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Date: Wednesday, 20 October 1999

Dear Mr Pearl,

Hepatitis C Litigation

As you know the Department has been reluctant to concede that body parts, even for the purposes of this case, are 'products' under the Consumer Protection Act (CPA). You requested further information about this stance. My understanding is that there is just one case, GRO-A, where this issue arises. In this case you state that on the balance of probabilities the heart was the source of the infection. I believe that no claim form has been served in the case of GRO-A

There are a number of reasons why it can be argued that organs do not fall within the CPA. Conceding that 'body parts constitute products', means conceding that all of section 1 of the CPA applies. In effect we would be conceding that 'body parts' (ie organs removed for immediate transplant from living or dead donors) are subjected to a 'process' and have a 'producer'. 'Body parts' or organs used immediately in this way are not subjected to any processing and in our view identifying a producer as defined by the CPA is not possible.

Blood, and more particularly blood products, appear to be capable of coming within the definition of 'products', linking back to the two definitions, 'goods' and more particularly, 'substance' in section 45(1) of the CPA. It is difficult to apply the word 'substance' as a description for a solid organ, but even if the organ was found to be a 'product' this does not mean that the producer can be identified.

Justin Fenwick advised that it is unlikely that the court would regard the person who donated the blood as its manufacturer. We consider that the same analysis would apply to donated organs. The argument applied to blood is that it is a 'substance' that has been 'won or abstracted'. In the case of blood the person doing the 'abstracting' can be clearly identified in the NBA, but there is no equivalent organisation for organs.

If we were to accept that organs from the living or the dead could be "won or abstracted" (and we do not) then the person 'abstracting' them would be the surgeon who removes the organ from the living or dead patient. This surgeon will almost certainly not be the surgeon that undertakes the transplant, and as in this case is unlikely to be from the same Health Authority or Trust.

Additionally body parts cannot be described as 'manufactured'. There is no processing involved in organ donation. The organ is removed from one person, kept in perfusion fluid, and generally transported elsewhere, to be transplanted usually within a matter of hours.

The wording of the Directive also suggests that a body part cannot be classed as a 'product', defined as meaning "a movable...even though incorporated into another movable or immovable".

The relevant definitions of "producer" in article 3.1 are (i) "the manufacturer of a finished product", (ii) "the producer of any raw material" or (iii) "the manufacturer of a component part". The only category of definition into which organs could fit would be 'raw material' as they are neither processed or manufactured.

In our view this kind of categorisation is inapplicable legally, and it is totally inappropriate from an ethical point of view when applied to a personal and altruistic donation that in many cases gives solace to bereaved families. The idea that an individual's heart could be categorised as a 'raw material' could also give offence to many who are committed to organ donation.

Indeed the whole notion of a product which is, or is derived from, a 'raw material' and is commonly bought and sold is not one which could apply in our domestic law in this context. The Human Organ Transplants Act 1989 makes it an offence to supply or offer to supply a human organ in the UK, whether from a living or dead donor, for money or any other form of payment.

Further, the Council of Europe Convention on Human Rights and Biomedicine (opened for signature in 1998 but not yet signed by the UK), in article 20, provides that "the human body and its parts shall not, as such, give rise to financial gain'.

In summary we consider that there are a number of ways to argue that 'body parts' are not 'products' under the CPA. These arguments focus on the fact that:

a) Organs are not manufactured or processed.

b) They do not have a clear 'producer'.

c) It is inappropriate ethically (and we think legally) to describe them as 'raw materials' (article 3 of the Directive) and difficult to describe them as a 'substance' (CPA).

In terms of the possible ECJ reference, your arguments outlined in your letter of 4th October (particularly point 1) in the main still apply.

Yours sincerely

GRO-C

MRS ANITA JAMES
(For the Solicitor)

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