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European Directive on Liability for Defective Products

Proposal to exclude the Transfusion Service from Strict Liability for the adverse effects of its products

Introduction

The Directive sets out to impose strict liability on manufacturers for their products and incidentally alters doctors' liability to their patients. These are two separate problems which should be considered independently. In the U.K. at present, the Committee on Safety of Medicines and the Medicines Inspectorate oversee manufacturers under the Medicines Act and the profession's liability is largely based on legal negligence. It is important to maintain this distinction in order to avoid an unintended and disastrous deterioration in medical practice.

The Transfusion Service ultimately depends on unpaid volunteers who act as blood donors. Obviously, the introduction of strict liability for donors is impractical as it would shortly result in the collapse of the Service. The relationship between the donor and the doctor who takes his blood is one of trust; the doctor attempts to prevent the dissemination of disease from donor to recipient by a combination of questions and laboratory tests. Unfortunately, a donor may deliberately conceal vital information or merely neglect to provide it. The donation is examined in the laboratory but it is impractical to carry out a comprehensive range of tests in the time available before the blood is required. It is not even possible for the laboratory to identify carriers of certain diseases which are known to be transmitted by transfusion, e.g. Non-A, Non-B Hepatitis. Thus, if the donor is excused liability, it is inequitable to hold the doctor liable unless he has been negligent.

The modern Transfusion Centre issues whole blood and components. The latter are inert plasma and concentrates of living cells e.g. red cells, white cells and platelets. If fresh plasma is separated and stored under appropriate conditions at the Centre, the risk of disease following its infusion emanates directly from the donor. Living cells are infinitely variable and all blood constituents are extremely sensitive to changes in conditions of storage. The Centre may control separation and storage on site but not the inherent viability and function of living cells, the conditions during transit, or peripheral storage arrangements. There are no strictly accepted criteria for good quality products; indeed, clinical efficacy may be sacrificed in the pursuit of absolute safety. The intrinsic variability of blood as a living product is similar to that of primary agricultural products which are exempted from liability by Article 1 of the Directive.

The Transfusion Service supplies:

(1). A central Blood Products Laboratory with fresh donor plasma for the preparation of Albumin, P.P.F., specific immunoglobulins and concentrates of the various coagulation factors. Many of these products are non-physiological concentrates of unknown composition which are utilised

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for their biological activity. It is vital to recognise that these products carry an inherent risk for the recipient which is quite independent of any system of quality control of the manufacturing process. The acceptability of this risk is the basis of modern, life-support therapy, which enables doctors to treat previously fatal conditions. The position may be compared with that of the Nuclear Industry, which is exempted from the Directive under Article 12.

(2) A Blood Group Reference Laboratory with serum donations to prepare diagnostic reagents for distribution to Transfusion Centres and hospital blood banks. These products are not administered to patients directly but used to select blood for transfusion. However, errors may be disastrous for patients, for example, the failure of an anti-A serum to detect an A_4 sub-group in a patient could result in a transfusion reaction. Again, the final products cannot be better than the source material which is donor serum. Current developments in this field may result in new and independent sources of reagents but viral and other contamination, which may interfere with specificity, has not yet been eliminated.

Example:

It may be helpful to consider the treatment of a haemophiliac involved in a major accident who undergoes surgery and subsequently develops hepatic failure. During treatment the patient has transfusions of whole blood, factor VIII concentrate from a variety of sources, cryoprecipitate and receives anaesthetic and other drugs and infusions.

The liver damage may be caused by the anaesthetic and the anaesthetist and the suppliers of the drugs and infusions used would be jointly liable. Alternatively, the blood and products may be responsible. If so, the potential defendants include the hospital blood bank, the Regional Transfusion Centre, the Blood Products Laboratory, Elstree, the Centre which was its source of plasma, commercial manufacturers of factor VIII concentrate and their plasma supplies and, occasionally, the Blood Group Reference Laboratory and commercial suppliers of reagents.

Overall responsibility falls on the clinical consultant who is certain to be the first target for any legal action by the patient because he is at the beginning of the chain. For his own protection, he has the unpleasant task of joining all potential co-defendants to the action with the certain knowledge that expensive litigation for a large number of innocent people will follow. Many clinicians will simply decline to accept such cases and the profession's main objective will become to avoid lawsuits rather than to secure the best interests of their patients.

Conclusion:

The imposition of strict liability on the Transfusion Service will undermine the relationships of donor and doctor, and those of the professions and the Department of Health, which finances the Service. It will eventually destroy the N.B.T.S. as we know it.

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