PROJECT RED

COMMENTS ON PRE 226 LETTER

FROM THE EUROPEAN COMMISISON:

Monday, November 24, 2003

General Comments

The plasma therapeutics market is characterised by the collection of plasma from donors and the fractionation of the plasma to produce products for the treatment of specific medical conditions

The current situation is that there is no reliable test for vCJD and that because of the competitive nature of the pursuit of such a test (the commercial benefits of which could be substantial) it is very difficult to establish in what timeframe a reliable test might be achieved. There are some very optimistic sources that claim a reliable test will be proven in a very short timeframe but even if this is the case, it will be some time before it has achieved the appropriate accreditation to be used for screening blood supplies. It is also unclear what effect the introduction of a vCJD test would have on the blood donor community. Given that the disease can lie undetected in humans for a long period and that it may exist in much higher levels than is currently visible, vCJD testing will raise the same ethical issues as did HIV testing and some experts believe it could result in up to a 50% reduction in pre-test level of donor supplies because of donors either staying away or being found positive.

Comment 1 - Services or Supplies

Instinctively, we (including our external legal advisors, Messrs Simmons & Simmons) considered that the supply of plasma involved the supply of goods. The term "*goods*" is defined to include substances which in turn is defined as "any natural or artificial substance, whether in solid, liquid or gaseous form or in the form of a vapour". Under Directive 2001/83/EC on the Community code relating to medicinal products for human use, the term "substance" is defined to include human blood and human blood products.

However, we did give further thought to whether an argument could be made that LRI will in reality be providing services. (If it could be said that the Services Regulations applied, only the limited rules concerning technical specifications and an obligation to inform the European Commission of the award of the contract would apply).

The Services Regulations provide that a services contract is a contract in writing that does not involve, among other things, the procurement of supplies or works within the meaning of the other procurement Regulations. The Services Regulations apply differently to Part A and Part B services. If the LRI/BPL arrangement were considered to be the supply of a service, we did not believe it would fall within Part A. The potentially relevant Part B services would be health services and most particularly either, services provided by medical laboratories; or -services provided by blood, sperm and transplant organ banks.

In relation to the former, it would seem more likely that this related to the testing of samples on behalf of the NHS and others for diagnostic or pathological purposes. The second category might well have embraced the collection of blood and its storage and possibly also the extraction of plasma. However, it would seem to be stretching construction of the Regulations to construe these activities (which are preparatory to the supply of plasma) as the principal subject of the contract in this case.

A search was undertaken against previous notices published in the Official Journal. A UK contract to establish a national programme centre for phenylketonuria and congenital hypothyroidism screening was considered to be a services contract. More interestingly, a contract advertised by the Venetian local administration for blood-bank services and "plasma conversion" services was described as a services contract, although in relation to the latter, it is not clear what precisely was required under the contract. By contrast the procurement by a German local authority of "human plasma extracts" was described as a supply contract. Again there is no further description of scope.

If a services element could have been distinguished from the supply of goods and the value of the services element exceeded the value of the supplies, the Services Regulation would apply. However, we considered that this distinction was somewhat artificial, although we looked into this aspect further including the relative values of the services/supplies provided by LRI. On balance, however, we were of the view that the contract would be considered as supplies, rather than a services contract. This view I understand is shared by Phinella Henderson of the OGC.

Comment 2

Correct.

As Counsel advised in writing, the Department had for very good reason chosen to purchase a business rather than to rely upon tendering for the supply of plasma and/or plasma derivative products in the open market. It would be bizarre if, having purchased LRI, the Regulations required a tender process in which, by definition, and the Department would have to consider obtaining plasma supplies from companies other than the company which it has purchased for that very purpose.

This situation was wholly exceptional; it should not create any broad precedent for the future. It is very unusual for a contracting authority to contemplate purchasing a company in order to secure supplies of its products. That situation has come about only because of the unique circumstances in the world market for plasma products and, in particular, because of the risk that vital products would not be available at all but for the purchase of a business. The Department was compelled to proceed in this way because, on the best evidence available, there was no potential supplier in Europe or the US which could meet its plasma requirements and would be willing to enter into a long term supply arrangement. There was no question of a strategy of avoidance: the Department was not motivated by a desire to structure its arrangements so as to avoid the impact of the Regulations.

