INFORMING DOD PERSONNEL OF EXPERIMENTAL DRUG ADMINISTRATION

HON. PATRICK J. KENNEDY

OF RHODE ISLAND

IN THE HOUSE OF REPRESENTATIVES

Thursday, April 10, 1997

Mr. KENNEDY of Rhode Island. Mr. Speaker, I have come to the conclusion that trust and confidence in the American Government could very well have reached a low point. No one can dispute that citizen trust is vital to the health and well-being of our country and our way of life. We especially need the trust of the men and women of the U.S. military, those who have served, those who serve today and those who will serve in the future. The men and women in our Armed Forces are willing to risk their lives in defense of our national security interests, therefore we must continually work to ensure the bonds of trust endure in peace and in war time.

Unfortunately, it appears that this trust has been called into question. One need merely read newspaper articles surrounding the Persian Gulf war to see what I mean:

On February 28, the New York Times ran an article entitled: ''Pentagon Reveals It Lost Most Logs on Chemical Arms: Missing From Two Sites: Gulf War Veterans Now Raise Questions of Cover-Up or Criminal Incompetence.''

Allegations of cover-up and criminal incompetence indicate to me that we have our work cut out for us if we intend to earn back that trust. Just 3 days earlier, a New York Times headline read: ''Army Warned Early of Chemical Exposure in Gulf.''

The article stated that the CIA gave the Army information more than 5 years ago that some American troops may have been exposed to nerve gas from the destruction of an Iraqi ammunition depot following the Persian Gulf war. The article further stated that these CIA reports discredit the Pentagon's continued assertion that it became aware of the potential exposure only last year.

And in today's Washington Post the headline of the lead article read: ''CIA Knew In '84 of Iraq Poison Gas: Agency Official Apologizes To Persian Gulf War GIs.''

Unfortunately, what we have here are glaring examples of why some of our troops and veterans may question the veracity of information provided by their own Government. It appears that this situation goes hand in hand with another major cause of mistrust: the unsolved mysteries of gulf war syndrome. Far too many of our troops who deployed to the gulf are suffering from undiagnosed illnesses that neither they nor their doctor can explain.

I commend the President for his efforts aimed at finding answers and restoring this trust. He directed the Presidential Advisory Committee on Gulf War Veterans' Illnesses to investigate and search for a cause of the symptoms experienced by so many gulf war veterans; he convened a White House Panel; and he appointed Bernard D. Rostker, Assistant Secretary of the Navy, to lead the DOD's investigation into possible chemical agent exposure during the war.

More can and must be done, however, to rebuild trust, to avoid repeating past mistakes, and to prevent future health consequences similar to those experienced during and after the gulf war. Our troops must be assured that when we send them into battle, they will be protected by the best military technology, the best leaders, and the best medicine. Protection also means proper education and training, as well as provision of critical information, including information about investigational new drugs that may be administered to our troops for their protection against chemical and biological threats.

Unfortunately, for our troops, the threat of chemical and biological weapons have become an increasing reality. During Operation Desert Storm, the DOD sought to utilize two investigational vaccines, Pyridostigmine Bromide [PB] and Botulinum Toxoid [BT], to protect troops against chemical weapons. The FDA deemed these drugs investigational because they were not originally approved for the purpose DOD intended to use them. Under FDA regulations, use of such Investigational New Drugs [INDs] required informed consent by recipients, except where not feasible. Concerned with its inability to obtain informed consent during the exigencies of war, the DOD sought an exception from the FDA of its informed consent requirement. In response, the FDA established an interim regulation defining ''combat exigency'' as one instance where informed consent could be waived. The DOD subsequently applied for the exception and the FDA granted it, subject to certain conditions, including:

1. Each BT vaccine was to be recorded in the individual's permanent immunization record.

2. The DOD had to maintain a roster of all individuals receiving the investigational vaccines.

3. Recipients were to report adverse reactions to the vaccines.

4. Most importantly, the DOD had to provide individuals receiving the vaccines accurate, fair, and balanced information about the vaccines. The information was contained in leaflets produced by the FDA.

Approximately 8,000 troops received the BT vaccine, while at least 250,000 received PB. However, the DOD believes that only 40 percent, and that is on the high end of the scale, only 40 percent of those services members actually received information about the vaccines administered to them. This is unacceptable.

Prior to Desert Storm, it was agreed that PB and BT constituted the best available preventative therapy against chemical agents our troops might face in the Persian Gulf. Even though the use of these investigational drugs could not have been avoided, failure to inform the troops about the drugs could and should have been avoided.

The men and women who served in the Gulf War had a right to know that the vaccines administered to them were investigational.

The same service members had a right to know about the side effects of the investigational drugs.

Let me give you an example of the importance of this information to our troops. PB is known to cause gastrointestinal problems, cramps, and headaches; but these symptoms disappear after the drug is taken for a certain period of time. Some service members stopped taking PB once they experienced these symptoms, making them dangerously susceptible to chemical agents. Had they known about PB's symptoms and that these symptoms eventually would disappear, they may not have stopped using the drug and would not have put their lives in further jeopardy.

In addition, some of our veterans who did not receive the information about the nature and side effects of the INDs may wonder today what lingering impact the drugs have on their health. With no information, a person has nothing to refute either misinformation or worst case scenarios. All of our military personnel have a right to know about the investigational inoculations they receive from the DOD. Today I rise to introduce legislation to ensure that this gulf war situation is not repeated, to ensure that in the future our troops are informed of investigational drugs, and to help ensure that our service members can and will trust their government.

The legislation will require the DOD to inform service members about the use of experimental drugs. Specifically, the bill requires that the DOD inform individuals prior to, or no later than 30 days after administration.

1. That the drug being administered is investigational;

2. The reasons why the drug is being administered;

3. The potential side effects of the drug, including side effects resulting from interactions of the drug with other drugs or treatments being administered to the individual.

While information about investigational drugs will not prevent possible side effects, the information will ensure our troops know that the Government is not intentionally misleading them or seeking to hide information from them. They will know that we value their service to our country and that we too are doing our best to protect them. Through sharing of this information can we contribute to the process of rebuilding the bonds of trust.

HAPPY 50TH ANNIVERSARY WALTER AND MARGARET BARBER

HON. JAMES A. BARCIA

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Thursday, April 10, 1997

Mr. BARCIA. Mr. Speaker, the sanctity of marriage is more precious than any other matter in the relations that people have. It is a commitment that seems easy to make on the day of the wedding, and more priceless to hold on to for each and every additional day.

Today marks the 50th wedding anniversary of Walter and Margaret Barber, two of my constituents who I have the pleasure to know personally, and who serve as an inspiration to all of us who treasure the value of devotion. They will celebrate this golden anniversary with friends and family this Saturday in Auburn, MI.

Walter Barber served our country as a member of the Army Air Force in Europe. After returning and working at Dow Chemical, he was fortunate enough to meet Margaret Ida Koch of Bay City. They were married at St. Mark's Evangelical Lutheran Church in Auburn, IN, by Pastor Allen Trout.

Their family grew with the addition of two sons, Dennis and David, and one daughter, Lynn. They now have eight grandchildren.

Their civic involvements hold great importance for Walter and Margaret Barber. He, with the support and understanding of Margaret, had been a longtime member of the