

**FRAMING FETUSES, FRAMING WOMEN: THE LEGISLATIVE
AND GOVERNANCE FRAMEWORK FOR THE COLLECTION AND
USE OF ABORTED FETUSES IN STEM CELL RESEARCH AND
THERAPIES**

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FRAMING FETUSES, FRAMING WOMEN: THE LEGISLATIVE AND GOVERNANCE FRAMEWORK FOR THE COLLECTION AND USE OF ABORTED FETUSES IN STEM CELL RESEARCH AND THERAPIES

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I. INTRODUCTION

It is frequently stated that the UK has a transparent, accountable and strict but permissive regulatory approach to research using pre-implantation human embryos and that this approach provides reassurance to the public in a particularly emotive area, has the full confidence of the scientific and medical research communities, and gives the UK a competitive advantage in the international field of stem cell research.¹ Aborted fetuses are another controversial source of stem cells although their use is less widely known. Indeed, one of the few milestones in the short history of stem cell science is the announcement in 1998 by John Gearhart, of Johns Hopkins Medical School, Baltimore, USA, that his laboratory had succeeded in keeping alive cultures of human stem cells derived from embryonic germ cells of therapeutically aborted fetuses.² The purpose of this paper is to analyse the legislative and governance arrangements for the collection of aborted fetuses for use in stem cell research and therapies. We argue that the arrangements are confused, lack transparency, are out of line with current good practice on seeking consent, and encourage the condoning of non-compliance. Furthermore, in our view, the separation of legal and governance arrangements for collection and use of pre-implantation human embryos and aborted fetuses could become increasingly problematic. Pre-implantation human embryos and aborted fetuses are treated differently not because they are *a priori* ontologically distinctive entities but because of how they have been constructed as regulatory objects. Though they may appear to

inhabit different social worlds (of for example the IVF and abortion clinic) we conclude by proposing that from a regulatory perspective there is increasingly a potential for leakage between them.

As social scientists, we use the conceptual tool of 'framing' to analyse how both women and aborted fetuses are represented in the legislative and governance framework.³ By framing, we mean the stories told in attempts to order and make sense of complex issues. Frames are constructed through intense social activity. Frames fundamentally alter how people see the world around them; they also enable, and even direct, people's actions. Frames create a moral order which is normalised so that their origins in conflict and controversy are lost.

Some of the elements found within one frame may fall outside another so that, for example, abortion providers and their patients will frame the aborted fetus differently to anti-abortion activists, policy makers and stem cell scientists⁴. Frames may also overlap and policy and law makers engage in types of 'boundary work' in an attempt to construct and maintain boundaries between different kinds of regulatory object.⁵

The social scientific approach insists identities are created and defined by social processes. It is different to that of law where the meaning of terms is sought in the wording of statutes, the minds of legislators or case law, and where, sometimes, none might be available. And where legal thinkers fail to recognize how their representations of the human body are discursively produced and materialized, they naturalize what is in effect their handiwork.⁶ Legal discourse therefore is itself an object of study for social scientists and the ways in which the law and other policy constructs concepts of the body, corpse, fetus, woman, or embryo, are sites for investigation and inquiry.

A social scientific approach is also different to that of medical ethics, which is linked to the legal framework but where the focus is on the relationship of

abortion and the moral status of the fetus. Ethical dispute centres on when 'life' of an individual human being begins with some people adopting an absolutist position, that is, claiming human life begins at fertilisation, and others taking a gradualist approach, that is, human life emerges as gestational age increases. Ethicists also question whether an activity such as abortion is right or wrong, morally innocuous or repugnant, irrespective of whether it is permitted in law. Following on from this are the questions of whether or not the aborted fetus may be treated instrumentally as research material or is material deserving of respect, and if good can ensue from a legally permissible but ethically problematic procedure. As social scientists we are also interested in how ethical debates frame notions of 'life', personhood, 'waste', human remains, means and ends.

At the centre of our analysis here are two major themes: first the framing of women who undergo an abortion (section II); second the framing of the aborted fetus as a source of research material (section III). We then consider how these framings have shaped law, policy and practice relating to the issues of consent (section IV); anticipate the potential impact of European Union (EU) Directives (Section V); and conclude by speculating on the impact of developments in the pipeline.

II: FRAMING WOMEN

It is common to hear abortion discussed in terms of rights – of the 'mother' (woman), the fetus and, sometimes, also the 'father'. English law, however, recognises none of these. The Abortion Act 1967 gives a 'right' only to doctors, to form an opinion as to whether or not abortion is justified. It provides that a registered medical practitioner may lawfully terminate a pregnancy that has not exceeded its twenty-fourth week, in an NHS hospital or on premises approved for this purpose, if two registered medical practitioners are of the opinion that continuance of the pregnancy would involve risk to the life of the pregnant woman, or injury to her physical or mental health, or to the physical or mental

health of any existing children. The risk must be greater than if the pregnancy were terminated. In reaching this decision, doctors are entitled to consider the woman's actual or reasonably foreseeable environment.

Abortion may not be a woman's right but, almost every year since the Act was placed on the statute book, the number of pregnancies legally terminated in England and Wales has increased from just over 54,000 in 1969, the first full year of the Act's operation, to around 185,000 in 2004. Abortion is now a common experience: at least one in every three women will have undergone one by the time they reach the age of 45 years.⁷

The Abortion Act was the seventh post-war attempt at abortion law reform. Its passage was achieved by presenting it as an issue of public health, to eradicate the problems of 'back street' abortions and 'latch-key' children, and not of women's emancipation.⁸ Paradoxically, despite making the procedure safer and more easily available, the Act is predicated upon negative stereotypes of women seeking termination of a pregnancy.⁹ In public and parliamentary debates preceding the passage of the Act, women who perceive a pregnancy as unwanted were, crudely speaking, placed in one of two frames: as an 'overstrained wife', a 'tired housewife', an emotionally weak, even suicidal, victim of desperate social and economic circumstances; as a rich frivolous woman for whom pregnancy inconvenienced her busy social calendar. The first frame was created by reformers and the latter by their opponents.

