

CONFIDENTIAL

REVLON HEALTH CARE GROUP

**A Report on Plasmapheresis
in the United States**

This report is confidential to Mr. W. Marguerre,
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Group, 21 Rue Boissiere, 75116 Paris, France, and its
contents may only be divulged with his permission.

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1: INTRODUCTION

In 1979 Mr. W. Marguerre, on behalf of the Revlon Health Care Group, invited Dr. Jones to visit Group facilities for the collection of blood products in the United States.

Revlon's interests in the medical field had been strengthened by the acquisition of Armour International, and by the creation, in late 1978, of an organisation for the plasmapheresis of donors within the Group. It was Group policy to achieve self-sufficiency in source plasma, and to this end Armour Pharmaceuticals had acquired the company Plasma Alliance, operating in the United States of America.

Dr. Jones' brief was to visit a number of plasma-pheresis centres managed by Plasma Alliance, to talk with management, staff and donors and to report his findings to Mr. Marguerre. It was an essential understanding within this agreement that "there was nothing to hide", and that the open nature of the visit was designed to demonstrate that Plasma Alliance were a sound, healthy and ethical organisation. On his part, Dr. Jones agreed to report back, in confidence, directly to Mr. Marguerre.

It is the purpose of this report to set out the results of the United States visit.

GRO-C

Peter Jones, MD FRCP DCH

June, 1980

2: PROGRAMME

27th February, 1980 - 28th February, 1980

1. Visit to Knoxville Centre, Plasma Alliance
2. Visit to Plasma Alliance Laboratories
3. Visit to Plasma Alliance Offices, Knoxville

28th February, 1980 - 29th February, 1980

1. Visit to Chattanooga Centre, Plasma Alliance
2. Visit to Atlanta Centre, Plasma Alliance

3rd March, 1980

1. Visit to St. Paul Centre, Plasma Alliance*
2. Visit to Minneapolis Downtown Centre, Plasma Alliance*
3. Visit to University Centre, Plasma Alliance*
(*Blood Plasma Services, Inc.)

4th March, 1980

Visit to Kankakee Plant, Armour Pharmaceutical
Company

3: REVLON HEALTH CARE GROUP PERSONNEL

The following were among the members of staff met during the visit. They include personnel from Plasma Alliance, Blood Plasma Services Inc., and the Armout Pharmaceutical Company as well as Revlon, Paris.

Eric Grunwaldt	Director, Product Management, Revlon
Steven Jones	General Manager, Plasma Alliance
Tyrone Foster	Vice President, Operations, Plasma Alliance
Joe Kane	Head, Quality Control, Plasma Alliance
David Wilson	President, Plasma Alliance
Jean Wright	Secretary
Connie Clift	Head Nurse
George Balshuweit	Centre Manager
Dr. Randy Hanzlick, MD	Director, Medical Services
Dr. Winebrenner, MD	Centre Physician
Bill Guinn	Centre Manager

Dr. Coombs, MD	Centre Physician
Mary Thompson	Serologist
Frank Pallifone	Assistant Centre Manager
Marilyn Chadwick	Donor Room Supervisor
Paul Jenks	Centre Manager
Galen Merrill	Centre Manager
Patty Rowden	Assistant Manager
Guy Stinson	Area Manager
Dave Peppard	Centre Manager
Dr. Rockwell, MD	Centre Physician
Dr. Waren, MD	Centre Physician
Dr. Tudor, MD	Centre Physician
Dr. Korchik, MD	Centre Physician
Pauline Pipho	Quality Control Supervisor
Barb Carlson	Donor Supervisor
Paul Smith	Field Operations Manager
John Sedor	Manager, Kankakee

Fred Feldman

Research and Development,
Kankakee

John Bona

Quality Control, Kankakee

Dexter Gaston

Operations Services, Kankakee

G. Floyd

Shipping, Kankakee

The author apologies for any names ommitted from this list which, it will be appreciated, covers nine visits in five days. Without exception all members of staff at all levels within the organisations visited were courteous, helpful and highly motivated.

4: THE CENTRES AND THEIR ORGANISATION

4.1 General Description

Plasma Alliance employ 888 staff (full and part-time) for the collection, testing and shipping of plasma obtained from paid donors in 22 Centres. Of these, 75 are '40 hour' employees. Total donor beds is presently 1037, with an average Centre size of 40-45 beds. Bed occupancy runs at about 60 percent. Each Centre has a Manager and an Assistant Manager, a Donor Room Supervisor, a member of staff with specific responsibility for quality control and a Physician, who is not necessarily in attendance throughout opening hours. When the Physician is not in attendance, arrangements exist with a local hospital for cover (in those Centres visited never more than 10 minutes away).

