LE BRASSEUR J TICKLE

SOLICITORS AND PRIVY COUNCIL AGENTS

OUR REF SAJ/JM/79 70

YOUR REF

RECEIVED
26 FEB 1999

25th February 1999

cc Dr A. Robinson
26/2/97.

Mr A Slopecki
National Quality Assurance Manager
National Blood Authority
Oak House
Reeds Crescent
Watford
Herts WD1 1QH

Dear Alan

Identification of Potential Donors

Thank you for your letter of 15th February 1999 and previous letters of 26th November 1998 and 29th January 1999. I am sorry for the delay in giving the advice requested.

Before identifying and advising on the issues I think are raised, I shall summarise the background information you have given. As I understand what you told me on the telephone, the diagnosis of new variant Creutzfeldt-Jakob Disease (nvCJD) is only made at death. Recent press reports suggest that the state of scientific knowledge is developing and that it may become possible to make the diagnosis in a living patient, but for present purposes I assume that what you initially told me remains the case.

All details of such diagnoses are sent to the CJD Surveillance Unit based in Scotland. The NBA is given information on confidential terms by the CJD Surveillance Unit if the deceased is thought to have been a blood donor.

You told me that there is no evidence that nvCJD is transmitted by donated blood. Furthermore, the disease cannot be treated. Despite these facts, it is the practice of the NBA to make a search back through its records to establish the fate of donations made by the deceased donor. For the reasons given, however, the individual recipients of blood or blood products derived from those donations are not informed. I assume that this practice will be regularly reviewed as scientific knowledge improves about the disease and possible methods of treatment.

O UANISCHS\79 70\990217.JM.LET.SLOPECKI.DOC

Robert Sumerling
Stephen Janisch
Ralph Shipway
Simon Dinnick
Michael De Graeve
Nicholas Rawson
Alex Leslie
Michael Thorniley-Walker
Michael Scanlan
Christian Dingwall
Simon Wakefield
Clare Brazell
Keith Mitchell

Jonathan North
Philip Garland
Rena Field
Catherine Williams
George Dodd
Stephen Everett
Geoffrey Sparks
William Hedley-Miller
Charles Atkins
Ricardo Bassani
Katie Costello
Sandra Butt
Peter Merchant

James Soulsby (Consultant)

DRURY HOUSE
34-43 RUSSELL STREET
LONDON WC2B 5HA
TELEPHONE 0171 836 0099
FAX 0171 831 2215
E-MAIL enquiries@lbjt.co.uk
DX No 37985 KINGSWAY

ALSO AT LEEDS

Although there is no evidence that nvCJD is transmitted by donated blood, the NBA nevertheless wishes to prevent blood subsequently donated by such recipients being used. This involves flagging them on the NBA computer database. The consequence of this is not that the individuals are thereafter excluded from the panel of blood donors but that, if they make further donations, their blood is not used and is discarded. Your letter of 29th January describes this as directing their units to be "not for clinical use". It appears that the direction is carried into effect by entering on the database a note that their components must not be used clinically. It is not considered appropriate to inform the individuals concerned.

On the telephone in November you drew an analogy between these donors and virology-positive donors. The latter are, however, informed when their blood is found on testing to be positive and they are asked not to donate again.

You said, according to my note, that three or fewer donors had so far been identified as recipients of blood donated by donors who had died from nvCJD. Because computer-flagging had not so far been instituted, it was possible that blood donated by these donors could have got into the system already. My note may however be inaccurate because your letter of 29th January says that there were no persons eligible to donate who you needed to identify but the situation has now changed.

It seems to me that the following ethical or legal issues are raised:

1. *Is it right that the NBA, having received information that a donor has died from nvCJD and being able to identify the recipients of blood or blood products derived from the deceased donor, does not pass on that information to the recipients or to those responsible for the medical care of the recipients?*

In my letter to Dr Hewitt of 25th June 1996 headed "Proposed CJD Lookback", paragraph 4.1, I dealt with the possible legal duty of care on the NBA to take some form of action with regard to individual recipients of blood donated by a person subsequently diagnosed as suffering from CJD. I was concerned that the NBA, as part of the National Health Service, could be said to owe a legal duty to such a person to inform him or her of the situation and arrange for the provision within the NHS of counselling or treatment. While it had at that time to be accepted (and I assume it still has to be accepted) that there is as yet no available treatment, I was not able to advise with confidence that there is no such legal duty owed to these individuals. That remains my view today.

