Who owns embryonic and fetal tissue?

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Background: why does ownership of embryonic and fetal tissue matter?

Until very recently the question of who owns embryonic or fetal tissue was of limited commercial importance, although there were applications of aborted fetal tissue in the treatment of Parkinson's disease, diabetes mellitus and other conditions. With a few exceptions the use of embryonic tissue was, so to speak, a non-issue (Boer, 1994), although the use of ovarian fetal tissue was specifically forbidden by Parliament.

By mid-1999, however, commercial exploitation of stem cells had been termed the most controversial ethical issue in biomedicine (Capron, 1999). The threshold event occurred in November 1998, when two separate teams of US scientists claimed that they had managed to isolate human embryonic and fetal cells and grow them indefinitely under laboratory conditions. These pluripotent and/or totipotent cells are effectively the parent cells for all bodily tissues, with an unlimited capacity to divide and the theoretical potential to become any body tissue. (Some authors equate pluripotent and totipotent cells, but others distinguish between totipotent cells, at the 2–4 cell stage, which are capable of giving rise to every cell line in the body and to an entire human individual, and pluripotent cells, which are derived from the blastocyst at a slightly later stage of development, when the outer and internal cells have already become differentiated.) Provided that the subsequent differentiation of embryonic stem cells can be controlled, it may conceivably be possible to use embryonic and fetal tissue to produce bone marrow, blood and brain tissue for transplant – eventually perhaps, any bodily tissue or organ, although this possibility is some years distant. For example, healthy cultured cardiac cells could be injected into damaged heart muscle following myocardial infarct. (In mice, heart muscle cells have been derived from embryonic stem cells injected into, and successfully integrated with, the heart muscle of adult animals.) Neurological stem cell transplants might be particularly promising because the risk of rejection is moderated by the brain's unique immunological status (Nuffield Council, 2000: p. 4). As one of the scientific teams stated,

We could make universal donors. More specific cells could become transplant therapies for diabetes, spinal cord injury, neurodegenerative disorders like Parkinson's disease, muscular dystrophies, arteriosclerosis and wound healing.

The use of stem cells would also streamline pharmaceutical testing; new drugs could be tested for safety and efficacy on cultured stem cells before being tested in humans. Thus pharmaceutical and biotechnology firms are hugely interested in the use of such cultured cells and in the development of tissue banks of both undifferentiated and specialized cells and tissues. Six to eight pluripotent cell lines have already been developed, in the US and Singapore, although some estimates (as of July 2001) cite up to 30 worldwide (Phillips, 2001). Eventually the need for embryo 'donations' should lessen as the self-replicating stem-cell lines grow in size. But does this mean that the ethical issues will disappear? Hardly. The enormous commercial value of these cell lines, which will increase with their size, raises profound issues of justice and exploitation, particularly issues of property rights.

Both the US teams were funded by the Geron Corporation, an American biotechnology company which is now seeking a patent on the technologies. At the time of writing, late in 2000, the UK's Roslin Institute, which produced the Dolly cloning technique, was reported to be exploring collaboration with the Wisconsin researchers, with a view towards deriving cells from adult patients that could be cloned using isolated embryonic stem cells. The aim is to develop cell therapy rather than manufacturing tissues and organs, with the advantage of avoiding immunological rejection problems. By a remarkable coincidence, the Geron Corporation also has a major interest in the commercial arm of the Roslin Institute. The globalization of stem cell research and application is already upon us. It will almost certainly mushroom into an international trade in embryonic stem cells. German research groups already are using embryonic stem cells imported from other 'less moral' countries such as Denmark, Finland, Spain, Sweden and the UK, since the German Embryo Protection Act of 1990 prohibits any retrieval of cells from embryos, under criminal penalties (Lunshof, 2000).

One of the US teams, based at the University of Wisconsin, produced their cells from blastocysts developed in vitro as part of infertility treatment. The second team, from Johns Hopkins, used what they called primordial germ cells, which would eventually have become gametes. Interest has mainly focused on embryonic stem cells (ES cells) rather than embyronic germ cells (EG cells), where attempts to derive adult cells in mice have led to abnormalities. Use of ES cells has also been assumed to be less ethically debatable, because it does not require abortion, or because pre-embryos are thought to have a lesser moral status than fetuses. I think it is far from obvious, however, that use of ES cells is ethically trouble-free; that is because I shall focus not on the status of the fetus/embryo, but on the rights of the mother.