The passage of the Act represents a victory for the reformers. Section 1(1)(a), sometimes called the 'social grounds', allows a pregnancy to be terminated where doctors deem that: 'continuance of the pregnancy would involve risk... of injury to the physical or mental of the woman... greater than if the pregnancy were terminated' with the section 1(2) proviso that 'account may be taken of the pregnant woman's actual or reasonably foreseeable environment.' It enshrined in statute Mr Justice MacNaughten's interpretation of the Infant Life Preservation

Act 1929 in *R v Bourne* 1938, a case which concerned pregnancy in a 14-year-old girl who had been raped by four soldiers, in which he recognised that continuance of an unwanted pregnancy might make a woman a physical or mental wreck. However, the reformers' victory did not defeat their opponents' frame for two reasons. First, the Act did not de-pathologise women but rather removed judgment of their moral worth and mental stability to the court of medicine. Second, its passage stimulated the anti-abortion lobby.¹⁰ We argue below that these stereotypes continue to influence policies on consent for collection of aborted fetuses for research.

III: FRAMING THE ABORTED FETUS AS A SOURCE OF RESEARCH MATERIAL

English law treats the aborted fetus as the woman's residual tissue. In other words, it places it in the same frame as say an appendix or gall bladder which has been separated from the woman in a medical procedure. It also discursively produces a regulatory object which has material consequences in that the aborted fetus can legitimately be treated as 'clinical waste'.¹¹ Nonetheless, policy makers recognise that not all body parts are equal and that this legal framing looks distinctly out of place in the presence of other framings of the fetus, in particular, the public framing of fetus as wanted child,¹² and its framing in anti-abortion propaganda¹³. Our interest here is in how law and policy makers accommodate these different framings in the development of guidelines on the collection of aborted fetuses as sources of research material.

We begin by revisiting the Peel Code, drawn up by the Peel Committee, named after Sir John Peel, a leading gynaecologist, which ended policy makers' silence on how aborted fetuses should be collected.¹⁴ The Committee had been set up by the government in 1970 in response to allegations by Norman St. John-Stevas, MP, now Baron St. John of Fawsley, that live aborted fetuses were being sold for use in medical experiments. The fetuses allegedly were being kept alive

by heart-and-lung machines and 'slaughtered' at full-term.¹⁵ Who was responsible for these experiments and where they were being carried out has never been revealed.¹⁶ The allegations had been made in a letter from an unnamed medical worker.¹⁷ St. John-Stevas found them credible. He was one of two of the chief parliamentary supporters of the Society for the Protection of the Unborn Child (SPUC) – the other was Jill Knight MP- which had been launched in January 1967 to campaign against the Abortion Bill. In the face of defeat, SPUC made reform of the Abortion Act 1967 its immediate aim, and its repeal a long term ideal.¹⁸

The Peel Committee's terms of reference excluded any discussion on the politics of abortion as this was Parliament's bailiwick. However, in the background of its deliberations was the thalidomide tragedy of the 1960s which had led to the insistence on the part of regulators that the teratological potential of a new medicine was thoroughly explored. The Committee, as a way of justifying its decision to allow instrumental treatment of the fetus under certain circumstances, introduced categories organised around 'viability' and 'death'. A viable fetus is defined as one which has reached the stage at which it is capable of functioning as a self-sustaining whole independently of any connection with the mother. Fetal death is the state in which the fetus shows no signs of life, and is incapable of being made to function as a self-sustaining whole (although the Committee recognised that fetal tissue and cells may continue to live after the fetus itself has 'died').¹⁹

The Committee considered but rejected as unnecessarily cumbersome a proposal that there should be legislation to provide for the licensing of those who wish to undertake research using aborted fetuses, fetal tissue and fetal material similar to the licenses issued to those undertaking research on animals. Instead, it developed a code of ethical practice [sic] which, it claimed, had the advantage of flexibility, but which has no binding legal force. The code prohibits non-therapeutic research (such as research *in vitro* or on animals) on a viable fetus

that has been separated from its mother, but allows research on the dead fetus and the whole pre-viable fetus which it defined as a fetus which may show some signs of life but has not yet reached the stage at which it is capable of independent existence, that is, it is incapable of being made to function as a self-sustaining whole. Although 28 weeks gestation was the stage at which a statutory presumption of viability then emerged (as stated in the Infant Life Preservation Act 1929), the Committee, for ethical, medical and social reasons, confined research to the whole pre-viable fetus up until 20 weeks gestational age, corresponding to a fetal weight of 300 grams, when 'those parts of the brain on which consciousness depends are, as yet, poorly developed structurally and show no signs of electrical activity'.²⁰ Responsibility for deciding which category a fetus fell into rested on the woman's medical attendant, never on the researcher.

The code states that all proposals for research should be reviewed and approved by an ethical [sic] committee. This recommendation still applies, yet research ethics committees (RECs) are unaccountable to the public and their proceedings and decisions are shrouded in secrecy.²¹ To this day there is no public record of research projects using aborted fetuses that they have approved. In contrast, the Human Fertilisation and Embryology Authority (HFEA) publishes in its annual reports and on its website a list of every research project using human pre-implantation embryos it has licensed following rigorous scientific peer review and approval by a REC. The HFEA is the regulatory body established under the Human Fertilisation and Embryology (HFE) Act 1990, the legal framework providing for the creation of and use in treatment and research of pre-implantation human embryos. Research outwith an HFEA license is a criminal offence.

Coverage in the tabloid press in 1988 of experiments in which fetal neural tissue was implanted into the brain of people with Parkinson's disease anticipated a huge demand for the apparently miracle-working procedure.²² Up to eight aborted fetuses were used in each operation and coordinating the termination of

that many pregnancies of similar gestational age and transplant operation was a major undertaking. The government, in response to public concern, organized a review of the Peel Code by a committee, known as the Polkinghorne Committee, named after its chairman the Reverend Dr John Polkinghorne, a scientist and cleric.

