd can be absorbed into the body by inhalation, ingestion, injection, or epidermal contact and is accumulated in tissues without regard to existing body concentrations. Cd is apparently not essential for growth and its exact physiological action is not completely understood. It is known to be toxic to almost all physiological systems and may be toxic in acute or chronic exposure. Recovery from Cd poisoning is variable and depends on the nature, intensity, and duration of exposure.

Although Cd toxicity is well-established and FP is commonly used as a tracer in atmospheric studies, no case of Cd poisoning resulting from the use of FP has been reported in the literature. This may be because none has occurred; however, it is more likely that such poisoning has been of a low-level chronic nature and its symptoms are less dramatic and more difficult to recognize than in the case of acute Cd poisoning. A general ignorance of the toxicity of FP and of the symptoms of Cd poisoning also contribute to the failure to recognize FP poisoning. No information directly concerned with FP toxicity and the potential health hazard associated with its use has been published. This paper presents a brief general review of the symptoms of acute and chronic Cd poisoning by inhalation and ingestion and a brief discussion of the potential health hazard associated with its use in atmospheric studies.

SYMPTOMS OF Cd POISONING*

Symptoms of Cd poisoning range from very mild to very severe depending on the kind and degree of exposure and the time elapsed since exposure.

* Over 150 papers describing case histories and experimental observations of Cd poisoning were assimilated into this review of symptoms. The author felt that this was too great a number to cite and refers the reader to the papers cited in the Introduction for greater detail on Cd poisoning symptoms.

Acute poisoning can result in pulmonary edema, pneumonitis, alevolur cellular proliferation and metaplasia, arterial thrombi, renal bilateral cortical necrosis, renal tubular degeneration, renal glomeryal infaraction, and death. Inhalation of dust or fumes initially affects the respiratory tract. Immediate symptoms include throat dryness, nasopharyngeal irritation, cough, dyspnea, chest pain, chills, weakness, headache, nausea, vomiting, and diarrhea. More severe exposure causes marked lung changes with persistent cough, severe chest pain, severe dyspnea, and prostration which may terminate fatally. Even brief exposure to high concentrations may result in pulmonary edema and death.

Delayed symptoms include lung damage similar to that from bronchopneumonia, acute kidney inflammation, dark urine, and fatty degeneration of the liver. These symptoms may be delayed several hours after exposure and fatal concentrations can be breathed without sufficient discomfort to warrant avoiding further exposure. Ingestion of Cd causes gastro-intestinal poisoning similar to food poisoning in symptomology. Nausea, salivation, vomiting, diarrhea, and severe abdominal pain begin almost immediately. Long term effects of eigher acute or chronic Cd inhalation or ingestion include proteinuria, emphysema, anemia, hypertension, kidney stones, testicular damage, bone lesions, teratogenic damage, growth retardation, anosmia, yellowing of dental necks, lumbar and lower extremity pain, and death.

The accumulation of Cd in body tissues has been surveyed experimentally and in autopsy specimens. The greatest accumulation was observed in the kidneys and liver with large amounts also in the spleen, pancreas, thyroid, adrenals, and testes. Inhaled Cd accumulates mainly in the kidneys, pancreas, and thyroid.

FP HEALTH HAZARD

A lack of published information about FP or CdS toxicity necessitates estimation of the FP health hazard from general Cd toxicology and the physical and chemical properties of FP. Many factors contribute to an individual's tolerance to Cd exposure including his physiological character and previous exposure from pollution, occupation, food, cigarettes and other Cd sources. Human threshold limit values (TLV) of Cd toxicity have been estimated from experimental and occupational exposure to CdO Dust and fumes to be 0.05–0.10 mg Cd m^{-3} (PRODAN, 1934 a, b). These levels have been adopted by the AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS (1971) as their recommended legal TLV. BARRETT *et al.* (1947 a, b) estimated the acute lethal dosage to be 2500 min mg Cd m^{-3} (5.2 mg m^{-3} for 8 h). A review of recent studies by FRIBERG *et al.* (1971) indicates that chronic exposure to concentrations as much as 100 times less than the legal TLV can also be hazardous. A total accumulated body burden from all sources of about 120 mg results in permanent serious kidney damage.

