'UNIVERSITY OF CALIFORN' DAVIS

STREELET + DAVIS + IRVINE + LOS ANCELES + REVENIDE + SAN DIECO + SAN FRANCISCO

SCHOOL OF MEDICINE DEPARTMENT OF PEDIATRICS DAVIS, CALIFORNIA 93616

÷.,

 \bigcirc

PRENAMENT OF PEDIATRICS UC DAVIS MEDICAL CENTER 4301 X STREET SACRAMENTO. CALIFORNIA 95617 (DIG 435-777)

April 25, 1983

HECEIVED

SANTA BARBARA - SANTA CRUZ

APR 29 1983

CLINICAL RESEARCH

Dr. Richard Schwartz Cutter Laboratories, Inc. 4th & Parker Streets Post Office Box 1986 Berkeley, CA 94701

Dear Richard:

Enclosed find the results of the assays of the Cutter Factor VIII Products. If you would like to have the Factor VIII multimer radiographs please let me know so that I can have these photographed and sent to you. Otherwise, perhaps when you are in the area we can review them.

Suffice to say, the Factor VIII procoagulant activity, using our in-house Factor VIII standard, is somewhat lower than the labelled unitage, and is pretty consistent with the work we have done with you before. The only real major discrepancies (no. PR 2861 and PR 2845), which are labelled as your highest unitage, ... we assay at our lowest units/ml.

The Factor VIII related antigen values are considerably higher than we would have expected, and in fact are way out of the range of previous published data for such materials. Specifically, most publications have indicated that the Factor VIII related antigen is approximately 2-3 times the Factor VIII procoagulant activity of most commercially prepared lyophilized concentrates. A number of references are available including McCue's article in the Amer. J. Hematol., vol 9, pg. 39, 1980.

The Factor VIII ristocetin cofactor are consistent with what other investigators have found, and again suggest that this level of cofactor activity is due to the lower molecular weight multimers.

As far as the Factor VIII multimer assay is concerned, the patterns are of two types. In some of the vials of concentrate i.e., #8434, 8433, and 2845, there is total absence of the high

> MDL-986 CONFIDENTIAL PER PRETRIAL ORDER NO. 2

> > -----

8 3 0 6 0 1**RSSa 1 2**

05

1941

Apr. 25, 1983 Dr. Richard Schwartz page 2

molecular weight multimer fraction. In the remaining four lots, although there is some high molecular weight multimer present, it is still reduced when compared to normal plasma.

Hope you find this information of value, please let me know if there is anything further that we may do.

Lastly, I would appreciate your sending the \$1500.00 for this study, as a check made to: The Regents of the University of California Davis, along with a separate note indicating that this is an unsolicited gift to support hemostasis research. You can make all correspondence out directly to ma.

Sincerely.

GRO-C

Jack Lazerson, M.D. Professor of Pediatrics and Pathology Department of Pediatrics Hematology-Oncology

JL/bs

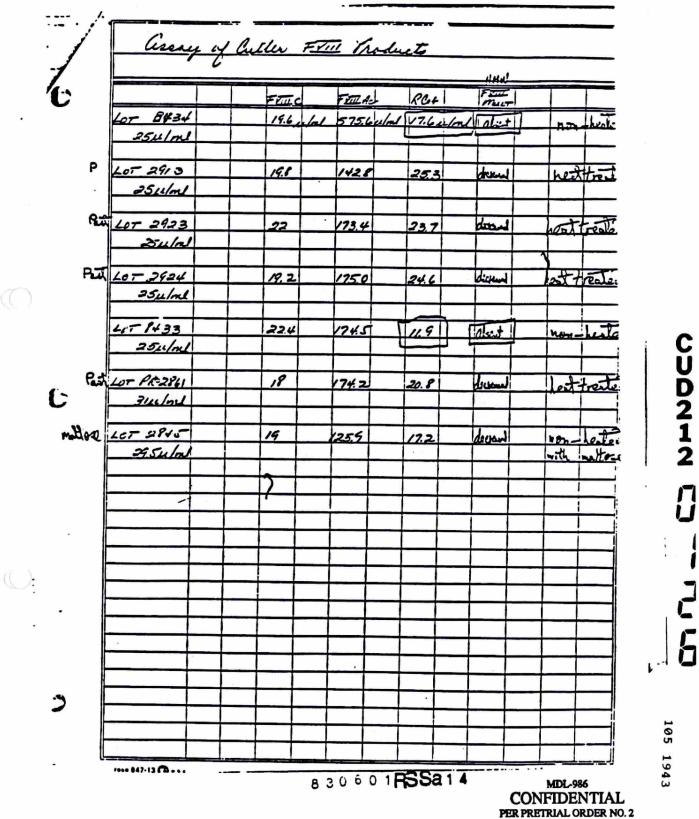
cc: J. Harrison C. Abildgaard



83060 1RSSa13

105 1942

CUD212



5 5

BAYP0004550 0003