P.J.C. SEP 12 1983 PJC

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_S. If the titre is 1:100 or higher it is considered there is enough antibody to cover potential antigen.

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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_SAg 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.

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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 automatical approval for subsequent shipments.

JCWW/ldm

GRO-C

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

CON 16014

CONNAUGHT
LABORATORIES LIMITED

INTER-OFFICE MEMORANDUM

CONFIDENTIAL

GRO-C: A.M Tabbara

Memo to: Note to File

26 September 1983

From: A.M. Tabbara

Subject: Meeting on 16 Sept 83 with Donna Mayo (DM) Continental Pharma (CP)

Purpose of Meeting

1. To review prevailing plasma situation and its effect on contracted deliveries.

2. To express Connaught's concern for not receiving from CP contents of letter which they received from Health Management Associates (HMA) on 20 June 1983.

Continental Pharma's Position

1. DM stated that reasons for not revealing contents of letter at that time were based on specific instructions CP received from HMA as to the unwarranted need to take any action on contents of Letter until further instructions are received from the U.S. regulatory authorities.

2. DM believes that decisions made by CP were handled responsibly and both Dr. Furesz and Dr. Sabbagh attest to that.

3. DM found it difficult to understand why a product recall was made by Connaught, especially when Dr. Furesz had stated (to Dr. Greenberg) that a recall was unnecessary. Also was there an over reaction on the part of Connaught to a situation which is frequently faced by plasma fractionators?

4. DM expressed disbelief that CRC will cancel a contract with Connaught because of such a recall. Surely there are other major reasons which prompted their decision.

Connaught's Position

1. AT expressed deep concern for CP not revealing contents of June 20th letter and discontent over explanations given. Reiterated importance of discussing all problems with Regulatory the moment such problems emerge and that Connaught expects to receive satisfactory information from CP re this letter.

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2. AT reiterated that the product recall was made jointly by Dr. Furesz and Mr. Weber and cannot explain statement given to Dr. Greenberg without involving Mr. Weber.

3. AT emphasized that Connaught is still assessing extent of damages incurred and certain action will be taken as soon as this information becomes available.

GRO-C

A.M. Tabbara

AMT:sl

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