FP is a finely powdered (1–5 μm dia.) mixture of approximately 20% CdS and 80% ZnS or about 0.16 g Cd g^{-1} FP. CdS is insoluble in water but soluble in weak acid. Since the recommended TLV is based primarily on CdO which is also insoluble in water, the TLV is assumed to apply directly to CdS and FP toxicity. Both the zinc and sulfur in FP are generally nontoxic. Experimental evidence indicates that zinc may even prevent or reduce the effects of Cd poisoning (GUNN *et al.*, 1968; SCHROEDER *et al.*, 1968). The body regulates tissue zinc concentrations at relatively constant levels whereas Cd is accumulated without regard to existing tissue concentrations (LUCIS

et al., 1970) and the protective effect of zinc, if it even occurs in the case of FP, may not be valid over a long period of chronic exposure to FP. In this discussion, the possible protective effects are therefore ignored. Assuming 1.5×10^{10} particles of FP g^{-1} (LEIGHTON *et al.*, 1965), any atmospheric FP concentration greater than 10^7 particles m^{-3} exceeds the recommended TLV and any exposure greater than 2500 $\times 10^8$ particle min FP m^{-3} exceeds the acute lethal dosage. A typical FP dissemination rate from a point source during an atmospheric diffusion study is about 10 g min^{-1} (LEIGHTON, 1964; LEIGHTON *et al.*, 1965). Under neutral conditions (wind 4 m sec^{-1}, overcast), the TLV would be exceeded closer than 160 m downwind and the minimum chimney height required to avoid a TLV concentration at ground level would be about 100 m (TURNER, 1969). The use of FP must be evaluated in relation to total atmospheric Cd concentrations in many urban areas where existing Cd levels are high (CARROLL, 1966).

In conclusion, FP does present a potential health hazard to experimenters and other humans exposed to it and precautions should be exercised to avoid or minimize exposure during its storage, handling, and experimental use. The accumulation of Cd in the body presents a special hazard to experimenters who are repeatedly exposed to FP.

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THE AMERICAN LAWYER

September 26, 1994

I am a senior reporter for The American Lawyer magazine in New York. I wrote an article about Elizabeth Barrett's suits against the government which was published in the September 1990 issue ("Elizabeth Barrett's Bad Trip").

I came away from the experience having reached the following conclusions.

If someone has been injured by actions of federal government officials, there are two main ways to sue--bringing a Federal Tort Claims Act suit against the government, or bringing a so-called Bivens-style civil rights action against the individual officials. Barrett tried each of these methods. But each path was blocked by bizarre, nearly insuperable obstacles, all of which could easily be swept away by legislative reform.

Her Federal Tort Claims Act claim was blocked by an array of seemingly senseless barriers. The strangest was the

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fact that the Barrett couldn't sue at all for either intentional torts by the government, or for injuries caused by a government official carrying out a "discretionary function . . . whether or not the discretion involved is abused." As a result of these exceedingly broad exemptions, the award Barrett ultimately won was not really for the crux of the outrage the government committed upon her father. She was suing because government officials chose to test chemical weapons on her father without explaining to him that that's what they were doing; those chemicals caused him great pain and anguish, and then killed him. Yet her lawyers informed her that she probably couldn't succeed on that theory, because the army's decision to use her father as a guinea pig was either an "intentional tort" or a "discretionary function," both of which were immune from suit. Instead, the lawyers figured out a theory that was peripheral to the real outrage, but one that seemed to thread its way through the narrow passage permitted for Federal Tort Claims Act suits. Barrett finally won money from the government on the theory that the U.S. Army negligently tested the fatal drug on mice before its officials chose to feed that drug to her father. She could sue over the fact that officials were negligent in testing this chemical weapon on mice. But Barrett couldn't sue over the fact that a government official chose to test that weapon on her father. That's bizarre and offensive.