The Wisconsin method uses embryos grown in vitro, developed through

fertilization of the mother's ova with the father's sperm – primarily 'spare' embryos which are not to be implanted. (It would also be possible to create embryos from gametes 'harvested' expressly for this purpose.) Stem cells are derived from the inner cell mass of the blastocysts; the outer cellular layer, which would normally develop into the placenta, is dissolved. Since the blastocysts are used before implantation, the mother's 'sweat equity' is reduced, but she has still undergone the labour of stimulation with fertility drugs (superovulation) and extraction of ova – painful and moderately risky procedures.

The Johns Hopkins method of using primordial gamete cells relies on aborted fetal tissue, into which the mother has put the labour of early pregnancy. John Gearhart's team at Johns Hopkins derived stem cells from primordial germ (gonadal) cells of fetuses aborted five to nine weeks after fertilization. Oddly, although using aborted fetuses might appear to be the more ethically and legally controversial of the two methods, the Hopkins technique does not contravene federal restrictions, whereas limitations have been imposed on the use of the Wisconsin method. The ethically significant difference seems to be that life is not deliberately created in the Hopkins case, as by the admixture of gametes to form early-stage embryos, and the fetus is dead before research starts, even if the cells are still alive. In the Wisconsin method, the embryo is effectively killed by removal of the outer layer of the blastocyst (Capron, 1999).

Although the two techniques raise separate moral and legal questions, commentators have united in approaching both of them almost solely through focusing on the moral status of the embryo or fetus. So far as the mother (and sometimes father) are concerned, the only legal and ethical issues are usually held to concern the quality of consent to further uses of the embryonic and fetal tissue. For example, the Nuffield Council on Bioethics group (2000: p. 1) concluded that 'the removal and cultivation of cells from a donated embryo does not indicate lack of respect for the embryo'. UK Parliamentary debate before the Human Fertilisation and Embryology (HFE) Act of 1990 had culminated in agreement that embryo research is morally acceptable if confined to the period before development of the primitive streak, and if no embryo on which research has been performed is re-implanted in a uterus. Since a donated embryo from IVF (in vitro fertilization) procedures is normally 'surplus' to requirements, and will not be implanted in a uterus, the Nuffield Council committee concluded that there were no moral objections to use of such embryos to create a stem cell line, provided that parental consent was obtained to this further use. The alternative is to allow the embryo to perish; the embryo has no future life, and thus it is not being robbed of any entitlement to life. Although the embryo does not benefit, it loses nothing, whereas other future persons may benefit from therapeutic research using embryonic stem cell lines (Nuffield Council, 2000: paragraph 22).

This is a straightforward utilitarian line, which appears to consider that the only deontological arguments that might be deployed concern the fetus. But even if we concede that the embryo or fetus has no rights which could give rise to duties to refrain from stem cell development, that says nothing whatsoever about the rights of the parents, and particularly about the rights of the woman. The remainder of this chapter will concentrate on the risks of exploitation of pregnant women, and conversely on the arguments in favour of their possessing a property right in stem cells derived from their embryos or fetuses, in addition to the procedural right to give or withhold consent to the further use of those tissues. This new focus is particularly urgent if the UK does implement the Nuffield Council recommendation to allow research involving human embryos for purposes of developing tissue from embryonic stem cells, amending existing legislation (Schedule 2 of the HFE Act). At present there is no plan to create ES cells deliberately for this purpose, provided that sufficient cells can be obtained from donated surplus IVF embryos. However, even this comparatively modest proposal raises difficulties about possible exploitation of vulnerable couples undergoing IVF, and particularly about the claim-rights of women.

These rights can be viewed in a Lockean fashion, as derived from the labour which women put into the processes of superovulation and egg extraction (for ES cells) or early pregnancy and abortion (for EG cells). Alternatively, a Marxist feminist interpretation would emphasize the added value which women put into the 'raw material' of gametes. If the Marxist interpretation is preferred, one would focus interest on women's alienation from their reproductive labour, and on the exploitative transfer of rights in the products of that labour to private commercial companies. For the purposes of this discussion, either the liberal or the Marxist model is valid. However, most of my discussion will be more Lockean than Marxist.

