y. High Hu MILES Office of J Sujeth RECIVED 1114 - 5 1983 CUTTER INTERNATIONAL Devis Dr. Dr. 101(15)(46082708-55) 5.2 272 - 0.5(1, 512)(1 PD37 DF6125 804 2317 Elseavelle - California 84452-1H 7181911011112111213141516 June 3, 1983 Prodet (415: 470 4003 4 Ref. N-3.127

Dr. L. K. Fowler Department of Health and Social Security Madicines Division Market Towers 1 Nine Elms Lane London SW8 5NQ, U.K.

Dear Dr. Fowler:

نى ئىرىنىيە

> Mrs Tatt has sent your letter of May 26, 1983 to us so we could supply additional information in answer to your questions. She will return this letter to you along with any other comments she wishes to add.

TELER VACCINES INTERNE 335 313 CASLE VACCINES BERKELEY

The questions are expressive of the concern that exists everywhere about this enigmatic syndrome. As you know, many countries have now reported AIDS in the medical literature.

One of the major difficulties in dealing with the many issues concerning AIDS is the absence of persuasive data and this is complicated by the oft-times sensationalistic and erroneous reporting in the press. We have seen recent examples in The Kail. As a result, false conclusions are arrived at and patient treatment as well as product supply are endangered.

The facts about AIDS are very limited:

- The syndrome is guite ill-defined and cases may not be fully reported outside the U.S. The WHO has recognized it as a world-wide health problem.
- The etiological agent is unknown. It is not known whether it is a virus.
- Hence, it can only be an assumption that AIDS can be transmitted by certain blood products. This has not been shown.
- Also, it is unclear whether the syndrome contracted by hemophiliacs really is the same as the AIDS syndrome contracted by other high risk groups.

As medicine and the plasma suppliers (commercial and NHS) struggle to find the correct actions to take to exclude the elusive AIDS donor, it is imperative that the supply of

CERCON ---4 104 6478

M005528 S

	1		· · · · · · · · · · · · · · · · · · ·
			Lutter,
			- storen
			and the second
Dr. L.	K. Fowler	-2-	June 3, 1983

products (in particular Factor VIII) not be reduced to levels where patients can not be treated. The statement by Professor Bloom in the attached communication from The Haemophilia Society is particularly pertinent.

All participants in the procurement and supply of Factor VIII (either cryoprecipitate or concentrate) face the same dilemma. There is no test for AIDS. What we (and presumably other countries, including the U.K.) are doing is to attempt an unproven and probably inadequate screening of donors by certain gross definitions of high risk groups and general physical examinations. Only time will tell if these checks on donors are accurate.

More specifically addressing your questions:

- By common agreement and with the regulatory pressure of the U.S. DHHS, all plasma donors are screened to an extent consistent with present medical-scientific knowledge. This program is spelled out in the attached Cutter documents and FDA directives which may be the same as already supplied to you by Mrs. Tatt. Cutter and the other manufacturers are complying in every detail.
- The cases of AIDS in hemophiliacs are of course complicated to follow up but our investigations indicate that none received Koate.
- 3. So far, we have not had to make a decision concerning disposition of a lot of Koate from a donor who has become an AIDS victim. It is our plan that if this circumstance should occur, the decision concerning the lot would depend on many factors including, most importantly, receipt of advice from government health authorities based on the latest knowledge concerning AIDS.

Cutter intends to keep aware of progress in the world in the identification of the mechanism of the syndrome itself, of possible tests which may be applicable and of methods of treatment of product designed to prevent transmission of AIDS.

bcc:	J.	Hjorth
	٧.	Shalson
	W.	Ewald

cc: M. W. Tatt B. A. Dyos

JNA/jwk

encl.

1

GRO-C J. N. Ashworth, Ph.D. Division Vice President Scientific Affairs

M005529 S

CHROCA --

LI\_\_

04

6479