File CBLA papers

1) HAVE ANY OF OUR PRODUCTS GIVEN ANYONE AIDS

2) DID WE STILL USE UNTESTED PLASMA UNTIL THE END - OF 1986

3) ARTICLE IN THE LANCET 3.8.85 PATIENTS IN SCOTLAND SEROCONVERTED - SURELY THE PRODUCT USED WOULD HAVE COME FROM SCOTLAND NOT BPL.

4) HAVE ANY PATIENTS CONTRACTED HEPATITUS AFTER USING OUR PRODUCTS

RSL to relay these answers to R.D.S.

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blood products in the United Kingdom and I feel we must write to you to express our grave concern regarding future supplies of blood products in this country and also the stability of the pharmaceutical companies involved in this field.

Our main concern relates to the opening of the new Blood Products Laboratory at Elstree. We feel that this new unit will undermine the activities of the companies involved in this highly specialised market. More importantly, as far as future supplies of blood products in this country are concerned, we feel that unless there is a policy of co-operation between the Transfusion Service and the pharmaceutical companies, we will see the supply of blood products seriously affected in the future and we are convinced patients lives could be at risk.

All major countries providing a high level of medical care and treatment operatd a system of joint co-operation between the National Transfusion Service or Red Cross and the pharmaceutical companies to provide regular supplies of high quality blood products for the benefit of the patients. Our own company co-operate with the Red Cross and Transfusion Services in many countries to provide blood products and also to collaborate in joint projects with them.

We understand the ideal of using voluntary donations to provide a so called free supply of blood and blood products although we feel that this will never be possible in the U.K. For whole blood this objective is acceptable and this we would support, but as far as blood products are concerned you need a highly motivated, well organised commercial enterprise with high expenditure on research and development to constantly update existing products and provide new novel products for the future.

we have been one of the major suppliers of blood products in the United Kingdom since 1973 when we were one of the first companies to licence Factor VIII concentrate. At this time, haemophiliac patients in the U.K. who required Factor VIII probably had the poorest level of treatment of any major Western country. We pioneered the use of this product which revolutionised the lives of haemophiliacs and enabled them to lead normal lives. Our company, together with others have supported the National Blood Transfusion Service in the U.K. which would have totally collapsed without the support and commitment from the commercial sector.

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We are particularly annoyed at the continuing criticism of commercial blood products in the U.K. when they have always been of a comparable, and in many cases superior quality to the State products. Blood products are amongst the most difficult to licence in the U.K. and every batch we produce is tested by the National Institute for Biological Standards and Control before release to hospitals. We strongly object to criticism when the products produced by the National Blood Transfusion Service are neither licensed and in the past have not even undergone independent batch testing. They do not obtain Clinical Trial Certificates for their products and their activities are totally unsupervised as they openly use crown immunity to enable them to sidestep many legal restrictions. This we feel is not in the best interests of the patient in providing them with safe products. We do feel that we are at a major disadvantage in competing with a State Institution which has no obligation to comply with regulations and testing procedures which are compulsory for pharmaceutical companies.

The commercial companies were the first to make heat treated products available and the first to supply donor tested products when the Transfusion Service was still supplying non heat treated products which were not screened for AIDS antibody. We voluntarily changed to HIV antibody tested products well in advance of being requested to do so by the C.S.M. From our information B.P.L continued to supply non donor tested blood products well after this date, possibly until the end of 1986. Although donations were being tested, the finished products were not as they were produced from stored plasma. Our own company started producing donor screened products from July 1985.

Although initially it was suggested that the problem of AIDS was attributed to imports of commercial Factor VIII, it was subsequently found that patients in Scotland who had only received Factor VIII from the Transfusion Service had seroconverted (Human T-Lymphotropic Virus Type III (HTLV-III) Infection in Seronegative Haemophiliacs After Transfusion of Factor VIII, Ludlam et al, The Lancet, August 3, 1985 pp233-6) showing that the problem was associated with all blood supplies. We have also seen reported patients contracting Hepatitis from intravenous immunoglobulin products by B.P.L. when it was given to twelve patients. (Non-A, Non-B Hepatitis Occurring in Agammaglobulinaemic Patients After Intravenous Immunoglobulin, Lever et al, The Lancet, November 10, 1984, pp1062-4). Did the B.P.L. obtain a Clinical Trial Certificate or a licence for their product? Three commercial companies have similar products on the market and they would have had to supply comprehensive pre-clinical and clinical data before obtaining a licence.