Property, persons, pregnancy and progeny

It is important to emphasize that Locke does not say we own our bodies; only God does. What we do own is our labour, which is the expression of our moral agency or personhood; this is what Locke is referring to when he declares that 'Every man hath a property in his own person' (Waldron, 1988; Dickenson, 1997). To extrapolate this argument to organs and tissue, no other parts of the body are owned, because we do not put labour into creating our own bodies. Only the products of pregnancy can be viewed as rightfully belonging to the pregnant woman, because she puts labour into them. On a straightforwardly Lockean account, women should have a presumptive property right in the products of pregnancy.

In the *Moore* case it was arguable that even if Moore lacked a right in his

T-cells, the hospital and researchers did as well, resulting in a stand-off (Gold, 1996). What we have here is an excellent example of the old maxim, 'Hard cases make bad law'. The *Moore* case exhibited such egregious abuses of the patient's informed consent that the legal judgment turned almost entirely on those abuses. (Not only was Moore never told that his original splenectomy had yielded T-cells with remarkable immune powers, developed into a $3 billion cell line; he was asked to keep returning to donate all manner of other bodily products on the pretext of further therapy and check-ups.) The wider issue of development rights in Moore's cell lines was decided in a manner that arguably breaches previous legal precedents (Gold, 1996), by awarding all such rights to the researchers and the hospital board of regents. It may be that the patient does not own the tissue, but does that necessarily mean that the researcher or hospital does? If we wish to avoid commodification of tissue by allowing the patient tradeable rights, why are we so willing to allow commodification by allowing them to the researchers?

The assumption in the case of ES and EG cells, however, must be that the woman has a presumptive right in these cells, outweighing the rights of the clinic and researchers. Possibly some such inchoate recognition of pregnant women's property rights in fetal and embryonic tissue actually lies behind the provisions in both the Polkinghorne report and the report of the US National Bioethics Advisory Committee (NBAC) prohibiting women from directing the uses to which such tissue should be put (Polkinghorne Committee, 1989; NBAC, 1999). Yet whereas women's exercise of rights in the tissue derived from their pregnancies is closely scrutinized, we can predict that if somatic cell transfer ever becomes a possibility, donors will be able to specify the use to which that tissue will be put. If there were similar rules for embryos to the Polkinghorne rules forbidding directed donation for aborted fetal cells (to family members or other named individuals), the commercial appeal of the somatic cell technique would vanish, since the main use is to be transplantation of autologous cells or tissues grown from stem cell lines derived from embryos cloned from patient's own DNA (Capron, 1999: p. 27).

In the case of both ES and EG cells, of course, the father has also made a genetic contribution, but, I would argue, not a donation of his labour. It is obscene in more than one sense to compare masturbation to produce sperm with superovulation and egg extraction. To argue for the father's ownership of either blastocysts grown in vitro or embryos, then, one would have to assert that his right derives from his ownership of his sperm or genes, but I have already argued that we do not actually own parts of our body, including gametes and genes. The 1990 HFE Act supports this interpretation insofar as it pays gamete donors expenses; the Authority and the clinics it licenses are not purchasing gametes, but recompensing donors for loss of time and travel expenses. I have argued elsewhere that abuses have occurred under the Act (Dickenson, 1997), not least the clinics' practices that have effectively left

women paying to donate gametes, but the principle in the Act is clear. In the US, common law has sometimes supported the notion of the father's genetic ownership of the fetus, as in the *Baby M* case. Here a commercial 'surrogate' mother was required to hand the baby over to the contracting couple, but on legal reasoning which actually invalidated the notion of contract at the same time as upholding the particular contract. In the judge's words, the father 'cannot purchase that which is already his', by virtue of his genetic input (*In the Matter of Baby M*, 1987). This case represents the unpleasant extreme of allowing ownership by virtue of genetic property in the body. Nor is it clear why the gestational mother, who was also the genetic mother, was not seen to 'own' the baby, on this reasoning. It is not a model I wish to follow.