The other obstacle any plaintiff faces in using the Federal Tort Claims Act is finding an attorney willing to take the case. Barrett relied upon essentially pro bono attorneys--attorneys who knew they were unlikely ever to recover fully either their costs or their fees. Unlike cases brought under the civil rights act, attorneys suing under the Federal Tort Claims Act cannot apply for reasonable attorneys fees from the defendant if the plaintiff wins. Instead, they take their fee--a contingency fee of 25 percent--out of the plaintiff's award. But, because of limits upon damages in Federal Tort Claims Act cases, the plaintiff's award will seldom fully compensate the plaintiff, and 25 percent of that award will seldom fully compensate the lawyer for the fees and expenses of bringing the suit. Accordingly, most lawyers will not want to bring the case in the first place. (Though there is a limit upon the percentage of the award that can be consumed by attorneys fees, there is no limit on the amount of that award that may be depleted by the reimbursement of attorneys expenses. Had several of Barrett's lawyers not waived their right to recover their expenses, Barrett would have been left with nothing whatsoever from her roughly $700,000 award in this case.) .

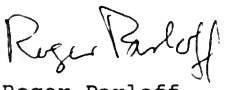
First, the Federal Tort Claims Act doesn't allow punitive damages awards. Without punitive damages, only wealthy victims or their estates will attract attorneys to represent

them, because only high-earners are capable of suffering large pecuniary injuries when government action puts them out of work or kills them. In Barrett's case, where her father was a tennis instructor, the compensatory damages from killing him were going to be low.

That problem was exacerbated in Barrett's case by the fact that the plaintiff, under the Federal Tort Claims Act, cannot get pre-judgment interest either. Cases of government wrongdoing on this scale will often be accompanied by a lengthy coverup, since government officials could otherwise never expect to get away with such conduct. In Barrett's case, the government had covered up the cause of her father's death for 22 years. The absence of prejudgment interest meant that anything Barrett was awarded had to be paid in 1953 dollars. Not only were her father's lost earnings computed based solely upon the earnings of a tennis instructor in 1953, uncorrected for inflation or interest, but even the award for his pain and suffering before he died was determined in terms of 1953 dollars.

The civil rights accion Barrett brought against federal officials was likewise beset with its own strange procedural obstacles. It was. for instance, virtually impossible to bring such an action because of a Second Circuit Court of Appeals ruling concerning the obscure issue of "personal jurisdiction." Since many of the federal officials

responsible for her father's death were geographically dispersed around the country and had not actually come to New York in order to injure Harold Blauer, Barrett's father, Barrett tried to sue them all in a single forum in New York, the place where she lived and her father was killed. But, while she would have been permitted to do just that had she been suing a defendant for almost any ordinary business injury, the law did not permit her to do so in a civil rights action against federal officials. Instead, she was required to sue each of the individual defendants in the state where he or she currently lived, which would have meant filing numerous actions in different states. See Green v. McCall, 710 F.2d 29 (2nd Cir. 1983). This procedural rule seems designed to serve no legitimate purpose except to make civil rights actions against federal officials prohibitively expensive and unworkable, regardless of their merit.



Roger Parloff
212-973-2866

Testimony of Elizabeth Barrett

House of Representatives
Committee on Government Operations
·· Legislation and National Security Subcommittee

September 28, 1994

Mr. Chairman, distinguished members of Congress, and Mr. Turner, thank you for the opportunity to testify about the death of my father, Harold Blauer, who was a victim of a government sponsored chemical warfare experiment when he was a civilian patient 41 years ago.

Walter Lippman's definition of the ideal public man: "Those in high places are more than the administrators of government bureaus. They are more than the writers of laws. They are the custodians of a Nation's ideals, of the beliefs it cherishes, of its permanent hopes, of the faith which makes a Nation out of a mere aggregation of individuals."