A tendering procedure conducted against the background of the purchase by the Department of LRI, would be an entirely arid exercise which would do little to enhance competition or free movement of goods in this case (this conclusion is based upon the reports prepared by independent consultants, KPMG and PA consulting). If LRI tendered, it would be bound to win: the factors which have led the Department to target LRI in the first place, and the fact that the Department is negotiating to buy LRI would inevitably combine to make its tender the most economically advantageous. If, as is more likely, LRI did not tender (having broken off negotiations altogether), the evidence thus far presented to the Department suggests that none of the tenders received (if any were submitted) would meet its

requirements. The Department would then be entitled to resort to the negotiated procedure under reg. 10(2) (b).

The difficulties of sourcing plasma from Europe with regard to the limited quantities available, and the potential safety risks associated with it, meant that free movement of goods between EC member states was not threatened.

Please see comments at 11 below and in addition, Counsel's advice on whether the Department would be justified in entering into a supply contract with LRI without having first gone through an open or restricted tendering procedure pursuant to the Public Supply Contracts Regulations 1995 (SI 1995/2001).

Comment 3

Correct: FP supplied by LRI is sourced from paid donors.Prior to the acquisition of LRI, the DoH acquired about 50% of the NHS' finished plasma derived product requirements from third party suppliers with FDA approval (e.g. Baxter, Bayer, Aventis).

Key finished products are:

- § intravenous immunoglobulin (IVIG) and other immunoglobulin products, used to boost a patients ability to fight off infection. There is a worldwide shortage of IVIG driven by an increasing number of off-label uses and rising levels of diagnosis of primary immune deficiency disorders.

- § factor VIII, a blood clotting agent used primarily to treat Haemophiliacs: The plasma derived product is being replaced by recombinant products. However currently there is a shortage of recombinant factor VIII due to the closure by the FDA of the Bayer plant. This is likely to have a short term effect. Globally, underdeveloped countries that cannot afford the recombinant product are continuing to increase their demand for plasma derived factor VIII.

- § factor IX, another clotting agent, and albumin used to introduce other drugs into the blood stream: These are unlikely to be a major constraint because there is an excess of supply over demand in the market

Please note that there was a global shortage of some finished products, especially IVIG (driven by Novartis' recent withdrawal from the market). Few fractionators were able to increase the volume currently supplied to the NHS. Global fractionation companies were increasing their production to meet demand. However the need for FDA approval increases the time before there was an effect on productive capacity and hence supply. These companies were also vertically integrating to secure their supplies of plasma (which also had the effect of reducing the availability of plasma on the open market, see below).

Comment 4

Chris Hadfield stated at the meeting on 14/11/03 that in a competitive market BPL supplies approximately 45% of the blood plasma product requirements for England and Wales. The remaining 55% is supplied by commercial fractionators (see below).

BPL does not therefore currently supply the whole UK market. The share will however vary depending on the product. This is not likely to be increased through normal marketing effort, since the NHS is free

to purchase the best clinical product for the best price from a range of suppliers. The total UK market for products areas where BPL is active was worth about £100m, and the BPL share is about 41%. Thiscomment raises however competition rather than procurement issues.

Comment 5

Correct.

You are referred to the Secretary of State's general obligations as set out in the National Health Service Act 1977. Section 1 provides that :- *"It is the Secretary of State's duty to continue the promotion in England and Wales of a comprehensive health service designed to secure improvement – (a) in the physical and mental health of the people of those countries, and (b) in the prevention, diagnosis and treatment of illness, and for that purpose to provide or secure the effective provision of services in accordance with this Act".*

This section places on the Secretary of State a fundamental duty, and he is at risk of being sued for breach of statutory duty or negligence if he fails to carry out that duty. Failing to take steps to secure and adequate supply of blood plasma could well be seen as a breach of this obligation.

In addition, section 2 says:-"*Without prejudice to the Secretary of State's powers apart from this section, he has power – (a) to provide such services as he considers appropriate for the purpose of discharging any duty imposed on him by this Act; and (b) to do any other thing whatsoever which is calculated to facilitate, or is conducive or incidental to, the discharge of such a duty*".

