IN THE MATTER OF HEPATITIS C

OPINION

1. The Haemophilia Society wishes the Department of Health to establish a scheme to compensate haemophiliacs who contracted hepatitis C through blood transfusions. We are asked to advise the Department whether blood is a product within the terms of the Consumer Protection Act 1987.

2. The control of the provision of blood in this country is covered by the Public Health Group within the Department of Health, which assumes responsibility for "ensuring the safety of blood, blood products and tissues for transplantation"[1], and the National Blood Authority which is a Special Health Authority with responsibility for the supply of blood and blood products (see the National Blood Authority (Establishment and Constitution) Order 1993 SI 1993/585, as amended by SI 1994/589)[2].

3. We suspect that there are many definitions of "blood", but, for the purposes of this Opinion we have adopted the following from Butterworths' Medical Dictionary:

> "*blood* - the fluid medium that circulates through the vascular system. It consists of a liquid portion, or plasma, in which are suspended the various red and white blood cells and platelets: dissolved in it are salts of different kinds, organic substances,

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[1] See page 7, paragraph 3.4, of the Department of Health *Statement of Responsibilities and Accountabilities*, issued in May 1995.

[2] The functions of the N.B.A. include "Art.3(2)(a) The provision of laboratories for the manufacture of blood products and for other purposes", and "Art.3(2)(aa) Collecting, screening and processing blood and its constituents and supplying blood, plasma and other blood products for the purposes of the health service".

hormones, vitamins, products of anabolism and catabolism, antibodies and enzymes."
"*banked blood* - blood that has been collected from donors and stored, after the addition of a suitable anticoagulant, in a refrigerator until required for transfusion purposes."
"*whole blood* - the natural blood as circulating in the vascular system, containing all its normal cellular and chemical constituents."
"*whole human blood BP 1973* - blood which has been mixed with a suitable anticoagulant."

These definitions may or may not be up to date - for example, other methods of storage may be appropriate, and our instructions refer to the addition of a preservative rather than, or in addition to, an anticoagulant. Although in paragraph 1 we refer to "whole blood", the debate centres on whole human blood which has been collected and, to some extent, treated and then stored - see below.

4. Blood that is to be used in transfusions is taken from donors. The blood is screened for a variety of diseases. A preservative (and/or anticoagulant) is added. It is stored in pint units, either fresh or frozen, until used in a transfusion. We shall refer to blood so treated as Blood.

Consumer Protection Act 1987

5. Part I of the Consumer Protection Act (ss.1-9) deals with product liability and came into force on 1 March 1988: SI 1987/1680. All statutory references in the Opinion are to this Act unless otherwise stated. Section 2(1)(2)(3) imposes, subject to a number of exceptions, strict liability on a producer or importer of, or person who marketed, a product which has caused damage because it is defective. A product is defective if its safety is "not such as persons generally are entitled to expect": s.3(1).

6. Section 1(2) defines "product" as:

any goods or electricity and (subject to subsection (3) below [which we consider at paragraph 10]) includes a product which is comprised in another product, whether by virtue of being a component part or raw material or otherwise....

The question is therefore whether Blood is "goods" within the meaning of the Act.

7. By s.45(1)

> "goods" includes substances, growing crops and things comprised in land by virtue of being attached to it and any ship, aircraft or vehicle

and

> "substance" means any natural or artificial substance, whether in solid, liquid or gaseous form or in the form of a vapour, and includes substances that are comprised in or mixed with other goods....

In our view, this definition of "substance" is apt to include Blood. Accordingly, the definition of "goods" is apt to include Blood.

8. However, the Act imposes liability only if there has been a producer of a product: s.2(2). By s.1(2):

> "producer", in relation to a product, means -
> ...
> c) in the case of a product which has not been manufactured, won or abstracted but essential characteristics of which are attributable to an industrial or other process having been carried out (for example, in relation to agricultural produce), the person who carried out that process....

In our opinion, it would not be a natural use of language to describe Blood as having been manufactured, won or abstracted - to treat donor humans as the equivalent of tapped rubber trees is unlikely to impress a judge. However, we do consider that the addition of the preservative and/or anticoagulant to whole blood should be seen as "an industrial or other process" which gives an essential characteristic to Blood, namely its ability to be stored for substantial periods. Without the preservative, the national blood transfusion service could

not function as it currently does. However, we acknowledge that we approach this analysis without the necessary technical information as to the detail of the processes involved. Whether screening, freezing or storing in pint units count as industrial or other processes is more doubtful and we have not reached a conclusion on these matters, not considering it necessary.