In the hope that you try to live this ideal, let me take you back to 1952. Divorce was made less common than today, and a father with custody of his daughter was unknown. This was my life. I adored my father, went to work with him whenever I didn't have school. I only remember him leaving me once to join a friend for an evening, and I had to insist he go.

When he died, my world came to an end. My mother moved us to Mexico, where it was much cheaper to live. She put me in a Mexico City boarding school and went to Cuernavaca with my sister to live. I was one miserable lonely 13 year old. I don't think my mother or sister were very happy either.

I loved my father. I think of him every day. Sixteen years of dealing with the many horrendous legal and political roadblocks I experienced every step of the way haven't made it easier. Although this is probably my last opportunity to get things changed, to make all these battles meaningful, I've been depressed and frightened ever since I got your invitation to testify.

I have been afraid ever since the true nature of my father's death was revealed. Friends warned me that the government considered me a threat and if I didn't settle the case, something terrible might happen to me. Columnist Jack Anderson told me he had the same concerns for his safety. I took his advice to take proper precautions and get on with life, but I'm always looking over my shoulder. I'm still frightened because I don't believe all the facts have been revealed. (At the least, I was to have seen all the original documents at trial, which the government refused to provide.)

The absence of my father from my life will always hurt. That is true for all children who lose their parents. But, I feel I also lost my country at the same time. This is something no American, brought up as I was to believe in our system almost as a religion, expects. There doesn't seem to be any way to understand or heal this pain. My country destroyed my family, as well as my father with grossly negligent and purposeful acts by professionals-- doctors and lawyers-- who are supposed to protect us from harm, not cause it. These people are protected by our immunity laws and other legal precedents that need to be changed. The potential victims we are talking about could be you, your wife, husband, daughter, son, mother, or father. It could happen again. Secrecy, lying, and lack of accountability enable the continuation of criminal activity. You, who represent us, need to change this.

My father sought help from physicians who killed him for chemical warfare research purposes. How would you feel if you found out your father died, not in Nazi Germany, but in the United States eight years after we hanged war criminals for the same offense? My father was forcibly given a chemical tested only on mice. Harold Blauer was a civilian. He never gave his consent. The hospital record shows he objected to all four injections that were given to him in the last month of his life. According to the Army Inspector General's report, Dr. James Cattell, who gave my father the deadly injection, said the chemical was an Army secret, "and we didn't know whether it was dog piss or --."

The Army Chemical Corps provided the untested chemical to a New York hospital because it wanted to develop psychotropic substances into military weapons. They were in a hurry to find answers, without regard for the safety of their human subjects. My father was told the chemicals were "therapy."

On January 8, 1953, my father was given a chemical dose more than 15 times the size of the first experiment.

As described in the book, The Mind Manipulators (Sheflin and Opton) "On the morning of January 8, 1953, tennis pro Harold Blauer was taken from his room at the New York State Psychiatric Institute to receive an injection. Blauer did not want it. Four injections he had been given the previous month had made him ill and he was scheduled to return to his family the very next day. He was well. He knew it, the doctors knew it, the staff knew it and his family knew it. Why should he have to take this last needle? It must have made him very apprehensive because the last shot had upset him, mentally and physically, for a week."

From the nurses notes on my father's last day:

9:53 A.M.	injection started - Legs being moved
9:55	"i.v.'s getting me now" - restless movements - protesting injection.
9:57	injection ended.
9:59	very restless - has to be restrained by nurse - out of contact wild flailing of arms. Sweating profusely
10:01	patient pulled up in bed - generalized stiffening of body. teeth clenched - frothing at mouth.

My father's pulse increased enormously and he finally lapsed into a coma. He died at 12:15pm that day. The record shows my father suffered from December 11, 1952 to January 8, 1953. On his last day he did not die instantly. The final deadly injection took two hours and twenty-two minutes to kill him, a torture comparable to those inflicted during the "Inquisition."