Your attention is also drawn to the power "*to do any other thing whatsoever*". This wide power, coupled with the obligation in the previous section appears, as a starting point, to provide the Secretary of State with a substantial degree of legal cover for any activities that he wishes to undertake which are conducive or incidental to the discharge of his duty under section 1.

In or about 2001, the NHS in England and Wales required the equivalent of 537,000 litres of plasma per annum and demand was growing at approximately 10% pa. Fractionators process the plasma to produce finished products which are used to treat patients. Half of the UK's requirement for plasma derived products was met by BPL and half was acquired by the NHS on the open market from third party commercial suppliers. The availability of suitable plasma supply was reducing because of increased demand and stricter supply controls. The NHS was at risk of failing to secure certainty of supplies for UK patients.

Options: The Department of Health (DoH) evaluated the following options to secure the supply of plasma derived products for the UK: purchase of finished products from third parties; purchase of US plasma from the open market for BPL to process; set up managed centres in the US to secure a supply of plasma for BPL; and acquire LRI, a US plasma collection company, to secure supply of plasma for BPL.PA and KPMG (both highly regarded independent firms of consultants) evaluated the options against a set of financial and non-financial criteria. To do this they researched industry data, interviewed stakeholders and industry participants, built a financial model of the cost of each option to the Department of Health. Security of supply to the NHS was considered by Ministers to constitute the overriding criteria. They both concluded that the acquisition of LRI (given the weightings attached to the criteria) was the most viable option for the Department.

Suitability of US plasma: US plasma was the only suitable source because of: the absence of BSE and vCJD in the US (unlike Europe); the well developed regulatory structure (FDA, QPP); the well developed collection industry with suitable trained, experienced and entrepreneurial managers and collection centre staff; the acceptance of payment for plasma donation; BPL contractual obligations (e.g. Haemacure contact) oblige BPL to seek FDA approval, which was currently only available if US sourced plasma was processed; the volumes of plasma available currently and in the future.

Quality of US plasma supply: in the US there have been no reported cases of BSE or vCJD; stringent FDA quality regulations in the US give patient groups confidence that the plasma is of high quality.

This is of particular concern to Haemophiliacs. In the past over 1,000 have died in the UK, nearly 20% of the total, and many other have been infected as a result of Hepatitis C and HIV contracted from plasma derived products.

The US collected 60% of the world's source plasma. Europe collected an estimated 5%. Nearly all of the collection facilities in the US and Europe were owned by fractionators. Only 600,000 litres in the USA and 360,000 litres in Europe were produced by independent collectors, and most of this was believed to be committed on long term contracts to fractionators. Europe imports large quantities of US sourced plasma.

Suitability of alternative plasma supplies from other countries: Australia collects and fractionates plasma, and exports it to Far East countries. However the population is too small to allow for the collection and export of large volumes of raw plasma. Japan has recently had cases of BSE, and published failures of its blood collection programme. It is seeking to import US plasma. China and India do not inspire sufficient confidence in patients and clinicians as potential sources of plasma. PA Consulting did not found any significant exports of plasma from anywhere other than the USA. In nay event, IVIG from regions far from Europe may not contain the right mix of immune response proteins to combat European pathogens.

Previous supplies: The supply of plasma from the US was organised over the last three years through ongoing contracts with independent plasmatheresis companies. In recent years BPL has had contracts with Sera-Tec, Nabi and DCI in the United States but all three hadgiven notice of their intent to terminate the ongoing contracts. DCI's contract expired in March 2002 and the other two in March 2003, albeit at a reduced rate in the final year.In the event that there was no other contracted source, BPL would have had to rely on the opportunities to purchase ad-hoc amounts of US plasma as it becomes available on the market.

If BPL failed to obtain adequate amounts of US stock, it would not have been able to continue to supply products to the UK market within the quality constraints that currently exist. The alternatives then would be limited to making products from plasma that was not approved by the FDA and consequently not currently acceptable to the English market or to contract fractionation of plasma for third parties and no longer supply the UK market through BPL.

