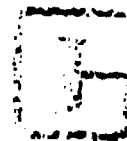


P.J.C. SEP 12 1983

CONNAUGHT



INTER-OFFICE MEMORANDUM

September 12, 1983

Memo to: See distribution
 From: J. C. W. Weber
 Subject: Use of Plasma from U.S. Centres located in Penitentiaries

During my visit to the Office of Biologics on the 6th and 7th of September, 1983, I inquired about the regulatory aspects and industry policies with respect to the use of plasma derived from centres in penitentiaries. I discussed the matter separately with these staff members:

- Dr. D. Donohue, Director, Blood Products Division
- Mr. P. M. Dubinsky, Compliance Branch, together with Mrs. Jean Lacerte - specialising in plasma problems
- Dr. B. Elisberg, Director, Division of Product Quality Control
- Dr. J. Finlayson, Director, Plasma Products Branch
- Mrs. C. Rookes, Plasma Products Branch
- Dr. R. Gerety, Director, Hepatitis Branch
- Dr. S. Gibson, Director, Product Compliance Division

Since there was no conflicting statements or opinions, the conversations can be summarized as follows:-

About six months ago, all U.S. fractionators decided not to use plasma from U.S. penitentiaries or "correctional centres" except for diagnostic products and a few rare, specific immunoglobulins.

Only a few penitentiaries are still being licensed. They are exclusively in the Southern States, including Florida, Louisiana, Mississippi and Arkansas. The respective States Department of Correctional Services request the licensing to continue as a moral booster for the inmates.

Since these centres are licensed and inspected as any other plasmapheresis centre, it is not illegal to use this plasma for the production of fractionation products for human use. It is, however, considered most imprudent.

Hepatitis B Risk:

- 1) If a plasma pool contains a Hepatitis B positive unit or an untested unit, the following action is taken:
 - Factors VIII and IX: Not released.
 - Immunoglobulins: Case by case decision based on other tests in protocol, especially anti-HB_e. If the titre is 1:100 or higher it is considered there is enough antibody to cover potential antigen.

CON 16012 ...2

611

X

2

- 2 -

September 12, 1983

Hepatitis B Risk: (continued)

1) (continued)

- NSA: As this is heated for 10 hours at 60°C, it is generally considered acceptable for release.

- 2) If a plasma pool contains a unit from a previously positive donor or a donor with a medical history of hepatitis, the onus is on the manufacturer to assure that additional testing rules out hepatitis. NSA and ISG are not questioned. If units and additional testing are negative, Office of Biologics will release. The control is the manufacturer's responsibility.

A.I.D.S. Risk:

NSA is generally viewed as safe and there is little evidence to associate A.I.D.S. with the administration of ISG.

The Coagulation Factors present a definitive risk.

Penitentiary Inmates as Carriers:Hepatitis:

While they are out of a population of drug users and therefore in a high risk group, today's third generation HB_eAg tests on the units generally cover the situations.

A.I.D.S.:

A study from the CDC Epidemic Intelligence Service documents that there are about 50 cases per 100,000 inmates per year in New York penitentiaries. This high rate is considered to be due to frequent intravenous drug use prior to incarceration, and not necessarily exclusively to homosexual practices (Dr. Gibson will send me an abstract of this report.)

Current product:

It is expected that the current lots of NSA awaiting release or already released by the Office of Biologics for distribution in the U.S.A. will be allowed.

Conclusion:

Connaught Laboratories Limited have at no time violated F.D.A. regulations in this case. We were unaware of the fact that the plasma came from penitentiary centres and were not informed of the U.S. Manufacturers' (through P.M.A.) decision with respect to such plasma.

Our decision to follow the American fractionators' example was considered not only prudent but essential.