His death certificate stated that a chemical compound had activated a previously unknown heart condition, causing a fatal heart attack. Harold Blauer did not have a heart condition.

My father was not the only victim in this tragedy. My mother died with a broken heart because she felt her divorce was responsible in some part for his death. She never knew my father was murdered in a chemical warfare experiment.

My daughter, Amy, has been a victim too. She was 13 when I found out about the reason for my father's death and its cover-up. The already stressful years for an adolescent daughter of a single mother were enormously complicated because I took an active role in pursuing reason and justice. I gave up my

career in health education and became a secretary so I could spend the time necessary to find law firms to represent me (I had eight law firms, one law school and the New York Civil Liberties Union), raise money for expenses, and attend depositions around the country to get at the truth. Now, I don't seem to be able to get my career back, or even get a job.

I tried to make my case, Barrett vs U.S.A., a springboard for new accountability laws and bills to prevent unethical experimentation from happening to others. There were discussions at the beginning about a settlement, but I felt the truth was necessary to prevent more tragedies and would not agree to sweep hidden facts under the rug.

I didn't get much help. My friends and I wrote letters to Congress, getting the usual form letter response. Marty Teitel, Director of the CS Fund, provided me with a grant of $10,000 to help me get accountability from those responsible. I will always be grateful to him and his foundation for that support.

I fought my lawyers as much as the government. My lawyers wanted to settle or drop important defendants like Warren Burger and Jacob Javits. Mr. Burger was the Assistant Attorney General in the U.S. Justice Department in the 1950s. Mr. Javits was a Major in the Army Chemical Corps during World War II and then the New York State Attorney General who helped Mr. Burger deceive the Court and my mother.

Even the press, which had been very interested in helping, became a problem. When the involvement of Burger and Javits was revealed, the stories about these horrors which had been on the front page of many newspapers and on the national television newscasts stopped. I was told by Lyle Denniston that Mr. Burger's press secretary told him that if he wrote another word, he would be sued. CBS rushed me into their New York studio for an interview the day Burger was officially named, but didn't run the story, saying their Washington legal correspondent wanted to check it first. It never ran. The New York Times, which had run several front page stories, not only stopped covering the story, but refused to cover the eight-week trial and never even did a story on the verdict!

As long as there is secrecy, and a lack of accountability for one's actions, tragedies like what happened to my father will continue. Please don't let these outrageous cases of human abuse be repeated.

Now there is no personal accountability for unethical military experiments on humans. Immunity is given to those officials who are supposed to be protecting American citizens, not hurting them. A lawyer, Robert King of Debevoise & Plimpton, commented, "In the eyes of the law, the more responsibility that is placed on a government official, the less liability is associated with his official conduct."

In 1986, when he dismissed David Marcus, the Assistant New York State Attorney General assigned to defend the hospital in 1955, Judge Walter Mansfield (U.S. Court of Appeals for the Second Circuit) stated that questionable or harmful conduct during his (Marcus') representation of the State was "irrelevant. . . . Immunity attaches to his function, not the manner in which he performed it." It is this type of irrationality that needs to be changed. All the rules on immunity for people who violate the constitution, have been made by judges.

1) Please pass a law to repeal this kind of immunity so the courts cannot continue this sham.

Who would have thought after Nuremberg that experiments like those of the Nazis would continue in this country? It can happen again, and we are painfully naive if we don't think so. Nothing has really changed since the 1950s: classified research still has no ethical scrutiny.

2) Congress must pass laws to hold those people who have the most power over our lives (doctors, lawyers, government employees and contractors) responsible for their actions.

David Rothman of Columbia University says, "Research by military or any Federal agency must receive special scrutiny not just from their own boards but from an independent body. This will help us be certain of the integrity of government research."

3) Everyone should have immediate access to their own medical records. This is illegal in many states: it should be illegal to deny anyone access to information about themselves. If patients have access to information, mistakes as well as harmful experimentation will be less likely to occur. If my father had been able to see his records, he might have had more help from friends when he protested.