9. The Act excludes liability in respect of any defect in any game or agricultural produce if the only supply of the game or produce by that person to another was at a time when it had not undergone an industrial process: s.2(4). Neither whole blood nor Blood is game or agricultural produce. But it is noteworthy that s.2(4) excludes liability only where there has been an industrial process. This suggests that the phrase "or other" in the definition of producer in s.1(2) was intended to ensure that the definition of producer was a wide one. In any event, we consider that the addition of preservative to whole blood is an industrial process: it involves frequent repetition of a task involving complex materials and trained staff.

10. The Act applies to the Crown: s.9(1). "Supply" includes "providing goods in or in connection with the performance of any statutory function": s.46(1). Supply which is made neither for profit nor in the course of business is exempt from liability: s.4(1)(c). But s.45(1) defines "business" as including the activities of inter alios "a local authority or other public body". We know little of the activities of the National Blood Authority, but it seems likely that the Act applies to the discharge of their duties of "supplying blood, plasma and other blood products".

11. Section 1(3) provides:

> For the purposes of this Part a person who supplies any product in which products are comprised, whether by virtue of being component part or raw materials or otherwise, shall not be treated by reason only of his supply of that product as supplying any of the products so comprised.

It appears that a person who merely supplies Blood but does not produce it is not automatically treated as a producer of the whole blood in the Blood. Such supplier could theoretically escape liability by identifying, at the patient's request, the blood donor: s.2(3). But this would be unrealistic. Further, if such a supplier in any way holds himself out as the producer of the Blood, he does attract liability (assuming for the moment that Blood is a product): s.2(2)(b).

Directive 85/374/EEC

12. Section 1(1) of the Act provides:

> This Part shall have effect for the purpose of making such provision as is necessary in order to comply with the product liability Directive and shall be construed accordingly.

Subsection (2) states that the relevant Directive is 85/374/EEC.

13. Article 2 of the Directive provides:

> For the purpose of this Directive "produce" means all movables, with the exception or primary agricultural products and game, even though incorporated into another movable or into an immovable. "Primary agricultural products" means the products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing. "Product" includes electricity.

Blood is not primary agricultural produce or electricity. Is it a movable? Literally, it clearly is. In most, if not all, legal systems that are based on Roman law, "movable" is a term of art, meaning an item recognised by the legal system as property and which is not an immovable. Leaving aside choses in action, the nearest equivalents in English law to

movable are "chattel" and "goods". It is a settled principle of European Community law that Community legislation is to be construed in a European sense, and not by individual Member States according to their own legal systems: see *Dicey and Morris, The Conflict of Laws* 12th Ed 1993 p.287 and the cases there cited. Research, which we are not in a position to undertake, is required into European comparative law on the status of blood.

14. Article 3 of the Directive defines "producer". The definition includes "the producer of any raw material". This is consistent with Blood being a product but does not throw any real light on issue whether blood or Blood is a movable.

15. If a purposive construction is adopted, as is generally the case in Community law, we think that the arguments favour including Blood as a product. It is a tangible. Recipients generally have no choice about what Blood they receive. The number of suppliers is very small (is it greater than one in this country?). In short, consumers are unable to protect themselves. On the other hand, the categorisation of Blood as a product may extend the opportunities for commercial dealing in it, which would be undesirable.

16. If the Directive does exclude Blood, does this require the English courts to construe the Act to the same effect? In our view it does not. The Directive is concerned with providing protection for consumers, not with giving an exhaustive definition of movables. Article 15(1)(a) of the Directive permits Member States to "derogate" by including primary agricultural produce and game within their definitions of "product". But such a provision mirrors the express exclusion of these things from the principal definition of "product" in Article 2: what is been expressly excluded requires express reference if it is to be included

by way of derogation. Conversely, anything implicitly excluded may be implicitly included by derogation if but only if such derogation would not offend the spirit of the Directive.

17. We consider that, if the natural reading of the Act is to include Blood as a product, this does not offend the spirit of the Directive. However, the question whether Blood and similar substances should be classified as goods is an important ethical and political question. An English court would in our view be slow to hold that Parliament in passing the 1987 Act intended to deal with this question by a side wind rather than by express words.