Potential demand for US plasma and Ad hoc availability: Fractionators were at that time running under capacity both in the US and throughout the rest of the world. Demand remained high as US plasma was regarded by many countries (including the UK) as one of the few remaining safe sources (see report prepared by KPMG and the comments on the vertical integration of the market).

Comment 6

Correct.

The following is the summary of the principal terms of the plasma supply agreement entered into as part of the LRI acquisition. This summary will need to be discussed with the client and Wendy Matthews to determine which information should be disclosed to the European Commission (please note the confidentiality provisions). In overview the supply agreement is for at least 5 years, is on a "take or pay" basis and gives BPL on entitlement to continued supply of plasma at (broadly) market price from time to time.

Parties and relationship with wider transaction: The Plasma Supply Agreement (the "Agreement") was entered into between Bio Products Laboratory ("BPL") and a newly formed company incorporated in Delaware that acquired the trade and assets of LRI ("Plasma Resources"). Plasma Resources is ultimately owned by the Secretary of State for Health.

Immediately following closing, certain vendors of LRI remained employed by Plasma Resources and by virtue of an "earn out", the relationship between Plasma Resources and BPL was not exactly the same as would normally apply between two wholly owned subsidiaries of the same entity. The vendors' entitlement to the earn-out is determined by Plasma Resources's EBIT performance (Earnings

Before Interest and Tax) against pre-agreed EBIT levels. One of the key assumptions behind these pre-agreed EBIT levels is future revenue from the Agreement (i.e. volume of plasma multiplied by price). The volume of plasma under the Agreement was fixed but the price is to be the market price agreed between the parties each year. However, for the purposes of calculating EBIT for the earn-out the price for each year was fixed and contained separately in the Asset Purchase Agreement.

Terms and Termination: The Agreement became effective upon execution by the parties and is to continue until 31 December 2006 or 2007 (check date). But the parties may agree to extend the term for further 12 month periods at that time (this is in effect an agreement to agree). The end of the term coincides with the end of the earn-out period and the related controls retained by the vendors (contained in the Asset Purchase Agreement) and so the DoH may then solely determine the volume, terms and price of supply of plasma from Plasma Resources.

The Agreement is also terminable by either party upon written notice if the other is in breach of a material term of the Agreement and that breach is not remedied within 30 days.

Assignment: The Agreement may not be assigned in whole or in part by Plasma Resources except with the prior written consent of BPL. But BPL may at any time assign all or any parts of its rights and benefits under the Agreement with the prior written consent of Plasma Resources (which may not be unreasonably withheld or delayed). (Note – this deliberately does not refer to a PPP of BPL and consent to an assignment would depend on its form and inter-relationship with other terms of the LRI acquisition).

Applicable Law: The Agreement is governed by English law and disputes are to be resolved by arbitration in London in accordance with the rules of conciliation and arbitration of the International Chamber of Commerce.

Confidentiality Provisions: There is a general prohibition on parties disclosing any confidential information received under the Agreement to any third party without the other party's prior consent.

But there are exceptions to the confidentiality obligations including where BPL is required to disclose confidential information in response to enquiries from Parliament, its members, its officers, committees, departments or offices (including without limitation the National Audit Office, the Public Select Committee, HM Treasury and the Public Accounts Committee or the Department of Health for the purposes of the UK Government). Such disclosures by BPL may only be made which are in BPL's reasonable opinion necessary in accordance with the ordinary standards of Parliament.

These obligations continue for a period of 10 years after the termination of the Agreement.

Principal Commercial Terms:

"Take or Pay"

The Agreement is a "take or pay" one which requires BPL to take a set volume of plasma (subject to an allowable variation of two per cent) per calendar year (which increases over the term) and to pay for all of such volumes whether or not it is surplus to BPL's requirements.

The agreed volumes are:

Calendar Year	Plasma Volume
2002	90,000
2003	200,000
2004	450,000

2005	475,000
2006	500,000

The delivery of plasma is to be in accordance with a pre-agreed range of monthly volumes (e.g. in 2003 the monthly volume range is between 12,000 and 25,000 litres per month) in order to ensure a smooth supply of plasma over each year.