Most legal cases about unethical military experiments have been settled out of court without the victims or the general public ever knowing exactly what happened. How can we rectify the problem if these acts are kept secret?

Health care costs, as well as injuries, could be greatly reduced if people were aware of the "risks" of many of the drugs and other treatments that are prescribed. The Physicians Desk Reference, a reference for prescription drugs, is a best seller which shows people are willing to try and understand.

Taxpayers who have been harmed by experiments are fighting for justice against a government using their tax dollars against them (over $50 million to defend radiation experiments so far). The Justice Department has a reputation for dragging things on for years so the victim will run out of money or time.

4) I suggest the government pay for the plaintiff's case, as it pays for the defendant (the government) after the courts have decided the case has merit. This would provide more equal access to justice.

In my case, as mentioned in the letter submitted by Roger Parloff of The American Lawyer, "attorneys suing under the Federal Tort Claims Act can't apply for reasonable attorneys fees from the defendant if the plaintiff wins. Instead, they take their fee -- a contingency fee of 25 percent -- out of the plaintiff's award. But, because of limits upon damages in Federal Tort Claims Act cases, the plaintiff's award will seldom fully compensate the plaintiff, and 25 percent of that award will seldom fully compensate the lawyer for the fees and expenses of bringing the suit. Accordingly, most lawyers will not want to bring the case in the first place. (Though there is a limit upon the percentage of the award that can be consumed by attorneys fees, there is no limit on the amount of that award that may be depleted by the reimbursement of attorneys expenses.)"

5) Discretionary function should be reviewed.

Our laws are made for a sovereign government. I was only allowed to sue for negligence. I was not allowed to sue for my father's intentional murder. Individuals working for the government are allowed to kill citizens for the greater good, and are protected by "intentional tort" or "discretionary functions," which are immune from suit.

Sovereign immunity is un-American! I thought we fought England in the 18th century because the King could do no wrong according to England's laws. Royal abuses of power made us want all people to be equal under the law here.

In the biological warfare case, Nevin vs U.S.A., the Court ruled, "Thus sovereign immunity is not waived if, as the government maintains in this case, the acts being sued upon were undertaken as part of the government's 'discretionary function.' Specifically, the government contends that the acts in question here constituted the discretionary function of providing for the national defense, so that they are not actionable under the Federal Tort Claim Act."

I'll say it again: sovereign immunity is un-American. I believe this government has a fiduciary responsibility to its citizens, who pay taxes to be protected by their government, not murdered. Too often we are told "national security" forces us to have secrecy, lying and cover-ups. I don't believe it. Secrecy, lying, and cover-ups create cynicism and despair, which makes "national security" most precarious. In most cases the records show that embarrassment was the reason for a cover-up, not national security.

6) No Statute of Limitations should be in effect if the Government causes the problem, especially if they try to cover it up.

My case was lost over the Statute of Limitations issue in the District court. I had to appeal. After finding that fraud tolled the Statute, the Appellate court returned my case to the District court to be tried. If the Statute of Limitations is frozen by explicit law when there is a cover-up or fraud, much time will be saved, and justice will be more likely.

My civil rights action against Federal officials was blocked because of the obscure issue of "personal jurisdiction." Roger Parloff of The American Lawyer comments, "Since many of the Federal officials responsible for your father's death were geographically dispersed around the country and had not actually come to New York in order to injure Harold Blauer, Barrett's father, Barrett tried to sue them all in a single forum in New York, a place where she lived and her father was killed. But, while she would have been permitted to do just that had she been suing a defendant for almost any ordinary business injury, the law did not permit her to do so in a civil rights action against federal officials. Instead, she was required to sue each of the individual defendants in the state where he or she currently lived, which would have meant filing numerous actions in different states. See Green v. McCall, 710 F.2d 29 (2nd Cir. 1983).