Although the terms of reference of the Polkinghorne Committee, like those of its predecessors, did not include the politics of abortion, its members placed on record that in their discussions they had been mindful of the enormity of the moral dilemma it poses. In the backdrop of their deliberations were the lengthy public consultation and parliamentary debates on the shape of the government's statutory response to the Report of the Warnock Committee on human fertilization and embryology.²³ However, whereas the pre-implantation embryo created *in vitro* was about to be afforded protection of the criminal law, the Polkinghorne Committee, like its predecessor, decided a system of professional self-regulation sufficed with respect to aborted fetuses. The reason it gave was no infringements of the Peel Code had been brought to its attention. However, that does not mean that none had taken place, only that infringement escaped notice, which is unsurprising as oversight was non-existent. In 1999, 445 intact fetuses and some that had had parts removed were found amongst van Velzen's infamous collection of body parts at the Royal Liverpool Children's Hospital NHS Trust (Alder Hey Children's Hospital). Most of the intact ones were awaiting a diagnostic examination having been aborted under Ground E of the Abortion Act 1967 which allows a pregnancy to be terminated where there is a substantial risk that the child would suffer from a serious physical or mental abnormality. The remainder had been collected and retained for research following an abortion under the 'social' clause. The paperwork was missing: signed consent forms were not found. The Inquiry concluded that during what it called 'the van Velzen years', a period between 1988 and 1995, many fetuses, rather than being buried as women were led to believe, had ended up either being stored or dismantled for research.²⁴

The Polkinghorne Committee, like its predecessor, justified its reasoning by introducing new categories. It rejected the Peel Committee's choice of gestational age and viability as the relevant categories of ethical significance, and replaced them with 'alive' and 'dead' and '*in utero*' and '*ex utero*'.²⁵ The cadaveric fetus *ex utero* is, it claimed, a legitimate source of research material by virtue of being wholly different to a living fetus *in utero* which is not a legal person but, nonetheless, it claimed, has a special status broadly comparable to that of a living person. In other words, once again, death allows a fetus to be treated instrumentally.

Placing the fetus in a similar frame to that of a dead adult organ donor, arguably, was an appropriate move given the review of the Peel Code had arisen over the controversy about experimental fetal tissue transplants. Yet, in English law, an aborted fetus of less than 28 weeks gestational age, then the statutory stage of viability, is not a person, and only the bodies of persons can be treated as a corpse. The Committee, unlike its predecessor, considered how death in a fetus might be established, and, once again, the criteria it used placed the fetus in the frame of a corpse, and not, as the law might have it, as a collection of cells which, despite their genetic difference, 'belong' to the woman. It found inactivity of the brain-stem, the recently agreed criteria of death in a potential organ donor,²⁶ is inapplicable to a fetus *ex utero* at the stage of development at which the law allowed it to be aborted, and recommended determining death by reference to the absence of spontaneous respiration and heartbeat. Furthermore, death, however determined, should be confirmed by a doctor responsible for the clinical management of the mother and the fetus, and not by someone involved with the subsequent use of fetal tissue.²⁷

The fresh fetus was introduced as a regulatory object in 1995 in a circular announcing an agreement between the Department of Health (DoH) and the Medical Research Council (MRC) that its Fetal Tissue Bank, based at the

Hammersmith Hospital, London, would be designated an intermediary organization between source and user as had been suggested by the Polkinghorne Committee.²⁸ However, the Bank (which was closed in 2005) supplied only frozen fetal tissue, and some research requires fresh. The DoH, in the circular, allowed 'local' collections of fresh material, 'local' being a euphemism for a nearby hospital or abortion clinic. It also advised investigators to submit justification for using fresh fetal tissue, together with an explanation of how they proposed separating source and user, for review by a REC.

'Fresh' can mean recently dead. But it also can mean material from the living but about-to-be-aborted fetus, that is, material collected *in utero* prior to the termination of the pregnancy and expulsion of the fetus.²⁹ The Polkinghorne Code prohibits collection of material from the living fetus *in utero* for non-therapeutic research, including stem cell research.³⁰ Where tissue is collected from the about-to-be-aborted fetus, the woman is treated instrumentally, as a vessel containing potentially valuable research material. Her abdomen and uterus are penetrated to obtain it. Furthermore, its collection has implications for choice of method of abortion, for example, it might be easier to collect the tissue where the woman is anaesthetized. The Polkinghorne Committee noted that while termination by one method might be safer for the mother, another might be more suitable for research purposes, and recommended that the method of termination should not be influenced by consideration of subsequent use of the fetus.³¹ Its Code stipulates that the practice of abortion must be separate from the use of fetal tissue in research or therapy and advised against allowing contact between women seeking elective termination of a pregnancy and those providing her care (together called 'the source') and those concerned with research and therapy making use of fetal material ('the user'). Indeed, separation of source and user must be complete: the source records the identity of the woman but does not divulge it to the intermediary, thereby ensuring the user knows nothing of the provenance of fetal material, although the committee allowed the transfer of non-identifying information which might have significance

for research such as whether the woman was a smoker or not. The Committee recommended an intermediary body be established between source and user but noted that compliance was possible without an intermediary.

The separation principle, as these rules came to be known, is controversial. The Royal College of Obstetricians and Gynaecologists (RCOG) claimed it is having an obstructive effect on research in fetal medicine where 'fresh' fetal material collected *in utero* is required. Furthermore, it objected to the inference that its members who undertake clinical research are incapable of conducting themselves ethically in relation to patients.³² The DoH, in *Human Bodies, Human Choices*, the consultation report on the proposed new law on human organs and tissue in England and Wales published in 2002, argued that the needs of research will not necessarily conflict with those of the woman.³³ Indeed, it implied that they might even make the procedure safer because removal of fetal tissue *in utero* is undertaken with ultrasound guidance, and ultrasound scanning is not considered by the RCOG to be an essential prerequisite of abortion in all cases (ultrasound guidance may prevent accidental perforation of the uterus).³⁴ However, the DoH suggested any modification to the procedure be permitted only where it poses either the same or less risk to the women, has been approved by a REC, and agreed to by the woman who has been told about the standard procedure. In effect, the DoH acknowledged that a REC may overrule the Polkinghorne Code. Put another way, the DoH sanctioned non-compliance with guidance, the development of which it sponsored and which it claims still applies.³⁵

Members of RECs need to be mindful that the grounds for deciding which method is best for women are shifting. The RCOG provides guidance on abortion care and identifies best practices.³⁶ Vacuum aspiration, the main surgical method, is recommended between seven and 15 weeks gestation, and dilation and evacuation (D&E), another surgical method, is recommended where gestational age is greater than 15 weeks. Surgical methods make it difficult to

identify the fetal tissue currently sought for what look like promising approaches to stem cell research. From some investigators' point of view, hysterotomy, which ensures the fetal sac is intact, is preferable because it is sterile, but is almost never performed. In 1991, the UK Licensing Authority approved the use of the abortifacient drug RU486 (mifepristone, an anti-progesterone, also known as Mifehyne), which terminates the pregnancy. It is used in combination with a prostaglandin analogue which expels the fetus out of the uterus and is given around two days after RU486 is administered. Together these medicines are called a medical method of terminating a pregnancy, or medical abortion for short. Mifepristone is licensed for use within the first 63 days of pregnancy and recommended by the RCOG for up to nine weeks gestational age. There has been a continuing upward trend in medical abortions since 1991, and in 2004, they accounted for just under one in five of the total.³⁷ Medical abortion completed at home has not been formally evaluated but research suggests that most women in the UK would welcome the choice of having a medical abortion at home or in hospital.³⁸ An increase in medical abortion at home will further limit the opportunities of collecting fetal material for research.