The agreed "take or pay" volumes are reduced by volumes of plasma that Plasma Resources is unable to supply:

- § in accordance with the monthly delivery range;
- § due to Plasma Resources' existing obligations to supply plasma in priority to Bayer (see below); and/or
- § due to not complying with the obligations under the Agreement including the Specifications.

Additionally, if BPL determines these volumes are in excess of its requirements BPL may give Plasma Resources 30 days' notice prior to a scheduled shipment that Plasma Resources is required to use its commercially reasonable efforts (acting as BPL's agent and for which there is an indemnity) to sell any excess plasma to third parties. To the extent that Plasma Resources is able to sell such plasma to third parties, monies received are set off against BPL's "pay" obligation (less Plasma Resources' reasonable costs). A system must be put in place by BPL to monitor its production needs in order decide whether the volumes deliverable in each year/month are required or are excess in which case it needs to give Plasma Resources the 30 days notice.

BPL has an express priority of supply over the quantities of plasma set out in the Agreement over Plasma Resources' other customers except for the term of the current contract with Bayer (which pre-date BPL's contract and which expires on 1 October 2004).

The Agreement allows Plasma Resources to give at least 30 days' prior written notice to BPL that it intends to collect Product from any Centre approved to effect such collection but prior to such Centre receiving the Applicable Licenses necessary to ship such product (called "Pre- Licensed Product"). BPL may in writing approve or refuse in its absolute discretion the purchase of such Pre-License Product. We understand from BPL that taking a small quantity of such plasma is standard market practice and is currently done by BPL. Where BPL has given such written approval such Pre-Licensed Product shall be:

- § counted in determining whether Plasma Resources has met its obligation to supply Product to BPL in the amount of the Volume for the applicable calendar year;
- § invoiced to BPL notwithstanding that such Pre-Licensed Product has not yet been shipped;
- § paid for by BPL within 10 days of invoicing by Plasma Resources; and
- § upon payment credited towards BPL's take or pay obligation.

A system is to be put in place by BPL to enable it to respond to any requests by Plasma Resources' to the use of Pre-Licensed Product. In practical terms, this will mean arranging for a BPL technician to inspect the relevant centre within 14 days of it receiving a notice from Plasma Resources.

Price: The initial price of the plasma is set at US$112 per litre. Thereafter each year the parties are to meet together to agree the price of the plasma for the following year and provide documentary evidence supporting the price increase or decrease including by reference to a number of listed factors.

If the parties are unable to agree a price then the matter is submitted to binding arbitration on the basis set out above. Before such arbitration is made price will increase at the rate of inflation in accordance with the All Urban Consumers – US City average all items inflator.

Note – the payment terms are net 10 days after shipment.

– the price payable is in US dollars and therefore involves exposure to currency movements.

– BPL is required to pay any US sales tax on the plasma in addition to the plasma price and we are informed that whilst there is an obligation to pay any UK VAT it will not currently arise as it is being purchased from the US.

– the price may increase or decrease (as the case may be) if there is any change in government regulations or product specification.

QUALITY : **THE PLASMA SUPPLIED UNDER THE AGREEMENT IS TO BE IN ACCORDANCE WITH BPL'S SPECIFICATIONS SET OUT IN AN ATTACHED SCHEDULE (WHICH WAS PROVIDED BY BPL). AND FURTHER, PLASMA RESOURCES GIVES CERTAIN REPRESENTATIONS AND WARRANTIES THAT THE PLASMA AND CENTRES ARE LICENSED BY THE US FOOD AND DRUG ADMINISTRATION AND ARE OTHERWISE IN ACCORDANCE WITH APPLICABLE LAW.**

BPL is required to undertake PCR testing for HIV, HCV, HAV, HBV and PARVO B19.

No plasma may be shipped to BPL by Plasma Resources from any Centre (and BPL is entitled to reject any plasma shipped from such a Centre) for which the Medicine Controls Agency approval and all other applicable licences have not been obtained or for which any such applicable licence has been suspended and which suspension is in effect at the time of the shipment.

The Department appointed insurers to review all insurance issues and requirements of Plasma Resources including product liability. However, if a decision was made by BPL to self insure then systematic vigilance to ensure that the quality of plasma produced is of the highest standard will be a critical way to mitigate this risk.