A report appeared in The Times on 16th December 1997 headed *"CJD" blood products given to 3,000 patients*. It reported that the Irish Health Ministry had decided to notify 268 patients who had been injected with the relevant blood product but the Department of Health in England took a different view. A spokesman was quoted as saying that it would put an enormous burden on people to tell them that they had a remote risk of contracting the disease and that the relevant ethics committee advising the Department had decided it was just not appropriate to tell them. This is clearly a mixed ethical and legal issue. I would not wish to question the ethical advice given by the committee (unless there has been a material change in the scientific position since then) but consider that the legal position remains unclear as referred to above.

2. *Is the answer to question 1 above different in relation to a recipient who comes into further contact with the NBA in the capacity of a donor, so that the NBA is in a position directly to inform him or her?*

I do not know whether the ethics committee advising the Department in 1997 had addressed itself to the position of a recipient of relevant blood or blood products who comes into further contact with the NBA in the capacity of a donor. It seems to me more difficult from an ethical point of view to say that such a donor should not be told that he or she has received possibly CJD-infected blood or blood products, because failing to tell the donor involves an element of deception rather than a simple, considered omission. From a legal point of view, I think it is more strongly arguable that the NBA owes a duty to the donor to inform him or her of the situation and arrange for the provision of counselling or treatment.

3. *Is it appropriate for the NBA to permit such an individual to continue to donate blood, assuming that the answer to question 1 is still affirmative in such cases?*

In my comments under 2 above, I referred to a deception taking place. This is the failure to inform the individual donor that he or she has received blood or blood products which may be infected with nvCJD, coupled with the positive reassurance of continuing to treat the individual as a "normal" donor without disclosing that the blood donated will be dealt with in a special way. Thus, not only is there a lack of candour in the information given to the donor, there is also a failure to explain to the donor the nature and purpose of the donation procedure he or she is going to be subjected to. In other words, informed consent will no longer have been given to the donation procedure.

At the very least, the NBA is putting itself in a very disadvantageous position if any complication occurs as a result of the venepuncture. The donor might be entitled to make a claim for exemplary damages if he or she found out that the injury suffered was the consequence of a "donation" which was a sham. To subject an individual to any form of medical procedure which is not validated by informed consent and does not fall within any of the exceptional cases where consent is not required would be directly contrary to general law and, of course, Department of Health policy.

You have told me that, in the case of virology-positive donors, they are told when their blood is found on testing to be positive and are asked not to donate again. I cannot see any good reason in law for adopting a different procedure in the present case.

4. *Where blood has been taken from such an individual, is it appropriate for the NBA either (a) to discard it or (b) to put it to some other use than it was understood by the donor it would be put to, without the knowledge or consent of the donor?*

As discussed under 3 above, the blood taken from such an individual will have been taken without his or her informed consent. It will not therefore have been taken on the terms, express or implied, which normally apply to donated blood. It is therefore difficult to see how the NBA could successfully argue that the blood may be put to some other use than had been assumed by the donor it would be put to. There would be no express or implied consent to such use and I think it must follow that the use would be unlawful. For practical purposes, it would be pointless to argue that merely discarding the blood as waste would be unlawful, since that would imply a duty actually to retain the blood. I do not consider that there is any such duty but, the blood having by definition been taken from the donor without his or her valid consent, the NBA could not reasonably contend that it had any rights over the use of the blood.

If it is desirable for the NBA to be legally entitled to put such blood through tests or other scientific investigations, that should in my view be validated by first obtaining the consent of the donor to the donation procedure in the knowledge of the intended use.

5. *Is it lawful to flag the records of such individuals on your database without their knowledge or consent?*

Subject to certain legal constraints, it is open to a person to keep documentary or electronic records about another person without his or her knowledge or consent. This applies to a particular entry in a record, such as the "flagging" which you have in mind. It is, however, subject to the data protection principles contained in the Data Protection Act 1998 (which entirely replaces the 1984 Act).

Section 4 (3) imposes a duty on a data controller to comply with the data protection principles in relation to all personal data under his control. The first principle is that personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless certain conditions are met. Special conditions apply to "sensitive personal data", an expression which is defined as including personal data consisting of information as to the physical or mental health or condition of the data subject. "Processing" means obtaining, recording or holding the information or data or carrying out any operation or set of operations on it. I think it is therefore quite clear that flagging these records on your database would constitute processing sensitive personal data within the meaning of the 1998 Act.

One of the conditions mentioned above is that the data subject has given his explicit consent to the processing of the personal data. If such consent is not obtained, it would be necessary to show that at least one of the conditions in the first list below is met and also at least one of the conditions in the second list.