Far from affording the pregnant woman rights in the embryonic and fetal tissue that she has laboured to create, most current policy documents concentrate on making sure that she freely gives up any such rights, through giving a clear and separate consent to use of the tissue for research and therapeutic purposes. This exhortation in the name of the 'gift relationship' (Titmuss, 1997) is the strategy suggested separately by the NBAC Report (1999) in the US, and by the Medical Research Council working party and the Nuffield Council commission in the UK. The advisory report from the Geron corporation ethics group (Lebacqz et al., 1999) is slightly franker in advising that women donating embryonic or fetal tissue should be told about market value, but one suspects that this proviso is inserted merely to stave off *Moore*-type legal actions. Given the vulnerability of IVF patients, and their typical gratitude towards the clinicians for giving them any chance of a child, there is plenty of room for exploitation. As Lori Knowles puts its, there is a 'tension between the altruism individuals are supposed to exhibit by donating their tissue for research and the current patent system, which encourages companies to stake lucrative property claims in that research' (Knowles, 1999: p. 38).

'In law, a tangible thing is either a person or property, and if it is one it cannot be the other' (Knowles, 1999: p. 39). In the US and UK, although palpably not in Germany, it is widely agreed that the blastocyst is not a person. Therefore it must be property, as the Geron Corporation is happy to agree; but it does not follow from this that the property necessarily belongs solely to the Geron Corporation or its equivalents. In the *Moore* case it was argued that granting any form of property rights to the tissue donor, Moore, would impede the free flow of scientific research – but so, of course, do patents on cell-lines and genes by biotechnology companies. The issue of *whose* property, for *whose* benefit, needs a wider airing than it has so far received in the stem cells debate. As Knowles (1999: p. 40) cogently states:

> Fears about a market in human body parts and about commodifying human reproduction have prompted many to suggest that couples should not sell their embryos. The same arguments are used to argue that donors should not share in the profits

resulting from research on their embryos. In property law, however, restrictions on sales are prompted by the nature of the property itself, not by the status of the person claiming a commercial interest. Therefore, if it is wrong to commercialise embryos because of their nature, then it is wrong for everyone. It is simply inconsistent to argue that couples should act altruistically because commercialising embryos is wrong, while permitting corporations and scientists to profit financially from cells derived by destroying those embryos.

Models of ownership for embryonic and fetal tissue

What are the models to follow in the stem cell debate? We could adopt one of at least three possible approaches to ownership of embryonic and fetal tissue.

Status quo

In this model we would uphold the law's primary concentration on obtaining consent from the donor of the tissue, rather than conferring property rights on her. This is the basis of guidelines from the American College of Medical Genetics, which establish that patients must be asked for consent before research is done on tissue samples (American College of Medical Genetics, 1995). It was also roughly the approach of the UK Polkinghorne Committee (1989), although the scope of profitability and commercial application of tissue has moved on enormously since then. Given, however, that 'informed consent is no part of English law' (*Sidaway*, 1985) this is unlikely to provide satisfactory protection for women. The very favourable public image of IVF is another problem: there is not going to be much pressure on IVF clinics to justify what they do with blastocysts obtained as part of infertility treatment. Couples may be pressured to agree that 'spare' blastocysts can be used for commercial purposes, perhaps in exchange for reduced cost of treatment cycles.

This first model continues to maintain what has become a fiction in actuality, if a fact in law: that tissue extracted after procedures is no longer of any interest to anyone. Yet between 1976 and 1993 Merieux UK collected 360 tons of placental tissue annually from UK hospitals for sale to French drug companies (Nelkin and Andrews, 1998). Almost certainly, none of the mothers was asked for consent to this use of the placenta grown in her body, and expelled as the final stage of her labour in childbirth. In Canada, a similar practice was reversed after a Sicilian woman asked for the placenta, in order to carry out the custom of eating it; only then did the extent of the scandal become known (J.-L. Baudouin, pers. comm., 1999).