Aids to construction

18. The Directive does not mention human organs or blood. Earlier drafts of the Directive expressly excluded human organs and blood. The editors of *Charlesworth on Negligence*, 8th Ed 1990, consider that this indicates that Blood is not a movable: paragraph 14-14[3]. But this seems to us to be a *non sequitur* - indeed, the fact that blood etc. was earlier specifically excluded, indicates that the later failure to exclude, or, more likely, positive decision not to exclude, supports the view that blood could fall within the Directive. However, we advise that the earlier drafts of the Directive should be obtained, if possible, so we can see exactly what changes were made. The editors of *Clerk and Lindsell on Torts*, 16th Ed 1989, state that the absence of any mention of blood or tissue in the Directive indicates that they are excluded: paragraph 12-22 note 5. Again, this seems a *non sequitur*.

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[3] It states ".....as there is no mention of them at all in the Directive, it must remain unlikely that any human tissue in its widest sense could be classified as being a product, within the meaning of section 1(2) and "goods", within the meaning of section 45(1)."

19. The position has been considered by the authors of *"Product Liability: Law and Insurance"*, edited by Mark Mildred, 1994, at paragraph 2.18 and 2.19. Their view is that "human blood, blood products, human tissue and organs transferred from a donor are products under Article 2 o the Directive and should therefore be assumed to be 'goods' under s.1(2) of the CPA," and "If these products are defective, for example, if they are infected or diseased, the producer will *prima facie* be liable." Contrast, however, "*International Product Liability*", edited in 1993 by Campbell and Campbell from the New York State Bar, in which it is said at page 605:

> "In addition, blood, parts of the human body and organs are raw materials and therefore are not products. Thus, an HIV-infected person aware of an infection who donates blood is not liable to the person receiving the blood on the basis of the EC Directive on Products Liability."

This conclusion does not address the position of the supplier of defective blood, nor does it deal with the process of collecting, treating and storing blood.

19. United States decisions may be of assistance. Perlmutter v Beth David Hospital [309 NY 100, 123 NE 2d 792 (1954)] concerned a plaintiff who was given a transfusion with blood infected with serum hepatitis. He brought a product liability claim. The Supreme Court of New York held that the supply of a blood in a blood transfusion was merely incidental to the provision of a service and that accordingly, there was no product.

20. In Cunningham v MacNeil Memorial Hospital [266 WE 2d 897 (Ill 1970)] the Supreme Court of Illinois, on similar facts to Perlmutter's case, held that it was artificial to characterise a blood transfusion as a service: Blood was a product. The Illinois legislature responded by enacting that the provision of human blood and tissue is the supply of a

service, not a product, for the purposes of liability in contract. Similar legislation has been passed throughout the United States.

21. In Belle Bonfils Memorial Blood Bank v Hansen [597 P 2d 1158 (Colo 1978)] the Supreme Court of Colorado distinguished between on the one hand a blood bank, whose primary function was the supply of blood, and on the other a hospital, whose primary function is to provide medical services: the former supplies Blood as a product, the latter does not. We think that there is an attractive pragmatism in such a distinction.

22. As a result of decisions in America such as those set out above, problems arose in that blood donors became more difficult to find and there was a threat to the continuity of blood supplies for transfusion services. The problems were dealt with by legislation indicating that, without express exclusion, Blood does fall within the term "product" - at least in the U.S.

23. Kennedy and Grubb in the second edition of their *Medical Law* (1994) content themselves with summarising the American position and do not give their own final view on whether Blood is a product: pp.1144-1145. However, the following extract (from p.1145) seems to indicate that, if only tentatively, they favour the conclusion that Blood is a product for the purposes of the Act:

> "By contrast, in the case of a supplier such as the National Blood Authority which does not provide medical services to patients, the proper analysis is that they supply a product and therefore could be liable under the Act."

Conclusion

24. Subject to research on whether other European legal systems treat blood as a moveable, and any further information on the processes involved in the collection and supply of Blood, we think that natural readings of both the Act and the Directive indicate that Blood is in at least some circumstances a product and that this is consistent with a purposive approach. This is in line with the recommendation of the Pearson Commission: Royal Commission on Civil Liability and Compensation for Personal Injury Cmnd 7504-1 paragraph 1276. Bonfils' case (see paragraph 21 above) illustrates the possibility that there may be no single answer to the question raised in our instructions but rather that it is necessary to look at the facts of each case to see whether the transactions is a supply of goods or of services.

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12 July 1995
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IN THE MATTER OF HEPATITIS C

OPINION

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