CON 16013

- 3 -

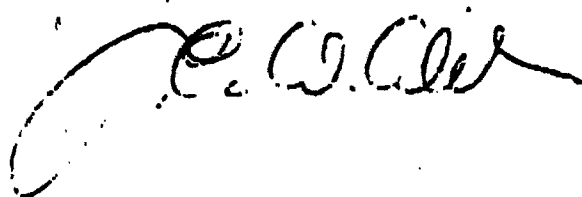
September 12, 1983

Action:

- 1) No plasma derived from penitentiary inmates will be allowed into C.L.L.
- 2) All such units received and still intact as individual units will be returned.
- 3) Any semi-fabricated product inhouse which includes such units will be brought to a stable state of manufacture, then quarantined until further decision can be taken. No coagulation factors may be made from this plasma.
- 4) No U.S. plasma centre will be approved by Q.C./R.A. without thorough investigation, generally including inspection.
- 5) No plasma shipment from any source other than the Canadian Red Cross will be allowed into Connaught Laboratories without specific approval by Quality Assurance in each case. A prior shipment from a plasmapheresis centre does not mean automatic approval for subsequent shipments.

JCWW/lam

Distribution: Mrs. M. R. Booth
Mr. P. J. Campbell
Mr. A. Davies
Miss C. D. Laurence
Dr. J. Mercer
Mr. J. Ramsay
Mr. K. L. Reilly
Dr. E. W. Pearson



CON 16014

Director,
 Bureau of Biologics,
 Drugs Directorate,
 Health Protection Branch,
 Health and Welfare Canada,
 Virus Bldg.,
 Tunney's Pasture,
 Ottawa, Ontario.
 KIA 0L2

Dear Dr. Furess:

re: U.S. Plasma Suppliers

Please find enclosed two copies of information used to approve the following sources of U.S. plasma in accordance with our SOP/ IQA-056.

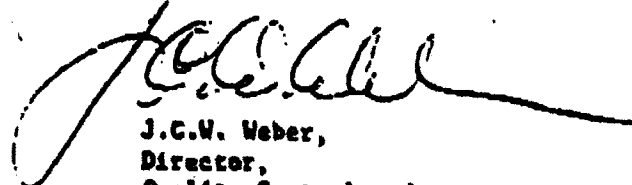
This information is supplied as an update to our current file.

GRADY CUMMINS →

1. Alabama Plasma Inc., U.S. License #478
2. Arkansas Blood Components, Inc., U.S. License #910
3. Broward Community Blood Center, U.S. License #913
4. Indianapolis Blood Plasma, Inc., U.S. License #760
5. Jacksonville Blood Bank, Inc., U.S. License #181
6. Lansing Plasma Corp., U.S. License #776
7. MD Anderson Hospital and Tumor Inst., U.S. License #874
 (also called University of Texas Systems Cancer Center)
8. Milwaukee Blood Plasma, Inc., U.S. License #600
9. Ohio Blood Plasma, Inc., U.S. License #484
10. Seattle Plasma Corp., U.S. License #762
11. Ysleta Plasma Corp., U.S. License #757.

In addition, we have enclosed a revised list of approved suppliers for your information.

Sincerely,



J.C.W. Weber,
 Director,
 Quality Control and
 Regulatory Affairs.

JCW/JDS/db
 Enclosure

CON 1631i

ACCEPTABLE SOURCES BY NAME OF ESTABLISHMENT

JUL 3

LIC	ESTABLISHMENT	ADDRESS	FOI	AIDS	CLL
478	ALABAMA PLASMA INC.	2401-2ND AV NORTH BIRMINGHAM, ALABAMA		840606	840606
LIC					
616	AMERICAN BIOLOGICS INC	709 FRANKLIN AVE WACO	830204	840307	
LIC					

LIC

867 ANTIBODY CORP OF AMERICA (SEE 790)

508-A OWEN DR FAYETTEVILLE

830525 800602

LIC

COMMINS
→

910 ARKANSAS BLOOD COMPONENTS, INC.

209 NORTH BLAKE ST. PINE BLUFF, ARKANSAS

840607 840607

LIC

222 AURORA AREA BLOOD BANK

1200 N HIGHLAND AVE AURORA

831206 831222

LIC

199 BLOOD BANK OF HAWAII

2043 DILLINGHAM BLVD HONOLULU

831122 840103

LIC

389 BLOOD CENTER OF CENTRAL IOWA

1050 7TH ST DES MOINES

831024 840103

LIC

913 BROWARD COMMUNITY BLOOD CENTER

1700 N. STATE RD. 7 LAUDERHILL, FLORIDA

840604 840604

LIC

CON 16312

648 CARTER BLOOD CENTER INC

1263 WEST ROSEDALE FORT WORTH

830918 801028