Donors are looked after by Registered or Licensed Practical Nurses or their equivalent in terms of training.

In each Centre an Immunization Programme was used; details of this were not available, nor were they in the brief of the visits.

All Centres were administered under FDA rules. An in-house Standard Operating Manual (SOM) was available in each Centre visited.

Plasma collected by Plasma Alliance is shipped to Kankakee for processing in refrigerated lorries. Prior to shipping all plasma is stored in temperature-monitored cold rooms. "Quarantined" plasma is stored separately, and not shipped until cleared by the company's laboratory.

4.2 Plasmapheresis Procedures

The regulations for the acceptance, screening, medical examination and plasmapheresis of donors is laid down in the SOM, and was followed through in detail in Knoxville, and in a curtailed form in the other Centres visited. In all cases all operating procedures were strictly observed, and the standard of professional expertise and donor care was impressive.

Of special merit were firstly, the safety checks used by Plasma Alliance to guarantee donor safety and plasma/red cell identification, and the institution of the NABSAF coded system in addition to donor details and signature and bed number is applauded. Secondly, the standards of the donor room staff were exceptionally high. They were smart, welcoming and quietly efficient, and were invariably dressed in freshly-laundered, clean uniforms.

Impression

A first class organisation with a sound commitment to quality control. The recommendations made at the end of this report are made in the light of this overall judgement. Donors questioned (photograph 8-11) had no complaints about the procedures and most seemed to enjoy the experience of taking a rest during plasmapheresis. This impression is not in accord with the reportedly low rate of reattendance.

4.3 A Note about Reactions

Reactions had been noted in each Centre, and from the Recommendations in this report, it will be seen that these were of special concern to the author. This is because any organisation which relies on blood/plasma donation must ensure the safety of its donors. The appended sheet (A) obtained from one Centre shows the much ammended list of emergency equipment (different from the SOM), and the confidential medical reports (B and C) - approved for inclusion by the Medical Director - illustrate what could have been a very serious incident without a Physician on the premises.

It is not unusual for donors to lie to questions, and the SOM and the staff are to be commended for the instructions about recognising fraud and how to deal with it. However, in one Centre it was admitted that two epileptics had not been spotted during the screening procedures. People like this, and those who experience reactions (on average twice a week in the Centres visited) should be covered in planning emergency procedures.

4.4 Education

Plasma Alliance had taken special care to inform their donors about the procedures involved, and about what happened to their blood/plasma. Examples are shown in D and E, and in the photographs.

This is good practice and is commended.

5: CONCLUSIONS AND RECOMMENDATIONS

5.1 General - The Centres

General standards were excellent, and there was nothing to criticise in the caring attitude shown by staff at all levels. The complete process, from donor entry to shipment was well organised and efficiently performed within the general guidelines laid down in the FDA and in-house regulations.

5.2 General - Kankakee

The open attitude of the helpful and highly motivated personnel was as apparent here as in the Centres. The impression gained in the short visit, which, for acceptable security reasons, could not include a complete breakdown of the manufacturing process, was very favourable. My one criticism concerned the number of outdated Red Cross and Community Blood Bank whole blood packs lying around, some in unrestricted areas. This practice, which I was assured was being altered (new building was in progress during my visit) raised questions of health hazard to staff (leaking packs), and quality control (use of plasma other than that obtained under in-house supervision).

5.3 Specific

Medical Supervision in Centres

The Physicians I met were all extremely helpful and I was grateful for their time and the demonstration of their concern for staff and donor health. However, I believe a number of improvements could be made:

- although a Director, Medical Services had been appointed a year previously he was unknown to some of the Physicians working in the Centres. This should be rectified.

5.3.1 Meetings

There was no organisation for regular meetings and/or exchange of information between Medical Staff in different areas (staff serving several Centres in one locality met, but that was all). I believe that the creation of this facility would be of importance because it would not only aid general on-going education with better motivation but would lead to standardisation in medical procedures which, being practical rather than theoretical, would be followed. In other words, the creation of suggested rules of conduct by the Physicians doing the work on a day-to-day basis would be more acceptable than an in-house code imposed from one source.

5.3.2 Emergency Kits

There was no standardisation of emergency kits in the Centres. Contents varied according to the wishes of individual Physicians. In one Centre, left without medical supervision on occasions during opening hours, a member of staff did not know how to turn the oxygen on. In another the Physician did not know where the emergency kit was kept, or what was in it.