IV. Consent

Consent brings together the various framings of women and aborted fetuses. Consent is patients' voluntary agreement to treatment, examination and other aspects of health care including the retention of bodily material removed for therapeutic purposes from a living patient. Capacity to consent does not translate into a right to abortion, but rather signals a woman's agreement to undergo a procedure which, according to two medical practitioners, falls within the law. At this stage, consent to termination of a pregnancy is the same as that required for other medical procedures which involve the removal of tissue and bodily fluids. As we have already pointed out, English law recognises no distinction between the tissue of a fetus of fewer than 24 weeks gestation and that of the woman in whom it was implanted: woman and fetus are regarded as 'one flesh' despite

their genetic difference. Put another way, tissue of a fetus of fewer than 24 weeks gestation *ex utero* can be treated like other tissue 'left over' following clinical and diagnostic procedures of which many millions are carried out each year. As the RCOG noted in its recent guidance on the collection and use of umbilical (placental) cord blood:

The point at which the fetus becomes a person legally is when it emerges from the mother's body. Until that moment, the doctor is bound to respect the autonomy of the mother and she has unfettered right to consent to everything that is done to her body.³⁹

However, the 'one flesh' model is neither unique nor universally accepted. It emerged in the eighteenth century when pregnancy was seen as a state of symbiosis with unborn child and woman living in a state of mutual harmony: whatever was good for the woman would benefit her unborn child, and vice versa. Two new understandings of the relationship between woman and fetus were introduced in the early twentieth century: parasite and host, with pregnancy seen as potentially detrimental to a woman's physical and mental health; and the fetus as a competitor in a struggle in which either woman or fetus is forced to make a sacrifice. In suggesting woman and fetus are separate beings, these new understandings undermine the one-flesh doctrine.⁴⁰ Furthermore, as we shall see, they encourage a view of the fetus *ex utero* as a corpse.

When the Peel Committee explored the issue of consent it found no statutory requirement either to obtain the consent of the parent [sic] for research on a fetus which had died following its separation from the mother (woman) or ignore their wishes. The Human Tissue Act 1961 dealt with corpses, and did not speak to issues relating to the use of parts of bodies of living persons. Nonetheless, because death was central to its reasoning, and also because some fetuses die as a result of miscarriage, the Committee considered the issue of disposal and recommended providing women with an opportunity to declare their wishes about

it. However, it recognised that this might be a source of distress and suggested the addition of an appropriate clause to the operation consent form. Hence, a consent form drawn up in line with the Peel Committee's advice might provide three competing frames of the dead fetus: a legal one in which it is residual tissue; an instrumentalist one where it is research material; a human remains one in relation to disposal.

As we have explained, the Polkinghorne committee organized its rules, including rules on consent, around the principle of *separation* which it operationalized in two ways. First, decisions relating to abortion and to any subsequent use of the fetus must be made separately, with the former always preceding the latter. In other words, consent for the use of the fetus in research or experimental therapy can be sought only after a woman has agreed to the termination of pregnancy so that choice of method is not influenced by the research. This requirement was in response to claims by anti-abortionists that women, ambivalent about whether or not to continue with a pregnancy, were being persuaded to terminate it by unscrupulous investigators seeking fetal material for research or therapy. However termination of a pregnancy in order to provide the fetus for research falls outwith the grounds specified in the Abortion Act 1967, and the clinician who agreed to perform the procedure for this purpose would commit a criminal offence. The rule also addressed a different concern, that timing and method of abortion might be orchestrated to meet the investigator's requirements rather than the health care needs of the woman.

Second, consent must be broad, never specific. The Polkinghorne Code states that women, in agreeing to the transfer of the aborted fetus to a third party, should not be allowed to specify how or where it should be used, nor should they be informed of any specific use for which the fetal tissue is used, or whether it is used at all. This stipulation was influenced by another claim of anti-abortionists that women, motivated by either altruism or financial inducement, would conceive and terminate a pregnancy in order to provide fetal material for a specific

scientific procedure or person (sometimes described as 'fetus farming'). Nonetheless the Polkinghorne Committee recommended that consent forms should not make specific reference to any particular research or therapy, and should never suggest that any use will, in fact, be made.

The Department of Health accepted the Polkinghorne Code in 1990, the same year in which Parliament passed the HFE Act which placed on the statute book some of the recommendations in the Report of the Warnock Committee. The HFE Act provided the legal framework for the creation of embryos and their use in IVF treatment and research and, as we have already explained, established the HFEA.

Both HFE Act and Polkinghorne Code are intended to facilitate public acceptance of the use in research and therapy of contested material produced by controversial means by placing them in a strictly controlled frame. Yet they are informed by different assumptions about women's capacity to consent and the process through which it should be sought. The Polkinghorne Code insists consent to 'donate' a fetus for research must be sought after a woman has given her consent to the abortion⁴¹ whereas schedule 3 of the HFE Act, and the HFEA's Code of Practice, set out extensive requirements for individual consent to a range of activities, including research, and specify that couples [sic], before signing any consent forms, must be offered relevant information and 'implication' counseling. And whereas the Polkinghorne Code rules out specific consent, the HFE Act says couples may specify conditions for which an embryo created in vitro out of their gametes may be used.⁴² The HFE Act also limits the field of research in which the pre-implantation embryo may be used, initially to an aspect of fertility, infertility and its treatment, however, in 2001 the Act was amended to allow the use of pre-implantation embryos for stem cell research and consequently the HFEA has the responsibility for regulating all human embryonic stem cell research in the UK.

