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VETERANS AT RISK: THE HEALTH EFFECTS OF MUSTARD GAS AND LEWISITE.

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Testimony given by:

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Good morning Mr. Chairman and members of the Committee. I am Dr. David Rall and am testifying because I chaired an Institute of Medicine committee that surveyed the health effects of exposure to mustard gas and Lewisite--a study that was requested by the Department of Veterans Affairs when it was revealed that World War II servicemen were used as human subjects in gas chamber and field tests of these chemical warfare agents. I have brought with me summaries of our report, *Veterans at Risk: The Health Effects of Mustard Gas and Lewisite*.

In 1991, the Secretary of the Department of Veterans' Affairs (VA), Mr. Derwinski, requested the Institute of Medicine (IOM) to assemble a committee to survey the scientific and medical literature regarding mustard gas and lewisite. The purpose was to judge, on the basis of the literature, the strength of association between exposure to these agents and specific health conditions, and to identify gaps in the literature. The committee was further asked to recommend ways to reduce any gaps found. The study was requested because it had become clear that United States servicemen had been used as human subjects in a World War II testing program in which they were exposed to mustard agents (sulfur and nitrogen mustard) and lewisite. Some of these men, by 1990, were filing claims with the VA for service-related disability. Thus, an additional element of the IOM committee's statement of task was to hold public hearings through which affected veterans could inform the committee about their experiences in the tests and their subsequent health problems.

The study that resulted from this request was a difficult, but successful, one. At the time it began, the VA had already identified seven health conditions as causally related to mustard agent exposure, including chronic bronchitis, chronic asthma, laryngitis, emphysema, corneal opacities, keratitis, and chronic conjunctivitis. By the conclusion of the study, our committee was able to identify several new health conditions associated with exposure to these agents and to determine that the levels of exposure in the gas chamber and field tests conducted during World War II (and in later years) were sometimes equal to that experienced by soldiers in the battles of World War I.

The study, however, was one in which discoveries and revelations built upon one another in a complex way. Therefore, my presentation will follow the development of the committee's work. This approach is not to inform you of the study "process", but to put into context the intricate background and underpinnings of the committee's findings and recommendations. I would also like to point out that all the committee's findings and recommendations were subjected to a rigorous review process in which the draft report was examined by 10 individuals with appropriate expertise, appointed and supervised by the National Research Council's Report Review Committee.

The IOM study began in September 1991 and the committee met for the first time in January 1992. It was clear at this first meeting that an important challenge was the

state of the scientific literature. This literature was replete with information regarding the acute effects of mustard agents, but was sorely lacking in information about the long-term consequences of exposure. To counterbalance these gaps and take full advantage of the information available, the committee focused on several areas. First, the assessment of the actual exposure levels in the gas chamber and field tests became important. The committee also looked at related literature including data about second cancers resulting from the use of nitrogen mustard as a cancer chemotherapy agent. We also examined other lung irritants and the connection, or lack of one, between acute symptoms and long-term damage. Finally, the committee paid special attention to the data available from long-term follow up of chemical munitions workers and to the very few follow-up studies done with World War I mustard gas casualties. In all of their evaluations, the committee was guided by established principles of risk assessment, including dose estimation, timing of symptoms, and plausibility of biological mechanisms of injury, among others.

Between January and April 1992, the committee sought to obtain as much detail as possible regarding the experimental protocols to assess what the actual exposure levels might have been. In addition, the committee began its public hearing process in which it solicited written, oral, or public statements from veterans—over 250 veterans contacted the committee through the study director, Dr. Constance Pechura, who still receives telephone calls from affected veterans. Both these activities helped shape the report.

The committee is indebted to the Naval Research Laboratory for providing technical reports and summaries of the gas chamber tests conducted there. These documents, some of which were included in Appendix D of our report, outlined subject recruiting methods, information about the concentrations of agents inside the gas chambers, number and length of individuals trials, as well as the variable use of "protective" clothing. These documents also made clear that the end point of the gas chamber experiments was tissue injury. These official documents strongly corroborated the veterans' own reports. We know that at least 2500 men were subjects in gas chamber tests and at least 1500 participated in field tests. These numbers, however, are from incomplete records and thus represent the absolute minimum number involved. Let me outline the experiments.