We have read with interest the recent report by Dr. J. Cash from the Scottish Transfusion Service in the British Medical Journal. We feel that we must agree with many of his comments. The cost of the new B.P.L. project is high at £60m. We also feel that it is an ill conceived project and will never completely achieve its objectives.

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There are a number of principal points regarding the new Blood Products Laboratory which we feel should be considered very carefully:

1). The Unit has been built to provide the basic blood products which we feel will never be achieved. As far as factor VIII and Albumin are concerned much improved products are on the horizon as well as products produced by Biotechnology which will make B.P.L. redundant in the not too distant future. Doctors will always use the safest and most effective products for their patients and will not be forced into using products simply because they are supplied free of charge.

2) High expenditure by commercial companies on Research and Development ensures that revolutionary new blood products come to the market and also improved product processing and viral inactivation methods are produced for existing products.

3) There are many blood products which B.P.L. will never be able to produce and there are many new products on the horizon for immunological disorders and thrombosis prevention, where B.P.L. has neither the expertise nor the commitment to high expenditure on Research and Development. Major new products can only be produced on a scale for worldwide use.

4) The real cost of providing blood products to hospitals by the Transfusion Service is high. Accurate costings should be carried out including the regional transfusion service costs for collection and processing as well as the production cost of the new B.P.L. unit. The capital investment of this unit should also be included.

5) The principal factor in the production of blood products is the supply of raw material - plasma. Even if B.P.L. manage to attain their target for collection, which is in doubt, the market for the basic products continues to expand and the commercial companies will, once again, have to make up the shortfall.

6) The most important factor in any supply situation is to ensure that you have alternative sources for your supplies. It would not be advisable to rely on a monopoly situation to provide life saving products for patients in this country. In the early stages of production at the new B.P.L. it is possible that we will see an initial surge of material and if this occurs commercial companies will start to reduce their stocks and will then be unable to respond to sudden deficiencies which we have had to do on a regular basis over recent years. Many factors affect the volume of raw plasma collected for processing at Elstree and this is always a constant problem. Without sufficient supplies of raw material you cannot produce the products.

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7) A serious shortage of blood products could occur at Elstree if serious production problems arise or batches are found to be faulty. As you are probably aware, this happened recently when 4 patients had severe reactions following the use of a plasma product from Elstree. All supplies throughout the U.K. had to be stopped and the commercial companies were asked to tender within 48 hours for 54,000 bottles to supply the whole of the country over a period of twelve weeks. We were only able to offer part of this quantity in the same way as other companies due to the large amount and urgency of the supply. If the situation occurs next year, the companies may not be able to offer any material as the normal production time including quality control is 12-16 weeks. Although production has re-started at B.P.L. we do expect a current shortfall of some 24,000 bottles of Plasma Protein Solution over the next three months.

Apart from the blood product situation I would also like to mention one of our other fields of interest - that of supplying medical diagnostic reagents to hospital pathology laboratories. Once again, we are finding the Blood Group Reference Laboratory - now incorporated into the Blood Products Laboratory - are actively increasing their production of material which is once again affecting commercial companies. We would expect under the current administration a clear commitment to help to expand commercial companies to provide the Health Service with high quality products. I enclose a recent letter from Dr. R. Lane at the B.P.L. on this subject. The reason why hospitals have purchased commercial products in recent years is the high quality compared to those supplied from the Health Service. We must ensure that we have an active diagnostic industry producing new diagnostics for hospitals. A study by NEDO on the Diagnostics Industry which we understand will be published in the near future will support this point.

In conclusion we hope you will give consideration to the following:

A) The B.P.L. should be forced to ensure that all their products are licensed in the same way as commercial products; that every batch is tested by the National Institute for Biological Standards & Control and that they operate under the same legislation of the Medicines Act. This will ensure that their products are of the same quality as those of the commercial sector.

B) Consideration be given to the problems concerning the viability of the commercial sector with the opening of the new B.P.L.

C) Thought should be given to the situation of B.P.L. as a monopoly supplier of such essential products and that consideration be given to providing commercial back-up material of equal quality.

D) As far as diagnostic reagents are concerned consideration should be given to discontinuing these activities to enable the commercial companies to be viable and justify their investment in new products.

E) The Government should give support and encouragement to the pharmaceutical companies involved in the production of blood products giving them credit for the major support they have given in recent years to the Health Service in the U.K.

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