The Polkinghorne guidelines, which, we have been reassured, are still current,⁴³ somewhat paternalistically frame women as needing protection from themselves because they might either be motivated to conceive a pregnancy in order to produce a fetus for a specific purpose or individual, or be subject to the influence of researchers who put pressure on them to have an abortion (and possibly alter the method) in order to procure tissue. The Committee's decision might make sense where the aborted fetus is framed as a potential organ donor: it had been convened to consider transplants of fetal neural tissue and rules governing organ donation deny 'donors' and their families an opportunity to specify how or where organs retrieved post mortem are used. However, transplants of fetal neural tissue were and remain experimental, and fetal material is used in other research contexts.

Furthermore, the Code, almost immediately after it had been drawn up, fell out of step with developing policy on consent which increasingly insisted people are provided with an opportunity to agree to or decline activities according to personal convictions. Its paternalism was criticised in 1993 in the context of the HFEA's public consultation on a proposal to extract ('salvage') eggs in the ovaries of dead women and cadaveric fetuses as a way of ameliorating the chronic shortage of donated eggs essential in research into and therapy in assisted reproduction.⁴⁴ The response was overwhelmingly hostile. The greatest abhorrence, in the more than nine thousand submissions sent in, was expressed in relation to aborted fetuses, with nearly 59 per cent saying fetal ovarian tissue should not be allowed in research, and 83 per cent saying it should not be used in infertility treatment. Strongest opposition came from opponents of abortion who rehearsed the argument that fetal material obtained this way was tainted, a view which led to coining of the term "yuck factor".⁴⁵ The HFEA decided against licensing treatment using eggs of a female cadaveric fetus *ex utero* – a child conceived in this way would have had a mother who had never been born - but acknowledged that, if it had permitted it, differences between its standards of consent and those of Polkinghorne would have had to be reconciled. Ironically,

as a result of its decision, research using aborted fetal ovarian tissue, including stem cell research which replicates and extends that of John Gearhart which we referred to in the opening paragraph of this paper, continues under the Polkinghorne rules.

A growing chorus of complaint about the anachronistic approach to consent insisted upon in the Polkinghorne Code reached a crescendo in 2000.⁴⁶ Nonetheless, the DoH, in *Human Bodies, Human Choices*, claimed the Polkinghorne Committee's concern to prevent women terminating a pregnancy for ulterior motives was still valid. But it proposed making a distinction between using fetal tissue for a particular purpose, and using it to treat a particular individual: the latter, it claimed, clearly gave rise to the Polkinghorne Committee's insistence on broad consent, the former did not. In other words, it upheld broad consent in relation to donation for experimental transplantation and proposed specific consent in relation to non-therapeutic research. Whilst recognizing that some women may wish to have a say in every particular purpose the aborted fetus might be used, the DoH proposed a shelter is provided for women who 'may prefer not to be reminded of the events that led up to the existence of the tissue'.⁴⁷ Once again a special case is made, without adducing any moral arguments or empirical evidence, for why consent procedures might differ between women seeking an abortion and other sources of 'residual' human tissue sought for research.⁴⁸

We found wide variability in the kinds of information currently given to women being asked to agree to the use of aborted fetuses in stem cell research.⁴⁹ Some information sheets describe at length the project for which aborted fetuses are sought; some provide a brief account of several different projects in which the fetus might be used; some set out briefly a very broad field. None offer women a choice to agree to the fetus being used in some projects but not others. This variability suggests uncertainty on the part of members of RECs about whether or not general or specific consent is required or desirable. It also provides

another example of condoned non-compliance with the Polkinghorne Guidelines. No-one has taken responsibility for clarifying the situation. Yet, when Austin Smith, a leading stem cell scientist, complained to the House of Commons' Science and Technology Committee of the failure of the HFEA to provide guidelines for drawing up consent forms for potential embryo donors,⁵⁰ the MRC agreed to sponsor a review of the paperwork by a nationwide network of stem cell co-ordinators working in IVF clinics associated with stem cell laboratories, a review resulting in a standardized approach organized around the specific consent requirements of the HFE Act.⁵¹

Consent, we are repeatedly told, is the fundamental principle underpinning the work of the Human Tissue Authority (HTA), the regulatory body established under the Human Tissue (HT) Act 2004, the government's legislative response to Alder Hey and related scandals. To quote one example: 'As a regulator, the HTA sees its role as embedding best practice when obtaining consent to ensure that professional and public confidence is enhanced in matters relating to the use of human organs and tissue – a confidence based on the assurance that obtaining consent involves not just a procedure but a true, open and honest dialogue'.⁵²

As we have seen, van Velzens' collection of body parts in Alder Hey hospital included aborted fetuses. But there is reason for uncertainty over whether or not aborted fetuses are included in 'relevant material' covered by the HT Act. 'Relevant material' is defined in section 53 as 'material, other than gametes, which consists of or includes human cells', but hair and nails from a living person and embryos outside the human body are excluded. The exclusion of embryos outside the human body acknowledges the jurisdiction of the HFEA in relation to pre-implantation human embryos created *in vitro* up until 14 days post fertilisation. But, strictly speaking, it also excludes most aborted fetuses. 'Fetus', a scientific term, only comes into effect after the eighth week of gestation, when morphogenesis is complete and the embryo has assumed the form and structure of its parents.⁵³ Since the Abortion Act was placed on the statute book, the

gestational stage at which pregnancies are terminated has been lowered so that nowadays six out of every ten pregnancies are terminated in the embryonic stage.⁵⁴ Tissue for stem cell research is sought from both terminations during the embryonic stage and at later gestational age.

The HTA's Codes of Practice suggest it has accepted some responsibility for the aborted fetus. Code 5 on Removal, Storage and Disposal of Human Organs states: 'The term 'fetal tissue' is used throughout for consistency, although it is recognised that 'pregnancy loss before 24 weeks' covers a large developmental range and many different kinds of loss'.⁵⁵ Abortion might qualify as a 'different kind of loss'. Later on it suggests that, 'In drafting their policies, NHS Trusts may wish to take into account gestational age and the nature of the fetal tissue'.⁵⁶ The reader is left to decide what 'nature' might entail.

Code 1 on Consent emphasises the fetus is the woman's residual tissue but nonetheless it requires special handling. It states:

The law does not distinguish between fetal tissue and other tissue from the living - fetal tissue is regarded as the mother's [sic] tissue. However, because of the sensitivity attached to this subject, consent should be obtained for the pathological examination of fetal tissue or products of conception and for their use in all scheduled purposes regardless of gestational age. Research Ethics Committee approval is always required for the use of fetal tissue and products of conception in research.⁵⁷

This guidance fails to clarify whether consent should be broad or specific. Responsibility for deciding on 'best practice' in relation to aborted fetuses still lies with RECs who may either insist investigators comply with Polkinghorne Guidelines or sanction non-compliance.