Young men in Navy boot camps were offered extra leave and "a change of scenery" if they would agree to test "summer uniforms" for a few weeks. Once at the test site, the men wore various amounts of clothing that had been chemically impregnated with substances developed to retard the penetration of mustard or other chemical agents. They were given gas masks and locked into a chamber, which was then filled with gas—most often sulfur mustard. These chambers were kept at ninety degrees Fahrenheit and sixty percent humidity. In some cases, the concentrations of sulfur mustard in the chambers would have been lethal without the gas masks. The men were required to remain in the chamber for an hour, after which they remained in the protective clothing for varying periods of time. This scenario was repeated either daily or every other day

until the men's skin burned, indicating failure of the protective clothing.

Four aspects of this testing are notable in terms of research with human subjects. First, the men were deliberately misled about what they were being exposed to until after they had been through one chamber trial. Second, official documents warned those conducting tests not to mistake symptoms such as laryngitis or conjunctivitis for gas symptoms, despite the fact that these were well known consequences of sulfur mustard exposure. Third, official documents guided those in charge to "dress down" any subject who wanted to withdraw from the experiments; according to veterans' reports, this dressing down often took the form of overt threats. Finally, the men were told never to reveal their participation to anyone.

Less is known about field testing of the protective clothing. However, it is known that concentrations in field tests were also high, that some field tests were done without protective clothing or masks, and that field tests were often followed by chamber tests of the clothing worn. Subjects in field tests were most often recruited from units of the Chemical Warfare Service, including the 95th Medical Gas Treatment Battalion and others.

After the subjects were released from the chamber test sites, they were sent home for leave and, later, sent to their various wartime posts. No attempts were made by any department of the U. S. Government to follow the men's health status and, in some cases, mustard agent-related illnesses were not recorded as such in infirmary or hospital records. The IOM committee concluded that this lack of follow up was not justified by a lack of knowledge about long-term health effects of these agents, because military doctors had published in the open literature in 1933 that chronic bronchitis, chronic asthma, emphysema, corneal opacities, and chronic conjunctivitis resulted from sulfur mustard exposure.

The committee also investigated the degree to which the gas masks used prevented inhalation injuries in chamber tests and found that, even assuming a protection factor afforded by modern gas masks, inhalation injuries would have occurred. Further, the type of gas mask used in the experiments, the Navy diaphragm type, was eventually rejected by the Chemical Warfare Service because it was unacceptably leaky.

By their second meeting and public hearing in April 1992, the committee was also concerned with the potential psychological effects of the gas chamber and field tests on the human subjects and with their own responsibilities as physicians and scientists to consider the conduct of the experiments and how to communicate most effectively with the affected veterans once the study was completed. Thus, the committee sought input from an expert in the psychological effects of chemical and biological warfare environments and from experts in bioethics and risk communication. We decided to appoint a psychologist to the committee to help assess the relevant literature. The human subjects had not only been placed into highly threatening chemical warfare

environments, they had also suffered real exposures to toxic substances. The committee reviewed the literature pertaining to psychological health effects of not only chemical warfare environments, but also exposures to other toxic substances, such as dioxin at Love Canal, and radioactive leaks, such as the Three Mile Island accident.

Between April and August 1992, the committee met twice to draft the report. Information about the poor safety record of chemical warfare production facilities emerged, partly due to the public hearing process and partly due to the search for additional exposure data. The committee was surprised to find that only Japan had done long-term follow-up studies with workers from chemical production facilities. To a lesser extent, Great Britain had studied such workers; the United States had not. In addition, the committee found that some servicemen, assigned to handle chemical weapons or train others in defense against them, had also suffered severe exposures. Finally, the committee heard from men who had been injured in World War II by sulfur mustard following the German bombing of the harbor in Bari, Italy, which destroyed a U.S. merchant vessel carrying a secret load of sulfur mustard munitions. The sulfur mustard leaked from the ship into the water and vaporized into the air, causing at least one thousand deaths among civilians and military personnel.

Now let me turn to the health conditions identified by the committee as causally related to exposure to mustard agents. I will also identify those conditions associated with exposure to lewisite, but the data on lewisite were quite scant. The committee's evaluation agreed with the original determination of the VA assigning a causal relationship to chronic bronchitis, chronic asthma, chronic laryngitis, emphysema, corneal opacities, keratitis, and chronic conjunctivitis. In addition to these, the committee found that exposure was also causally related to:

- * respiratory cancers, including cancer of the nasopharyngeal tracts and lung;
- * skin cancer, as well as pigmentation abnormalities of the skin, chronic skin ulceration, and scar formation;
- * acute nonlymphocytic leukemia resulting from exposure to nitrogen mustard exposure, and probably sulfur mustard exposure as well;
- * bone marrow depression and a decrease in the competency of the immune system (An acute reaction that can render a person more susceptible to infectious diseases with serious long-term consequences, such as rheumatic fever that can cause lifelong cardiovascular problems.);
- * psychological disorders from gas chamber and field tests due to the combination of repeated threatening circumstances and toxic exposures (The committee was only able to identify general classes of psychiatric diagnostic categories because there is little known about the long-term expressions of untreated post-traumatic

stress disorder. However, the committee believes that the causal relationship between the experimental situations and development of psychological disorders in some subjects is clear.); and

- * dysfunctions in sexual performance as a result of severe burns and scarring of sexual organs.