It is recommended that the contents list in the Plasma Alliance SOM should be reviewed, updated, and standardised. It should be the responsibility of the Physician in charge at each Centre to review the emergency procedures with the Centre Manager and Donor Room Supervisor at regular intervals.

5.3.3 FDA 640.62

It would appear that the FDA ruling 640.62 is not always followed. This regulation states:

"Medical Supervision

A qualified licensed physician shall be on the premises when donor suitability is being determined, immunizations are being made, whole blood is being collected, and red cells are being returned to the Donor."

To my knowledge the careful requirements for nearby hospital staff to be 'on call' in the event of an emergency (especially when this might involve a haemolytic crisis) laid down in the Plasma Alliance SOM, are not in accord with this regulation.

In general, the absence of a Physician from some Centres during plasma pheresis worried me. I realise that the practices in the USA are different from those employed in the UK, with which I am more familiar, but I think serious consideration should be given to continuous medical supervision. This suggestion is not meant, in any way, to reflect on the efficiency and competence of the non-medical staff, but would provide additional cover for Revlon in the event of serious mishap. The argument that 'a serious mishap has never occurred so why go to additional expense' is not valid; accidents are only accidents because they have not been anticipated!

In addition the SOM lays down at least 16 occasions when a Physician's judgement is required. Continuous supervision by well-motivated medical staff should save waiting time for 'problem' donors, expose more of the community to the knowledge that it is company policy to ensure donor health, and may well have a 'spin-off' effect in increasing the average number of times a donor attends from the present 4-5.

It was my impression that the overall medical commitment to Staff and donor health could be improved and, in particular, that Physicians should be given more responsibility in managerial roles. This may be one way to attract Medical Staff of the calibre required.

5.4 Donor Health

5.4.1 Vomiting

In addition to the comments made about emergency kits and medical supervision above, I recommend that the SOM section on vomiting (5.4) be ammended. As there is a danger of inhalation of vomitus when lying on the back (especially if vomiting is associated with a faint or fit) a donor who feels sick or is being sick should not be left lying on his back. He should be turned on his side so that vomitus flows out of his mouth, and the likelihood of inhalation and subsequent respiratory obstruction is minimised.

I also recommend that some form of suction be present in each Centre in addition to the 'Brook' type airway for mouth-to-mouth resuscitation. I am aware that some initial extra expense will be involved and that, in the words of one member of staff, "we can't cater for every emergency", but, in view of the high donor attendance and of the reactions I was told about, consider this equipment to be as important as the provision of oxygen.

5.4.2 Occupation

There is no mention in the abridged SOM of donor occupation or hobbies likely to involve hazard. It is a requirement of the UK Blood Transfusion Service that donors involved in occupations or hobbies which could be hazardous to themselves or others (pilots, police, armed forces, those working with heavy machinery) be given special consideration, and only be bled at specified times unlikely to impede their performance.

5.4.3 Confidentiality

I was concerned that specimens and 'open' records from donors with syphilis were named and suggest that the procedures for donor confidentiality be tightened or that diagnoses are only available to senior personnel.

5.5 Staff Health

It was noted in most Centres that the severing of the set tubing after stripping and clipping was performed with the same pair of scissors every time. The scissors were then returned to the nurse's pocket, occasionally being wiped on a swab or, on one occasion, a uniform. A pair of scissors, inspected specifically to prove the following recommendation, had dried blood on their blades.

It is recommended that, in order to avoid cross infection between donors and between staff and donors, that scissors be kept in antiseptic between use.

It was noted that the plastic-lined bins used for the collection of disposable plasmapheresis sets following donation remained open throughout the day. This may create hazard from aerosol transmission of hepatitis and/or other viral particles.

It is recommended that some way be found of removing this potential hazard, perhaps with self-closing swing lid type bins.

5.6 Company Image

5.6.1 General

The 'bad' image associated with procedures involving paid donors has not been helped in any way by secrecy. The organisation managed by Revlon Health Care and Plasma Alliance Inc. is, in my opinion, of so high a standard that it lends itself to a more open attitude. I strongly recommend that consideration be given to more exposure (within the bounds of necessary industrial security) and suggest that:

- an article on plasmapheresis by Plasma Alliance be approved by Revlon and submitted to the medical press for publication.
- the occasion of the World Fair in Knoxville in 1981 be used to teach the public and the medical professions about the ethical standards maintained by industry.

5.6.2 Source Plasma

It is imperative that the Revlon Health Care Group become totally self-sufficient in terms of source plasma. Whilst the need for buying in plasma from other organisations exists - even when these are FDA approved and of impeccable character - there will be doubt within the medical profession.