'Sensitivity' is again invoked to explain why the dead non-viable fetus should be accorded the respect normally given to a dead person:

Under the HT Act, fetal tissue and products of conception are treated no differently from other tissue taken from a living person. Clearly however there are particular sensitivities relating to the use and disposal of such tissue.⁵⁸

However, the HTA has not clarified the kind of sensitivity it has in mind: is it the one associated with miscarriage, abortion or research? They are fundamentally different. Crudely speaking, sensitivity in the context of miscarriage relates to the sad loss of a 'wanted' child; sensitivity in abortion relates to the conflict and objections to its practice; sensitivity in the context of research might refer to objections to instrumental use of the fetus in general or in particular field of controversial research.

Guidance on disposal appears unequivocal. Code of Practice 5, Appendix B, states that a woman's wishes are to be taken into account on the disposal of fetal tissue following pregnancy loss before 24 weeks' gestation, whether spontaneous or induced termination or following ectopic pregnancy. Furthermore, the tissue may be buried, cremated or incinerated in accordance with earlier guidelines.⁵⁹ Maceration and sluicing are not acceptable methods of disposal. Burial may be at home or via local burial authorities and there may be a communal burial for disposing of fetal tissue. Yet disposal of fetuses of less than 24 weeks' gestation by communal cremation falls outside the law.⁶⁰ The Cremation Regulations apply to persons, not to pre-viable fetuses. Nonetheless, the Home Office, in the DoH's Code of Practice, *Families and post-mortems*, has sanctioned non-compliance: fetuses and fetal tissue may be cremated at the discretion of a local crematorium.⁶¹

As an afterword, paradoxically, pre-implantation human embryos are afforded the protection of the criminal law in relation to their creation and use, but both law and policy are silent on their disposal. Yet between 1991 and 2004, 814,537 were 'allowed to perish' [sic] and their 'remains' were disposed of by sluicing.⁶²

V: LEGISLATIVE CHANGES IN EUROPE RELATING TO THERAPEUTIC USE OF TISSUES AND CELLS

So far the focus of our discussion has been the collection of aborted fetuses for research in England and Wales. In Europe, the governance arrangements for the collection and use in therapies of tissue and cells from aborted fetuses have followed a different trajectory. In 1990, researchers in Europe formed NECTAR (Network of European CNS Transplantation and Restoration), aimed at developing 'efficient, reliable, safe and ethically acceptable transplantation therapies for neurodegenerative diseases', in other words, treatments using fetal tissue of diseases such as Parkinsons.⁶³ The Network identified a lack of consensus in existing national laws and guidelines, many of which were incomplete or non-existent, and decided to produce its own which drew heavily on the separation principle developed by the Polkinghorne Committee.⁶⁴

The separation principle enshrined in the Polkinghorne guidelines has been influential in other European law and policy. There is widespread agreement on the wisdom of separating the decision to terminate a pregnancy and the seeking of consent to use of the aborted fetus in research. Timing of the decision to give tissue for experimental transplantation was also considered critical⁶⁵ and different views expressed about whether consent should be sought prior to the abortion taking place or afterwards and after an appropriate 'waiting period'.⁶⁶

European law and policy also tended to frame women as needing both protection from themselves and others. The NECTAR guidelines refer to informed consent, but do not discuss whether consent should be broad or specific. However, the

European Group on Ethics (EGE), a neutral, independent, pluralist and multidisciplinary body which advises the European Commission on ethical aspects of science and new technologies in connection with the preparation and implementation of Community legislation or policies, in 1998, insisted consent should be specific:

No abortion should be induced for the purpose of obtaining foetal tissue.

In the case of deliberate or spontaneous abortion, the retrieval of the tissue requires the specific [our emphasis] free and informed consent of the woman and, where appropriate, of the couple. The timing of the termination and the way in which it is carried out must not be influenced by the retrieval of the tissues.⁶⁷

The NECTAR guidelines are voluntary, a form of professional self-regulation lacking a legal sanction. Changes in the European law may be expected to have a more significant impact on collectors and users of aborted fetuses.

The European Directive on Tissues and Cells (EUTCD) sets out standards for donation, consent, storage, testing and processing in order to protect public health and safety. This Directive arose from Europe-wide concerns in the 1990's about the shortage of organs for transplantation, global distribution of contaminated and poor quality tissues, commercialization and trafficking of organs and tissues.⁶⁸ It followed recommendations by the Council of Europe⁶⁹ and the EGE on the need for harmonization and control of standards in Europe to assure quality and safety of tissues and cells in therapeutic use. While initially intended to set standards for the collection and use of 'traditional tissues' (such as skin, bone, eyes, cornea and other tissues 'stored' in tissue banks) and to introduce international standards for tissue banks, in its passage through the EU Parliamentary process it became broader in its scope to include all tissues and cells used therapeutically (including haematopoietic peripheral blood, umbilical

cord blood and bone marrow stem cells, reproductive cells, and tissues and cells used for industrially manufactured products).

The EUTCD specifically includes fetal tissue and cells, pre-implantation embryos, and adult and embryonic stem cells used therapeutically, that is, in clinical applications.⁷⁰ So fetal tissues and cells used to derive stem cells and stem cell lines which will be transplanted into patients fell under this Directive with effect from April 2006. However, the Directive excludes all research materials, solid organs (hearts, lungs, kidneys, and so on), blood and blood products. It also does not cover non-therapeutic research using human tissues and cells, such as *in vitro* research or in animal models. Only those cells and tissues that in clinical trials are applied to the human body need comply with the quality and safety standards laid down in this Directive.⁷¹

Simultaneously, in response to lobbying from manufacturers of medical devices and tissue engineers, both of whom sought to create 'a level playing field' across industrial and non-commercial sectors, the definition of a tissue bank was extended to include all tissue establishments whether non-profit or for-profit as eligible for licensing.⁷² With effect from April 2006 in the UK and other member states, all establishments procuring, storing and processing human tissues for therapeutic use have required a license issued by a competent authority. So if fetal tissue, cells or stem cell lines derived from them, are to be stored and used for transplanting into a patient, a tissue establishment license will be needed.

