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Prime Minister.

I understand from Michael Alison that you wanted a note on this, following your meeting with Ken Hargreaves.

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DEPARTMENT OF HEALTH & SOCIAL SECURITY

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From the Secretary of State for Social Services

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Private Secretary
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Dear Tim

RESEARCH ON FETAL MATERIAL

As discussed, following the query raised with the Prime Minister yesterday by Ken Hargreaves MP and others, I enclose a note on the legality of the use of fetal material for research.

If there are any points on which you would like further information please let me know.

Yours sincerely

Elizabeth

Elizabeth Mothersill
Private Secretary

LEGALITY OF USE OF FETAL MATERIAL FOR RESEARCH

1. For legal purposes, fetal material for research use falls into two categories - material from stillborn fetuses of more than 28 weeks gestation and fetal material from earlier stages of pregnancy. The former is governed by the Human Tissue Act, which allows research on fetal and other human tissue with relatives' consent. There is no legal provision governing the use of the latter in research.

2. However, the second category is very closely controlled, in accordance with the attached Code of Practice recommended in the Report of the Advisory Group on the use of Fetuses and Fetal Material for Research (Peel). That Report was concerned principally with the research use of fetuses or fetal material deriving from abortions. It recommended that tissue deriving from dead fetuses can be used for research provided there is no monetary exchange for material. It also recommended that the whole pre-viable fetus might be used for research provided the above condition is observed and the fetus weighs less than 300 grammes. The responsibility for deciding that the fetus falls in the latter category rests with the medical attendants at birth and not with the intending research worker. One of the report's recommendations is that any research on fetal material should carry the approval of the local ethical committee.

3. In the NHS, research use of fetal material is the responsibility of health authorities. In the private sector, proprietors of nursing homes approved to carry out abortions give the Secretary of State an assurance that the nursing home will not supply fetuses or fetal material to any organisation or institution without prior consultation and his express approval. Seven approved nursing homes (out of 66) are at present authorised to provide fetal material to certain named institutions for bona fide research purposes. Use must be in accordance with the Peel Code of Practice, and the arrangements are monitored closely by the Department.

RECOMMENDED CODE OF PRACTICE

This code has no binding legal force but is the result of a careful consideration of all relevant factors in the light of the available evidence. It is hoped that it will prove acceptable to the bodies statutorily responsible for disciplinary matters in the medical and nursing professions.

1 Where a fetus is viable after separation from the mother it is unethical to carry out any experiments on it which are inconsistent with treatment necessary to promote its life.

2 The minimal limit of viability for human fetuses should be regarded as 20 weeks' gestational age. This corresponds to a weight of approximately 400–500 grammes.

3 The use of the whole dead fetus or tissues from dead fetuses for medical research is permissible subject to the following conditions:

(i) The provisions of the Human Tissue Act are observed where applicable;
(ii) Where the provisions of the Human Tissue Act do not apply there is no known objection on the part of the parent who has had an opportunity to declare any wishes about the disposal of the fetus;
(iii) Dissection of the dead fetus or experiments on the fetus or fetal material do not occur in the operating theatre or place of delivery;
(iv) There is no monetary exchange for fetuses or fetal material;
(v) Full records are kept by the relevant institution.

4 The use of the whole pre-viable fetus is permissible provided that:

(i) The conditions in paragraph 3 above are observed;
(ii) Only fetuses weighing less than 300 grammes are used;
(iii) The responsibility for deciding that the fetus is in a category which may be used for this type of research rests with the medical attendants at its birth and never with the intending research worker;
(iv) Such research is only carried out in departments directly related to a hospital and with the direct sanction of its ethical committee;
(v) Before permitting such research the ethical committee satisfies itself: (a) on the validity of the research; (b) that the required information cannot be obtained in any other way; and (c) that the investigators have the necessary facilities and skill.

5 It is unethical to administer drugs or carry out any procedures during pregnancy with the deliberate intent of ascertaining the harm that they might do to the fetus.