5.6.3 Quarantine

It is recommended that plasma placed under quarantine until laboratory tests are available, be stored in locked, standard, containers in each Centre in order to avoid the admittedly remote chance of premature release.

6: SOURCES OF INFORMATION AND REFERENCE MATERIAL

1. Code of Federal Regulations 21 Food and Drugs
Parts 600-640, Revised as of April 1, 1979,
Washington DC, 1979.
2. Plasma Alliance Inc. Standard Operating
Manual, Revised October 1979, US License 758
(abridged; received E. Grunwaldt, 12 May, 1980).
3. Notes for Donor Attendants
Issued by the Regional Transfusion Centre,
Newcastle upon Tyne, UK, September 1979.
4. National Blood Transfusion Service Memorandum
of the Selection, Medical Examination and Care
of Blood Donors, December, 1972.
5. Various memoranda, records, documents and
advertising leaflets obtained from the
plasmapheresis Centres, 1980.

1. Blood Plasma Services Inc., University
Centre of Plasma Alliance in Minneapolis/
St. Paul.

All the Centres seen were compact with
clean functional and bright interiors.
This Centre provided an example of
cleancut exterior without advertising.
Photography within this building was
forbidden.

2. Centre lobbies were invariably bright and informal with coloured wall hangings. Records were stored within easy reach of the receptionists. Plants added to a welcoming atmosphere.

(Knoxville: Plasma Alliance)

3. Most Centres allowed for preliminary screening to be performed in semi-privacy with potential donors seated. Although this was said to slow 'throughput' it was more attractive and more in keeping with usual medical practice than the policy adopted in one Centre in which donors stood at a counter without partitions.
(Knoxville: Plasma Alliance)

4. The staff at every Centre visited were clean, bright, welcoming and intelligent. Uniform varied in style but was predominantly white and always freshly laundered. Personal hygiene (hair, nails, appearance) was of a very high standard.

This girl checks the blood pressure of a potential donor. She had just refused to process the author for plasmapheresis because of a previous history of infectious hepatitis.

(Knoxville: Plasma Alliance)

5. Laboratory test areas - in this area behind the cubicles shown in Photograph 4 were clean and well monitored. Staff were familiar with the correct use of all equipment, and this familiarity was in part responsible for the calm, professional atmosphere evident in even the smallest, most potentially claustrophobic Centre in Atlanta.

(Knoxville: Plasma Alliance)

6. In most Centres visited an attempt had been made to educate the new donors by wall posters and audiovisual displays.

In general these were good but there is greater potential here to increase donor 'loyalty' and reattendance. This photograph also shows the entrance to the Medical Officer's room.

(Knoxville: Plasma Alliance)

7. Security and cross-checking were excellent in all Centres. Here packs are being labelled and checked next to the camera which recorded donor signature as well as names and features (7a).

(Knoxville: Plasma Alliance)

8-11 Views of the plasmapheresis area in Knoxville. Although apparently crowded (this was a late afternoon/evening session) adequate corridors separated rows of couches. Television was provided, and this facility together with the opportunity of sitting with friends helped maintain an informal atmosphere. Several of the donors shown in these pictures were questioned (see text); all gave permission for their photographs to be taken (indeed some were pleased to be given the additional attention). After the session a member of staff commented that he thought photograph 11 had been taken with the intention of demonstrating how informally dressed blacks were plasmapheresed and in some way exploited. The series of photographs shows that this attitude is false, and suggests that a more open policy of public explanation might be beneficial.

(Knoxville: Plasma Alliance)

12. Centrifuge and leaf-press section of
Knoxville Centre. Note plastic-lined open
bins, also seen in donor area (photograph 8)
(Knoxville: Plasma Alliance)

13-14 Separation of plasma from red cells after centrifugation. Identity checks used before transfusion of red cells were stringent, quality control and handling excellent throughout in all Centres.
(Knoxville: Plasma Alliance)

15 Single-donor source plasma running into
plastic flasks prior to heat sealing.
Note multiple labelling technique.
(Knoxville: Plasma Alliance)

16 Sealed flasks ready for fast freezing.
From this stage to factory processing
plasma is kept frozen, whether in short-
term storage or transit in refrigerated
lorries.

(Knoxville: Plasma Alliance)

17 Aliquots for screening for HB_sAg positivity,
and serology stand in back room. From here
they will go to central laboratory and quality
control facility.

(Knoxville: Plasma Alliance)

18 A nice touch. The Union Jack flies in
Kankakee!

(Kankakee: Armour Pharmaceutical Company)