Similar issues arise in relation to umbilical cord tissue. In 1988, a French team under Dr Elaine Gluckman developed a process for turning umbilical cord blood into a substitute for bone marrow in transplantation. The team

originally envisaged communal, non-profit banks of umbilical cord blood, but the process was quickly taken over by private firms, who marketed their own reprocessed blood back to the mothers as a form of insurance, to be stored for their babies (Sugarman et al., 1997). Likewise, a method of cryo-processing stem cells from neonates was patented by the US-based Biocyte Corporation in 1991, assuring the firm rights over therapeutic services in both the US and Europe.

In the face of full-scale commercialization elsewhere of life forms, following the 1980 US decision in *Diamond* v *Chakrabarty* and the 1998 decision by the European Parliament to support patenting of life in order to maintain competitiveness with the US, we need better protection than the common law has previously afforded us. The amount of original input necessary to obtain a patent is minimal – for example, a patent on a diagnostic test for Down's syndrome was given to a researcher who merely established a correlation between a particular hormone level and the syndrome, not the test itself. Researchers have been given patents on particular gene sequences without even having established their function. Not much labour has been 'mixed' with the natural substance in these cases.

What restrictions have the biotechnology companies so far imposed upon their researchers? The Geron Ethics Advisory Board code (Lebacqz et al., 1999: p. 31) specifies that 'the blastocyst must be treated with the respect appropriate to early embryonic human tissue'. This means 'ensuring that it is used with care only in research that incorporates substantive values such as reduction of human suffering' (Lebacqz et al., 1999: p. 33). But as Knowles points out, this is a very low threshold, met by almost all medical research. In any case, Geron had already obtained and begun stem cell research on embryos before appointing an ethics board to draw up guidelines, implying that these guidelines were purely an afterthought (Tauer, 1999).

There are straws in the legal wind, however, of which the UK *Kelly* decision (*R.* v *Kelly*, 1998) on theft of body parts could be one (an argument which I shall develop further in the third option). Other jurisdictions also offer alternative legal models, for example, France, where human tissue cannot legally be bought or sold, although limited use of embryonic tissue is allowed (in contradistinction to the apparently ethically correct but commercially wide-open situation in Germany.). This leads us on to the second option.

Strict regulation of commercialization

So far, this second approach has not manifested itself much in practice in the US or the UK, and it is likely to face even greater obstacles as commercial interests gather further momentum. To some considerable extent, however, the UK already regulates assisted reproduction, through the statutory regulatory body established by the HFE Act 1990. In vitro research on human

embryos is illegal without a licence from the Human Fertilisation and Embryology Authority (HFEA), for both the project and the premises in which it operates. The uses of fetal tissue (relevant to EG cells) are regulated by guidelines set down by the Polkinghorne Committee (1989), aimed at maintaining a strict divide between the decision to undergo an abortion and the decision to allow further uses of aborted tissue. The Polkinghorne review also concluded that research ethics committee approval must be sought for 'all proposals for work with fetuses or fetal tissue, whether alive or dead, and whether classed as research or therapy, because of the high level of public concern'. In the wake of the Bristol inquiry and the Alder Hey hospital scandal over the retention of dead children's organs, the public is no doubt still concerned. But there are no statutory provisions in the UK governing the uses which can be made of aborted fetal tissue; as with the *Moore* judgment, the focus is solely on the correctness of the procedure, not on the uses made afterwards of the 'tissue' removed.

No research can be authorized on embryos older than 14 days, but that provision would still allow the method developed by the Wisconsin team, using blastocysts, under license from the HFEA. None the less, there are mounting commercial pressures, by which I include pressures from the leading IVF clinics, to repeal the 14-day rule and to end regulation altogether. These pressures were manifest in the deliberations of the Chief Medical Officer's expert advisory group on therapeutic human cloning, where IVF specialists argued that schedule 2 of the HFE Act already permitted stem cell line development – even though the techniques described in this chapter, and the cloning technologies which give them commercial importance, were completely unknown at the time the Act was passed in 1990. This argument was successfully resisted by the legal expert on the committee, but pressure will continue to mount for altering schedule 2 – particularly now that the Nuffield Council on Bioethics has recommended doing so. Likewise, the HFEA and the Human Genetics Advisory Commission have recommended that the Secretary of State should add two further purposes to the primarily reproductive diagnostic ones now mentioned in schedule 2: 'developing methods of therapy for mitochondrial diseases' and 'developing methods of therapy for diseased or damaged tissues of organs' (HGAC/HFEA, 1998). This latter proviso, very broadly couched indeed, would effectively give *carte blanche* to the IVF clinics for commercial exploitation of stem cell lines. The arguments for therapeutic benefit of stem cell commercialization seem to be in the ascendant in the UK at the moment, which does not augur particularly well for strict regulation.