Stem cell scientists in the UK face an additional challenge: not only do they have to familiarise themselves with the ways in which the EUTCD has been implemented here but, at the same time, they have to come to terms with their responsibilities under the sections of the HT Act dealing with research. Fetal tissue and cells collected, stored and used in research falls under the HT Act research licensing requirements and from 1 September 2006 requires a license from the HTA. But, to make matters more complicated, material collected for a

specific research project approved by a REC does not.⁷³ So where fetal tissue has been collected for a specific research project the researcher needs only the approval of a REC. The licensing requirements and controls over fetal tissue and cells are therefore different depending on whether they are for *in vitro* or animal research, or for therapeutic use in clinical trials or clinical practice. The HTA now has a dual role: as the competent authority responsible for implementing the EUTCD in relation to all tissues, excluding gametes and embryos which are regulated by the HFEA; and as the statutory body set up under the HT Act 2004 which includes the use of tissues and cells in research. Stem cell lines, whatever their source, fall outside the scope of the HTA Act but within the terms of the EUTCD if used therapeutically.⁷⁴

While the EUTCD specifies fetal tissues as falling within its remit, it does not override the ability of member states to restrict 'the use or non-use of any specific type of human cells, including germ cells and embryonic stem cells' or 'to prohibit the donation, procurement, testing, processing, preservation, storage, distribution or use of any specific type of human tissues or cells from any specified source'.⁷⁵ So while harmonization of standards is intended, member states may introduce stricter controls over the therapeutic use of specific types of cells, a principle of what might be called 'ethical subsidiarity' operates.⁷⁶

The EUTCD therefore has set new standards for the procurement and use of fetal tissue and cells in clinical applications.⁷⁷ While it does not apply to aborted fetuses collected for research it does apply to clinical trials or experimental transplants. However, the difference between what is called 'research grade' and 'clinical grade' material is being blurred, especially in the context of stem cell research, by the new requirement of traceability. Traceability from 'source' or donor to recipient is central to reducing the risk of transmission of viral, bacterial, fungal and protozoal agents in tissue used in transplantation or other kinds of clinical application. 'Research grade' material is material which will only be used in a laboratory setting where the safety of people handling the material is

ensured procedurally, that is, by following Good Laboratory Practices (GLP). The Medical Research Council (MRC), in the Code of Practice of the Stem Cell Bank, states that traceability is best practice for research grade stem cell lines and is required for clinical grade stem cell lines.⁷⁸ In order for a stem cell line derived from an aborted fetus to qualify as clinical grade, the woman who agrees to 'donate' the fetus for research will also have to agree to being tested for HIV antibodies, and other markers, and volunteer her medical and behavioural history, as is currently demanded from blood donors.⁷⁹

Under the new EUTCD member states have responsibilities to ensure that procurement is properly supervised and carried out by persons with appropriate training and experience and that they take place in conditions accredited, designated, authorized or licensed for that purpose by the competent authority or authorities.⁸⁰ At the centre of the discussions around consent in the European parliament was concern to uphold the principle of donation as voluntary and unpaid. However, what all of this means in relation to the collection of 'clinical grade' stem cells from aborted fetuses has received virtually no consideration. In 2002 the European Commission funded a project which aimed to produce an ethical framework for stem cell research. In its draft document no mention was made of abortion or fetuses.⁸¹

In addition new European product legislation which will relate to cell therapies and tissue engineered products placed on the market is being prepared and debated in the European Parliament.⁸² This will add another dimension to the regulatory requirements for therapies and products derived from fetal material. While the final form of the regulation is yet to be agreed, controversially it could place therapies using fetal stem cells within the regulatory regime for medicinal products.⁸³ Compliance with 'good manufacturing practices' (GMP), additional quality assurance procedures and testing of products will be necessary for the commercial exploitation of therapies using materials derived from aborted fetuses. In other words, the aborted fetus itself will acquire exchange value in a

system which insists on so-called voluntary gifting of tissue. This development raises issues about whether women will be willing to support the development of commercially available therapies from aborted fetuses and what kinds of information might be given to them at the time of collection about end use of such products. Patentability issues relating to the inventions using embryonic and fetal tissue will also need to be resolved.⁸⁴

While the new European Directives do not ‘interfere with provisions of Member States defining the legal term ‘person’ or ‘individual’⁸⁵ (para 12) they represent new challenges for the effective regulation and governance of the therapeutic use of fetal tissue and cells.

VI. CONCLUSIONS: CONVERGENCE, CONFLICT OR RE-FRAMING

The Polkinghorne Committee, in its report, rehearsed the Warnock Committee's comment on the illogicality in their proposing stringent legislative controls on the use in research of very early pre-implantation human embryos while a less formal mechanism governed the use in research of whole live embryos and fetuses of more advanced gestation.⁸⁶ The Warnock Committee met in 1984 and was referring to the Peel Code; it suggested the anomaly be given urgent consideration. However, as we pointed out, the anomaly was perpetuated when the Polkinghorne Guidelines were published just a year before the HFE Act was placed on the statute book.

Arguably, the disparities between the different regulatory frameworks present little inconvenience where pre-implantation embryos and aborted fetuses are sought for separate and distinct fields of research, for example, where the former are collected for research into miscarriage and the latter for virology. However, stem cell scientists collect and use both, and must negotiate the disparities between the two regulatory frameworks. In the UK, up until now, the licensing of

IVF clinics by the HFEA has provided an exceptionally high level of scrutiny, transparency and accountability for the creation and use of pre-implantation embryos in stem cell and other research. But, as we have argued, almost the opposite situation applies in relation to aborted fetuses.

Nonetheless, the regulation of pre-implantation embryos and aborted fetuses, which have hitherto been distinctive, are being drawn into the same regulatory space. As we explained, they both fall under the EUTCD and in 2008 the HFEA and HTA will merge to create a Regulatory Authority for Tissues and Embryos (RATE) with statutory responsibilities for the implementation of the EUTCD, the HFE Act (currently under review),⁸⁷ and the HTA Act. Under RATE and the EU legislation, we anticipate the regulatory boundaries between pre-implantation embryos and aborted fetuses becoming increasingly problematic: neither is a stable regulatory object. The pre-implantation embryo, like the aborted fetus, lacks integrity because it simultaneously occupies several different frames. As has been suggested:

The human embryo may be represented as a person-in-the-making in the informal practice of an in vitro fertilization (IVF) clinic or an 'adoption agency' that 'places' it for implantation. At the same time, it may be denied personhood under laws governing abortion or compensation for personal injury.⁸⁸

We suggest that while hitherto 'embryos' and 'fetuses' appear to inhabit different frames, these changes in law and governance arrangements increase the potential for leakage between them. Pre-implantation embryos and aborted fetuses are not *a priori* ontologically distinctive entities but are constructed regulatory objects.

