Summary Overview

It is the view of BPI. that, notwithstanding the very real concern about the hypothetical risk of transmission of nvCJD by blood, blood components and fractionated plasma products, evidence-based rewiew indicates that fractionated plasma products derived from UK plasma remain safe, effective, therapeutic materials.

There is however a develooing tide of opinion, evident in statements and positions adopted by European regulatory bodies and increasingly reflected to BPI. by its Customers, that UK plasma should be excluded as source material, based on the concern that the population is at high risk ofnvCJD and that the risk of transmitting nvCJD cannot be positively excluded.

There is also a very real concern, based on the fact that 40% of the UK population donate blood at least Once in their lives, that a significant proportion of newly diagnosed cases ofnvCJD will be associated with post-donation review and recall of fractionated plasma products. Such events will ftrther erode user confidence in BPL's products and will have a profound effect on confidence in UK Blood Services as a whole

It is also relevant that the global availability of fractionated plasma products is seriously compromised by events in North America, which leave several major US fractionators operating, either under consent decree from the US FDA, or with major problems affecting one or more product lines. These problems are compounded by recurrent recalls of albumin and intravenous immunoglobulin derived from US volunteer donor recovered plasma as a result of post-donation information on classic"al CJD. BPL is not only the major supplier Of fractionated plasma products to the UK, its output is essential if product availability to patients is to be maintained.

It is in the light Of these facts alone, and no reflection on BPL's commitment to the principle Of optimal use of blood and blood products derived from voluntary nonremunerated donations to a national service, that BPL seeks permission to fractionate non-UK plasma. The proposal to use US paid donor plasma as an alternative to UK olasma re".ects the available evidence of donor population freedom from fivCJD risk the existence Of effective, auditable, quality Systems governing donor selection and the collection and supply of plasma

S availability Of sufficient quantities Of plasma from an source

BPL has developed a programme of work which would support such a change and IS confident that the change can be managed. Key to that programme, and essentlal

to the continued viability of BPL as a manufacturing supplier to UK Health Services, IS early approval of the purchase of non-UK plasma.

Bio Products Laboratory 1 April, 1998