The first list is -

- necessary to do with the contract involving the data subject
- necessary for data controller to comply with a legal obligation
- necessary to protect the vital interests of the data subject
- necessary for the exercise of functions conferred by or under any enactment
- necessary for exercise of any functions of a Minister of the Crown or a government department
- necessary for the exercise of any other functions of a public nature exercised in the public interest
- necessary for legitimate interests pursued by the data controller or other party to whom data are disclosed (except where processing is unwarranted in any particular case by reason of prejudice to the rights and freedoms or legitimate interests of the data subject).

The second list is -

- necessary in order to protect the vital interests of the data subject or another person and the data controller cannot reasonably be expected to obtain the consent of the data subject
- necessary for the exercise of any functions conferred by or under an enactment
- necessary for the exercise of any functions of a Minister of the Crown or a government department
- necessary for medical purposes and undertaken by a health professional or person who

> owes an equivalent duty of confidentiality ("medical purposes" defined as including preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services).

I have not included in either of the above lists other statutory conditions which are clearly not applicable to these circumstances.

It may be possible for the NBA to define its aims in flagging the records of these individuals in such a way as to meet the above conditions. It could be said that the data processing was necessary in the exercise of the functions of the Secretary of State which have been delegated to the NBA (or other functions of a public nature exercised by the NBA in the public interest) and that the processing was necessary for medical purposes and undertaken by a health professional or person owing an equivalent duty of confidentiality. It would, however, be necessary to define quite clearly what those medical purposes were, having regard to the definition quoted above and the fact that the care of the individual concerned is not a factor. I do not have enough information to be able to give you a definition.

Even if the NBA could bring itself within the two lists of conditions I have mentioned, it would still be difficult to discharge the primary duty imposed on a data controller by section 4 (3), to comply with the data protection principles in relation to all personal data under his control. Not only would it be difficult to show that the personal data were being processed "fairly and lawfully" (which terms are not defined in the 1998 Act) if the flagging was not disclosed to the individual concerned, but also the data controller has a duty to provide information to the data subject about the purpose for which the data are intended to be processed and any further information which is necessary to enable processing to be fair. I cannot at present see how it would be possible to comply with the first data protection principle while withholding from the individuals concerned knowledge that their records had been flagged as you propose. This is quite apart from the fact that, as discussed under 6 below, there is a statutory right of access to information about the flagging.

6. *If the database records of such individuals have been flagged, are the individuals entitled to disclosure of or access to those records in any circumstances?*

The right to access may arise under the Access to Health Records Act 1990 and the Data Protection Act 1998.

The 1990 Act applies to health records. These are defined as meaning records which -

(a) consist of information relating to the physical or mental health of an individual who can be identified from that information, or from that and other information in the possession of the holder of the records; and

(b) has been made by or on behalf of a health professional in connection with the care of that individual.

I think we have always taken the view that donor records were likely to be covered by the 1990 Act even though the NBA is not responsible for the general "care" of donors (see for instance paragraph 3.4 of my letter to Dr Hewitt mentioned above). The right of statutory access may be partially excluded if any part of the health record contains information which would be likely to cause serious harm to the physical or mental health of the patient or any other individual. The

County Court has the jurisdiction to deal with applications for access where the holder of the record has failed to comply with the requirements of the Act.

The 1990 Act has been amended by the Data Protection Act 1998. The expression "health professional" is now defined in the 1998 Act. It includes a registered medical practitioner or a scientist who is a head of department employed by a health service body.

Under the 1998 Act, an individual has a right of access to personal data. This includes being informed by the data controller whether personal data about him is being processed, being given a description of the data and the purposes for which the data are being processed and to whom they may be disclosed, and to have the information communicated to him in an intelligible form. There is no obligation to comply with the request if doing so would involve disclosing information relating to another individual who can be identified from that information unless the other individual has consented or it is reasonable in all the circumstances to comply without consent. I do not believe that this exception would apply.

It seems to me therefore that a donor's statutory rights would clearly extend to being informed about flagging on your database. Even if the information did not immediately include the fact that the donor had received "nvCJD blood", it would clearly lead to that information being given.

This is a complex issue but I hope I have covered the points of immediate concern to you. Please may we discuss this letter if anything has not been covered or is unclear.

Yours sincerely

GRO-C

STEPHEN JANISCH
direct tel GRO-C

O:\JANISCH\SJ\9 70000217.JM.LET.SLOPECKI.DOC