Indemnities: There is a general indemnity given by each party any loss, liability, cost, damage or expense (including reasonable legal fees) ("Losses") arising from any breach of the representations and warranties by such party.

A specific indemnity has been negotiated by BPL in relation to Anti-D donation being mis-branded and treated as Product. This arose as a result of a specific problem encountered by BPL in the past with another supplier.

The Agreement contains the following limits on Plasma Resources' liability under the Agreement:

§ damage or loss equal to the replacement value of larger volumes of Products with which any non-complaint Product supply to BPL may be combined and which must be destroyed;

§ in the event of a third party claim against BPL which is due to Plasma Resources's failure to provide the Product in accordance with the Specifications, damage or loss equal to the losses or damages awarded to, ordered or judgement given in favour of any third party against BPL by any arbitrator or court of competent jurisdiction ; and/or

§ If BPL suffers loss of income, loss of profits, business interruption, or incidental damage which is due to Plasma Resources's failure to provide the Product in accordance with the

Specifications damage or loss to the extent that:

(i) the amount of any such loss or damage is covered by insurance in force for the benefit of Plasma Resources on the date of this Agreement or which is reasonably requested by BPL to be put in place after the date hereof; and/or

(ii) any amount of such loss or damage in respect of which Plasma Resources has any other right of recovery against, or indemnity from, any person other than BPL (whether under any provision of law, contract or otherwise howsoever).

The Agreement is governed by English law, thus the Unfair Contract Terms Act 1997 will apply. This Act prohibits the exclusion of liability for products causing death or personal injury – the key types of product liability risk that BPL faces in its line of business.

WARRANTIES: **EACH PARTY GIVES CERTAIN BASIC WARRANTIES AS TO HAVING ALL NECESSARY POWER AND AUTHORITY TO EXECUTE AND PERFORM THE AGREEMENT.**

Additionally, Plasma Resources gives specific warranties as to each of the Centres where the plasma is produced being in compliance with "Applicable Law" and holding the "Applicable Licences". It also warrants that all Product shall be in conformance with US Federal Regulations as well as BPL's Specifications.

Force Majeure: In the event of a Force Majeure event occurring the obligations of the party subject to such event are suspend for the period of the event but if the period exceeds two months the other party may terminate the Agreement on 30 days' notice.

Force Majeure includes strikes, fires, explosions, war or refusal by Governments to grant import or export licences.

For the duration of any period during which Plasma Resources is so prevented or delayed from performing its obligations, BPL is entitled to obtain from third parties the quantity of plasma that Plasma Resources is unable to supply and BPL's obligations to purchase the quantity of plasma for the calendar year in question is reduced by the amount so obtained.

Note that, as a result of negotiations relating to the "earn out", the force majeure entitlement to purchase plasma from third parties can reduce the "take or pay" obligation in certain circumstances where plasma is purchased from third parties. But those circumstances could be ones in which other third parties are also affected and unable to supply plasma.

Comment7

Please refer to the report prepared by KPMG.

The largest (not last) independent plasma collector operating in the United States prior to the acquisition was Diagnostic Chemistries, Inc. (DCI) (known also as LRI). They collected in the region of 400K litres per annum from 21 collection centres. They were one of the existing suppliers who had given notice that they wished to terminate the supply contract to BPL and were due to stop the existing arrangement as of 31/3/2002. They had however at that time expressed an interest in selling at least part of the business to BPL and this would enable BPL to guarantee that they had access up to the maximum collected by DCI.

DCI at that time had further plans to expand their operations over the next few years e.g. they intended

to open one new centre every 3 years starting in 2003/4. The new centres were assumed to have a maximum capacity of 30K litres and to produce at a level of 1/3 of full capacity in the start up year 2/3 in the following year and to deliver to full capacity thereafter.

TheDepartment's review of the market confirmed that the recent vertical integration continued as fractionators sought to buy their own plasma suppliers. DCI, being aware of this trend were content to take advantage of their increased value by offering a partial sale. The consequence of this was that BPL was under competition (a bidding war) to buy DCI and therefore only had a very small window of opportunity to complete a sale agreement if a commercial competitor was not to beat them to it.

