Cutter

MILES

GMA-5-054

CUTTER BIOLOGICAL

March 18, 1985

Gary B. Carpenter, M.D.
LTC, MC
C, Allergy-Immunology Svc
Department of the Army
Headquarters, Tripler Army Medical Center
Tripler AMC, Hawaii 96859-5000

Dear Dr. Carpenter:

We do not, at this point in time, test plasma donors for HTLV-III antibody; however, we do plan to start this in all plasma centers just as soon as the test is available and approved by Federal Regulatory Agencies. We have had an intensive screening program in all plasma centers for quite some time, in effort to exclude all high risk donors from the pool. The program includes requiring donors to sign a statement that they are not in a high risk group, careful physical examination on a routine basis by the center physicians with emphasis on eliciting signs and symptoms related to HTLV-III infection, etc.

You and your patient will be relieved to know that there has never been a report of any viral infection resulting from injection of any gamma globulin product, I.V. or I.M., as made by the Cohn Cold Ethanol Fractionation Procedure used by Cutter, and, I believe, all the other manufacturers in the U.S. There have been several reports of late in the European literature suggesting a relationship between non-A non-B hepatitis and an I.V. gamma globulin. This was apparently made by a technique using a variation on Dr. Cohn's procedure, not the technique we employ. There has been no concern expressed by the CDC, the FDA, or The Office of Biologics with respect to potential for AIDS or hepatitis transmission by U.S. made gamma globulin.

The only plasma fraction possibly related to AIDS transmission to date has been the hemophilia coagulation factors, Factor VIII and Factor IX. We believe we have

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now eliminated this potential by the development of a heat treating process for Factors VIII and IX, which we have shown, in cooperation with the CDC, to inactivate AIDS related virus.

If you have further questions, please let me know.

Sincerely yours,

GRO-C - GM Akin

G.M. Akin, M.D.
Director, Medical Services

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