This procedural rule seems designed to serve no legitimate purpose except to make civil rights actions against federal officials prohibitively expensive and unworkable, regardless of their merit.

Robert King believes the New York State Assistant Attorney, David Marcus (who participated in the cover-up) acted as agent for these officials within the State and therefore subjected them to the jurisdiction of the courts in New York. I believe they were all part of the same action and should be sued in one place, at one trial.

7) We must make individuals who have no integrity accountable for their crimes, especially those politicians, scientists, and doctors who are held in the public trust. If we don't, as we have seen for ourselves, history will repeat itself.

8) Punitive damages and pre-judgment interest should be the rule when individuals in government are so negligent. We can no longer make laws with the assumption that people are inherently good: we must create laws to prevent evil people from harming others.

In "Barrett v. United States: Dark Side of Uncle Sam," Joseph and Robert Kelner said (New York Law Journal, May 13, 1987) "... when an activity is so obviously, grossly negligent, wanton or reckless, punitive damages should be awarded as a deterrent, whether the culprit be an individual or government agent, servant or employee."

Without punitive damages, as Mr. Parloff says, "only the wealthy victims or their estates will attract attorneys to represent them....."

Mr. Parloff continued, "That problem was exacerbated (in your case) by the fact that the plaintiff, under the Federal Tort Claims Act, can't get pre-judgment interest either. In your case, the government had covered up the cause of your father's death for 22 years. The absence of pre-judgment interest meant that anything you were awarded had to be paid in 1953 dollars. Not only were your father's lost earnings computed solely upon the earnings of a tennis instructor in 1953, uncorrected for inflation or interest, but even the award for his pain and suffering before he died was determined in terms of 1953 dollars."

9) In 1987, Judge Constance Baker Motley's opinion said the question of pre-judgment interest should be addressed by Congress. Well, I'm here now and I hope you will correct this wrong.

This Congressional hearing is a breath of fresh air in a country that has avoided the truth about itself for decades. I hope we can now take action and make our laws fair to all, not privileges for the powerful. As Elie Wiesel said at his 1986 Nobel Peace Prize ceremony, ". . action is the only remedy to indifference: the most insidious danger of all .... One person of integrity can make a difference, a difference of life and death." Will at least one of you help?

10) I suggest that as a representative victim of the laws as they are now, I could help when you draft new laws to correct these problems. We can learn from our mistakes if we want to.

11) At the very least there should be a public advocate or Ombudsman for a plaintiff suing the government when a cover-up or fraud is discovered. This person should be hired at taxpayer's expense to get the case on the "fast track." Justice is not provided when cases are drawn out over many years. It can approach justice only if resolution is timely.

Wiesel: "I swore never to be silent whenever and wherever human beings endure suffering and humiliation. We must always take sides. Neutrality helps the oppressor, never the victim. Silence encourages the tormentor, never the tormented."

12) I hope you agree that a good symbolic start, other than your recognition and interest today, would be for my family to get a Presidential apology for my father's death.

Not one administration, Republican or Democrat, since 1975 (when the truth was revealed) ever said "I'm sorry." Instead, they, through the Department of Justice and the Pentagon, continued to lie and kept me in court for sixteen years, wasting taxpayers' money and ruining my life. It is sadly ironic and unjust that I, the victim's daughter, was treated as if I was the criminal, an impediment to just government rather than a solution.

I believe that in my father's case, individuals in government broke their moral, and I think, fiduciary contract with my father and his family when they actively pursued him against his will and killed him.

13) This apology should be accompanied by a refund of all taxes paid by my father, his wife and his children, and a recognition that taxes should never be paid by his children. This is to show that the Government recognizes that taxes paid incur an obligation of service for those taxes. I have not filed a tax return since I was told of my father's death. I am very afraid the government will use this to put me in jail and keep me quiet.

I challenge this representative body to make a difference and help me be a catalyst for change so I can some day hold my head high when our National Anthem plays, not lower it, as I have done for years, in shame.

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Backup material has been provided to the Committee.

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