It may be the case that the emerging contradictions provide incentives for reorganizing collective understandings of kinds and categories into new, more

coherent and encompassing frames. However, in our view, it is unlikely that pre-implantation embryos and aborted fetuses will be fitted within the same framework primarily because that would necessitate a review of the Abortion Act, something which government seems unwilling to encourage. In all probability, informal regulatory techniques such as quasi-official guidelines and sanctioned non-compliance will continue to be used with respect to aborted fetuses. This seems to be the official line: in researching this paper, we experienced considerable difficulties in finding out whether or not the Polkinghorne Code still applies but received assurances that it does even though some researchers operate outside the guidelines with REC approval. The DoH organised an informal review, behind closed doors, of the Code of Practice in 2004 but it was abandoned in anticipation of the HT Act 2004 which transferred responsibility for the Guidelines to the newly established HTA who themselves claim not to have responsibility for this area of policy development.⁸⁹ There is a continuing reliance on the research governance system, via RECs, which meet in secret, to approve this research outwith national oversight. What this means is that a transparent and accountable system of regulation may not emerge for aborted fetuses and that the claim that British scientists enjoy a transparent, open and accountable system of regulation for stem cell science will continue to apply only in relation to pre-implantation human embryos.

None of this precludes a review of the Polkinghorne guidelines paternalistic position on consent which would bring them into line with currently accepted standards for other 'residual' tissue collected for research, take into account the additional burden on women where traceability is required, and consider issues around commercialisation. It should acknowledge that abortion nowadays is a common procedure which one in every three women under the age of 45 will undergo,⁹⁰ and that these women are capable of making complex decisions in difficult circumstances. Put another way, women who perceive their current pregnancy as 'unwanted' should be re-framed in a positive light.

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¹ See, for example: In a 2004 press release it was reported that 'The Human Fertilisation and Embryology Authority (HFEA) is announcing details of all research licence applications. From today, titles of all research licence applications along with lay summaries of the proposed project will be published on the HFEA website. Suzi Leather, HFEA Chair said: "Giving everyone access to this information is the latest move by the HFEA to increase the transparency of the Authority's work. Human embryo research is strictly regulated in the UK. Parliament has provided the framework in which human embryo research can take place and the HFEA looks very carefully at the scientific, ethical and medical issues before granting a licence." Press release 7th May 2004 at <http://www.hfea.gov.uk/cps/rde/xchg/SID-3F57D79B-51DE0B78/hfea/hs.xsl/1039.html>.

In 2004 HFEA Chief Executive Angela McNab said in presenting its Annual Report: "As an organisation, we have undergone substantial modernisation over the past year, which has resulted in a more effective performance, greater transparency and improved communications with our stakeholders and the public". Press release 25th November 2004 at <http://www.hfea.gov.uk/cps/rde/xchg/SID-3F57D79B-51DE0B78/hfea/hs.xsl/1053.html>.

See also HFEA 2005 *Public attitudes to fertility treatment, embryo research and the regulation of this work*

Preliminary findings from the UK at <http://www.hfea.gov.uk/cps/rde/xchg/SID-3F57D79B-51DE0B78/hfea/hs.xsl/1053.html> (all accessed October 2006).

Medical Research Council 2005, *Code of Practice for the use of human stem cell lines*. "In the UK, research involving human embryos, including the generation of human embryonic stem cell lines is under statutory control by the HFEA. Embryonic stem cell lines once established are not embryos and the Government decided that research involving established stem cell lines does not need the same level of regulation to which embryo research is subject to by the HFEA. However, as the generation of embryonic stem cell lines involves the destruction of human embryos oversight in the form of a Steering Committee was recommended to ensure that research is conducted within an ethical framework that is transparent to the public and is in keeping with HFEA Regulations" page 2. And "The Code should provide confidence and reassurance to professionals and the public alike that stem cell research in the UK is performed to best practice and is conducted within a transparent and ethical framework. The main emphasis

of the Code is on human embryonic stem cell lines but reference to stem cell lines derived from other human tissues are included...." page 5.

"UK legislation ...is considered to be among the most clear, comprehensive and responsible in the world." N. Perrin, UK Trade & Investment 2005, *The global commercialisation of UK stem cell research* page9;

"Without doubt, the enabling and consistent regulatory environment is currently one of the strongest assets to UK stem cell research." UK Stem Cell Initiative 2005, *The Pattison Report: Report and Recommendations* page43;

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⁸ N. Pfeffer, 'Fertility counts: from equity to outcome' in S. Sturdy (ed.), *Medicine, health and the public sphere in Britain, 1600-2000* (Routledge 2002) at 260-278.

⁹ S. Sheldon, *Beyond control: medical power and abortion law* (Pluto 1997) at 33.

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See also Audit Commission 1997 *Getting sorted: the safe and economic management of hospital waste*, (London Audit Commission).

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³⁰ The Polkinghorne Report *Review of the Guidance on the Research Use of Fetuses and Fetal Material* (HMSO) (Cmnd. 762 1989) at 6: section 3.2.

³¹ The Polkinghorne Report *Review of the Guidance on the Research Use of Fetuses and Fetal Material* (HMSO) (Cmnd. 762 1989) at 9: section 4.3.

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"It is worrying that the separation is encouraging a lack of interest in research among clinicians and a lack of awareness of the human background to their work among researchers. We should be aiming to develop a cadre of clinical academic researchers who are ethically literate and who are capable of conducting this type of research in an ethical manner. Such individuals have a breadth of knowledge and experience that can be a safeguard against unethical practices and we are in danger of losing them." Royal College of Obstetricians and Gynaecologists 2004 *Response to MRC draft code of practice for the UK stem cell bank* section 4.3. <http://www.rcog.org.uk/index.asp?PageID=1349> (accessed 25 February 2006).

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³⁵ Sanctioned non-compliance or acceptable non-compliance is preferred where either strict adherence to the law could render certain processes inoperative or where legislation is felt to be out of step with public opinion. B.M. Hutter, *Compliance: regulation and environment* (Clarendon Press 1997) at 81.

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