THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

AUG 9 2001

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE

SUBJECT: DoD Policy on Blood Donor Deferral Criteria for variant Creutzfeldt-Jakob Disease

In accordance with DoD Directive 6000.12, "Health Services Operations and Readiness," April 29, 1996, this DoD policy establishes blood donor deferral criteria relative to variant Creutzfeldt-Jakob Disease (vCJD).

In response to the increased incidence of Bovine Spongiform Encephalopathy (BSE) and vCJD in many European countries, the Food and Drug Administration (FDA) is publishing draft guidance for deferring individuals who may have been exposed to the agent for vCJD. The FDA deferral criteria are:

(a) Cumulative travel to or residency in the United Kingdom from 1980 to 1996 for $\geq$ 3 months;
(b) DoD personnel stationed in Europe from 1980 to 1990 North of the Alps for a cumulative period of $\geq$ 6 months;
(c) DoD personnel stationed in Europe from 1980 to 1996 South of the Alps for a cumulative period of $\geq$ 6 months;
(d) Any traveler to, or resident of, Europe from 1980 to present for a cumulative period of 5 years (applies to DoD personnel after January 1, 1997);
(e) Anyone having received a transfusion of blood or blood products in the United Kingdom since 1980;
(f) Anyone having taken bovine insulin produced in the United Kingdom since 1980.

The American Red Cross (ARC) has announced that it will begin indefinitely deferring donors who have resided in or traveled to Europe for a cumulative period of 6 months or more since 1980 and donors who have resided in or traveled to the United Kingdom for a cumulative period of 3 months or more since 1980.

I have carefully evaluated, in conjunction with the Service Surgeons General and the Director of the Armed Services Blood Program Office, the two deferral policies and determined that it is in the best interest of the DoD to adopt the deferral criteria recommended by the FDA. I agree with the FDA that, in weighing the theoretical increased risk of the FDA policy against the more significant adverse impact on the blood supply under the ARC policy, the balance in the public health interest for those served by the Military Health System favors the FDA policy. For ease of implementation, the Services, in coordination with the Armed Services Blood Program Office, have determined that it is in the best interests of quality assurance to combine the deferral periods for personnel stationed either North or South of the Alps for the period 1980 – 1996.

The transmissibility of vCJD by human blood or blood products is unknown, and laboratory and epidemiological studies are underway to evaluate the risk. Until such studies are complete, there remains a theoretical risk that vCJD could be transmitted via transfusion. To date, there are no known cases of vCJD having been spread through human blood or blood products. This deferral policy is being implemented to ensure the safety of the blood supply. As more information becomes available, this policy will be reviewed and updated. The DoD deferral for possible exposure to the agent for vCJD will be changed to:

(a) Anyone who resided in or traveled to the United Kingdom for a cumulative period of 3 months or more from 1980 through the end of 1996 will be indefinitely deferred; in addition:

(b) DoD affiliated personnel that resided in or traveled to countries with a risk of BSE for a cumulative period of 6 months or more from 1980 through the end of 1996 will be indefinitely deferred;

(c) DoD affiliated personnel who resided in or traveled to countries with a risk of BSE for a period of 5 years or more after January 1, 1997;

(d) Others who resided in or traveled to countries with a risk of BSE for a period of 5 years or more since 1980 to present will be indefinitely deferred.

(e) Anyone having received a transfusion of blood or blood products collected in the United Kingdom since 1980 to present will be indefinitely deferred;

(f) Anyone having received bovine insulin prepared in the United Kingdom since 1980 to present will be indefinitely deferred.

The ASBPO will include a specific list of the countries with a risk of BSE (primarily Europe) with forthcoming implementation instructions.

Since it is likely that some civilian blood collection agencies will implement slightly different rules regarding donor deferrals, DoD personnel may find themselves deferred by one agency while being accepted by another. Every effort will be made to ensure that DoD personnel understand that the deferrals are purely precautionary, as the vCJD agent has not been demonstrated to be transmissible via transfusion. Steps shall be taken to notify all appropriate commands of these guidelines and to incorporate them into respective Military Department and, where necessary, unified command blood program regulations. The ASBPO shall issue specific implementation instructions to the Military Services through the Service Surgeons General.

This policy will be implemented by all blood donor centers on September 14, 2001. The point of contact for this matter is Colonel G. Michael Fitzpatrick, Director, Armed Services Blood Program Office, at DSN 761-8024, commercial (703) 681-8024, or e-mail at glen.fitzpatrick@otsg.amedd.army.mil.

J. Jarrett Clinton, MD, MPH
Acting Assistant Secretary

cc:
Service Surgeons General
Director, Armed Services Blood Program Office