As mentioned above, the contraction of the market share provided by independent collectors had continued to accelerate prior to the acquisition. At the beginning of 2000 there were 425 FDA licensed collection centres in the United States of which 164 were owned by fractionators. In August and September of 2001 two of the largest independent atherisers, Sera-Tec and Nabi had their collection centre businesses purchased by fractionators, Baxter and ZLB (owned by CSL) respectively. This meant that by September 30th 2001 whilst the number of FDA approved centres had fallen to 415, of those 371 were now directly owned by fractionators.

One of the fundamental threats to securing supply for the future was that not all of the big fractionators had secured themselves a collection source, meaning that the competition for the remaining few was likely to intensify substantially. This was especially so given that the demand for US plasma was significantly greater than the supply and in addition, that the likely global demand for the raw material was expected to double over the next 10 years. Of the total 11m litres of US plasma collected in 2001, market research estimated that only about 2.1m litres was available to contract for, and there wouldhave been intense competition for this from the major fractionators as well as other independents.

Until recently BPL has acquired US plasma on a long term contract from independent collection companies. Following the expiration of three supply contracts and the recent vertical integration within the industry very little source plasma was at that time available on the open market: For example, four recent acquisitions of US collection centre businesses by major international fractionators had removed 5.4 million litres (53% of the total US source plasma supply) from the open market and this was mostly exported to Europe. Independent supply was largely committed to fractionators on long term contracts. Two of those acquisitions led to the termination of BPL supply contracts.

It is important to note that the production capabilities of the remaining independent plasma collectors were usually tied to existing customers under long term contracts. Competition for the remaining, reducing, source plasma volumes haddriven up the market price over the last twelve months. Interviews with industry participants confirmed significant volumes were unlikely to become available, and certainly not under secure supply contracts. The shortage on the open market appeared likely to become more acute in the medium term whilst UK plasma remained unavailable for use. Demand was growing at 10% pa, and it was difficult for supply to meet that growth rate. If rising incidences of vCJD forced other European countries to turn to the US for plasma, pressure on supply could have increased further.

As the number of acquisition targets has fallen, the price paid per litre of output capability has soared.

As much as 94% of the normal source plasma litres collected in the USA was currently owned by the large international fractionators It was considered highly likely that once existing contracts to supply third parties (e.g. BPL) expired, the plasma output from those vertically integrated centres would be used for the fractionators' own requirements.

Comment 8:

Richard Lawes to revert regarding the reporting structure of the company etc.

Please note that BPL was not legally empowered to acquire the shares in LRI. Nor was its parent body, the NBA. The purchaser of LRI was therefore the Secretary of State for Health. The Health and Social Care Act 2001 inserted a new section 96(c) in the 1977 National Health Service Act enabling the Secretary of State to form and invest in limited company to supply goods to, for example, the NBA.

Section 96c(4) of the National Health Service Act 1977 defines "*companies*" for the purpose of the section as being "*companies within the meaning of the Companies Act 1985*". Section 735 of the Companies Act 1985 ("the Act") provides, 'The term "company" means (a) "A company formed and registered under this Act, or an existing company"; (b) "Existing company" means a company formed and registered under the former Companies Acts, but does not include a company registered under the Joint Stock Companies Acts, the Companies Act 1862 or the Companies (Consolidation) Act 1908 in what was then Ireland; (c)"The former Companies Act" means the joint Stock Companies Acts, The Companies Act 1862, the Companies Act 1862, the Companies (Consolidation) Act 1908, the Companies Act 1929 and the Companies Act 1948 - 1983." The section was subject to the proviso, *"unless the contrary intention appears*".