All other health conditions fell into one of two remaining categories. The second category is quite small and contains those conditions for which there are suggestive data, but not enough to establish a causal relationship. It includes leukemia from exposure to sulfur mustard and reproductive toxicity, including increased miscarriages or infertility.

The last category contains the majority of health problems reported by veterans during the public hearing process. This category covers those health problems for which few data exist to argue for or against a causal relationship. These include all cardiovascular problems (except those resulting from acute infectious diseases as mentioned previously), and neurological, hematological, and gastrointestinal diseases. The category further includes any reproductive effects that might result from exposure to lewisite. As you can see, the gaps in the literature still outweigh the certainties.

To close as many gaps as possible, the committee made a number of recommendations to the VA, but also to the Department of Defense. The committee asked the VA to identify the subjects from the gas chamber and field tests, to evaluate their health status, treat any causally related health problems found, and to initiate morbidity and mortality studies. I would like to emphasize here that the VA anticipated this recommendation and, under the direction of Dr. Susan Mather, initiated an investigation of the feasibility of identifying the subjects. This investigation began in the winter of 1992 and reports of progress were shared with our committee in June and August 1992.

The committee made a further recommendation to the VA to pay careful attention to the special problems of these veterans, stemming from years of official denials, the burden of secrecy, and the decades of silent worry about their health problems and their possible cause. Many of the affected veterans understandably feel betrayed and, over time, have come to believe that all their health problems are related to their exposure. Certainly, on the basis of the scientific literature, no one can be sure whether they are right or wrong. The VA system operates, however, on the basis of scientific proof and this is, and will continue to be, a difficult concept to translate to the affected veterans. It is especially difficult to do with people who have been secretly living with serious health concerns for five decades, or, in some cases, have been telling the truth only to be told that no such thing ever happened.

We also recommended that the Department of Defense attempt to identify former military and civilian workers exposed during gas handling and production, and to find

those exposed following the Bari disaster. The records of military personnel should be turned over to the VA for notification and medical evaluation and civilians should be notified by the Department of Defense and advised about their options for appropriate compensation. Finally, the committee recommended that the VA and the Department of Defense widely advertise that any oaths of secrecy taken in World War II related to testing of mustard agents or lewisite are no longer binding.

In the preface to their report, the committee asked that each veteran who served as a human subject in the testing programs be honored for his sacrifice and that any continuing military research with human subjects be held to the same standards and guidelines applicable to civilian research; specifically, we recommend the inclusion of civilians on all research protocol review panels.

There are a variety of viewpoints regarding the ethics of these experiments. Many would argue that it was wartime and that, because they pre-dated the Nuremberg Code, no formal code of ethics had yet been formalized about human experimentation. It is, therefore, difficult to say clearly what the "standards of the day" were in the early 1940s. As a medical student, I volunteered as a human subject for medical research in the late 1940s. I knew what the experiment entailed and I had the right to withdraw from the experiment at any time. Professor Jay Katz from Yale University, a bioethicist who served on the panel that reviewed the Tuskegee experiments and whom our committee consulted, took the position in a letter to me (and reprinted in one of the appendices to our report) that the World War II mustard gas experiments did violate ethical standards and the Government should be held accountable. It is also true that the "standards of the day" were held up at Nuremberg by the U.S. Military Tribunal as the measure against which Nazi medical atrocities should be judged.

Members of our committee individually expressed differing opinions on the ethical issues presented by these experiments. Nevertheless, the consensus was that the combination of misleading the subjects, exposing them to high levels of toxic substances, demanding them to remain in the experiments and keep it secret for decades, and then neglecting to follow the subjects' health status required, at the very least, comment. We also believed that these abuses justified our recommendations to the government agencies involved to do everything possible to aid these men now and to ensure that adequate protections, equal to those in the civilian research arena, were in place for the present and future human subjects of military experiments.

Thank you.