To be "*formed and registered under the Act"*, means the company must have been incorporated under Part 1 of the Act (or one of the former Companies Acts). Therefore only such UK companies fall 'within the meaning of the "*Companies Act 1985"* for the purpose of section 96c of the NHS Act 1977 and a Delaware incorporated company would not satisfy that definition. This being the case it would have been ultra vires for the Secretary of State for Health to directly hold shares of a Delaware company. Section 736 of the Act, which defines the terms "subsidiary", "holding company" and "wholly-owned subsidiary", includes 'any body corporate' in the meaning of 'company' for the purposes of that section. Section 740, in turn, provides, "*References in this Act to a body corporate or to a corporation ... include a company incorporated elsewhere than in Great Britain."* Hence, an English company could be a holding company for a foreign company such as one incorporated in Delaware; there appeared to be no "down-stream" restrictions in the National Health Services Act on what the company held by the Secretary may in its own right hold. In summary therefore, the transaction was structured by the Secretary of State for Health holding the shares in a UK company, which in turn owned the US holding company.

The supply agreement for FP was annexed to the acquisition agreement.

Comment 9

The NBA is a special health authority under the National Health Service Act 1977which has a status independent of the Secretary of State for Health. BPL is part of the NBA. The NBA itself is wholly government-owned and non-profit making. It is subsidised by the Government to the extent that its revenues from sales of blood products do not cover its liabilities. The Government also makes a capital investment in the order of around £5 million a year. (The Government's and the NBA's respective obligations and commitments in terms of financial support are dealt with in the National Health Service Act 1977 (ss97, 97A, 97AA and 99)). Therefore in this respect at least, the NBA is arguably not subject to normal market disciplines. More than half its members are appointed by the State and are, I believe, paid by the State.

The statutory basis for the NBA is the National Health Service Act 1977 which, provides in Article 1 that the Secretary of State has a duty to continue the promotion of a comprehensive health service. The NBA was established pursuant to s.11 of that Act by the National Blood Authority (Establishment and Constitution Order 1993) and it subsumed the Central Blood Laboratories Authority and the North Western Regional Health Authority.

The NBA is charged with performing on behalf of the Secretary of State the functions specified below and any other functions as the Secretary of State may direct. Anauthority must act subject to and in accordance with such directions as the Secretary of State may give to the authority. However no special health authority is regarded as a servant or agent of the Crown or as enjoying any status, immunity or privilege of the Crown.

The NBA's statutory functions are as follows: a) the provision of laboratories for the manufacture of blood products and for other purposes; b)collecting, screening and processing blood and its constituents and supplying blood, plasma and other blood products for the purposes of the health service; c) the preparation of plasma fractions and other products for therapeutic, diagnostic and other purposes; d) research and development in plasma protein fractionation and for other purposes; e) the manufacture of blood grouping re-agents and other related re-agents; f) the supply of products prepared or manufactured under sub-paragraph b) or d) above for the purposes of the health service; g) the promotion, by advertisement and otherwise, of the giving of blood and its constituents for the purposes of the health service, with a view in particular to maintaining an adequate number of persons who are willing to give blood or its constituents for those purposes.

The Secretary of State also has specific powers under the 1977 Act to make supplies of certain substances that are not readily obtainable (e.g. human blood) to any person on such terms as he thinks fit subject to certain limitations (Section 25). He also has more general powers under Section 26.

Chris Hadfield has confirmed that BPL does place "*calls for competition in the OJEU*".

Comment 10

Richard Lawes to revert.

Comment 11

Disagree. The Department proposes to rely upon Counsel's advice on the procurement issues arising from the long term supply contract for FP (copy previously provided). Counsel advised that the Department would have reasonable prospects of justifying entry into a plasma supply contract with LRI without first going out to tender in an open or restricted procedure. The arguments most likely to succeed in his opinion were:

(1) The Regulations do not apply because the proposed supply contract with LRI would be merely an ancillary and integral part of a business sale agreement which is not itself governed by the Regulations; and

(2) The use of the negotiated procedure was justified on the grounds that technical reasons and reasons connected with the protection of exclusive rights dictated that LRI was the only potential supplier of the plasma sought by the Department.

The Department may also be able to develop an argument that the proposed contract is excluded by reg. 6(c) as going to the basic interests of the security of the state.

Comment 12

See above.

Comment 13

See above for information pertaining to the payment for FP and the length of the contract. Richard Lawes to revert regarding division of capital, ownership and management of LRI. I also reiterate my previous comments concerning the confidentiality clauses in the long term supply agreement.

SHIELA EISA
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