In the US, the NBAC has approved stem cell research if done with close oversight, as long as embryos used as sources of stem cells would otherwise have been discarded. Federally funded research is now permitted on stem cells themselves, so long as the work of deriving cells from embryos is done

with private money – getting around a ban which has existed since 1996 on embryo research. This seems an unattractive variant of regulation, however, leaving the biotechnology companies to garner federal funding for further development of the cell lines which they have already produced themselves (Cahill, 1999).

Some commentators (e.g. Gold, 1996; Knowles, 1999) have proposed that commercial researchers and firms should be permitted to 'commodify' stem cells and other bodily tissues, but only under the condition that they return a share of the profits to the National Health Service or the wider political community. In this model, donation would remain altruistic, but firms should be obliged to make cell lines widely available and to price the products derived from them at an affordable level – under pain of penalties from a patented biotechnology products review board. As a pragmatic solution, this proposal is attractive, but I want to propose something different.

Vesting control over all tissue in the mother, and treating alienation of it from her as theft

A feminist model sensitive to women's alienation from their reproductive labour might want to take a more radical tack than regulating commercial interests. I have already hinted that the recent decision in *Kelly* might be construed favourably to women, provided we make two assumptions:

(1) embryonic or fetal tissue is akin to parts of a corpse (even though it has never been a living person) and putting labour into bodily parts of a non-living body conveys some sort of property right;
(2) the labour which the woman puts into superovulation and egg harvesting (in the case of blastocysts and other forms of human embryo) and into pregnancy and childbirth (in the case of umbilical cord blood and placental tissue) gives her a right over the tissue.

This need not be a fully-fledged property claim, and given the legal and philosophical incoherence of the concept of property in the body, it probably should not be. It need only be as great as the scope delineated in *Kelly* – enough to protect the tissue from being appropriated by others, under penalty of the Theft Act. In his influential model, *A Theory of Property*, Stephen Munzer argues that 'persons do not own their bodies, but they do have limited property rights in them' (Munzer, 1990: p. 41). These he views as primarily powers (to transfer, waive and exclude others from the use of one's body parts) rather than as claim-rights (to possess, use, manage and receive income) (Munzer, 1990: p. 22; following Honore, 1961).

Even with these two assumptions, there are still problems. Vesting control over tissue in the mother may not be sufficient to protect the woman from exploitation by commercial interests. Those interests surpass any in surrogacy, where it is difficult enough to distinguish between allowing women to

contract as equals and opening them to exploitation. Arguably, thinking of the mother as having any kind of property interest in fetal tissue or the tissue by-products of pregnancy is also false to the uniqueness of the relationship between the woman and the developing fetus (Mahowald, 1994).

None the less, the great advantage of this model is that it recognizes what women do and endure in infertility treatment, pregnancy and childbirth. It gives them a property in the labour of their persons and the products of that labour. This is not the same as owning a baby, which is not what we are talking about in the case of embryonic stem and germ cells. It is difficult to believe that placental tissue could have been 'harvested' without anyone's noticing that the mother might have something to say about it. Yet the ignoring of women's labour is pervasive throughout the discussion of rights over fetal and embryonic tissue (Mahowald, 1994). This third model makes sure that women's labour gets noticed.

If the second model is unlikely to succeed, however, why should the third have any chance at all? One reason is that it foregrounds the need to assign an owner to the tissue, that is, the bankruptcy of the traditional doctrine of *res nullius* in the face of commercial interests that want to make very sure that the *res* is definitely not *nullius*. Whereas regulation, in the second model, accepts that commercial interests or academic researchers own the tissue, but must bow to a certain degree of societal control over their actions, the more radical model actually affords a better chance of litigation establishing that their ownership is not free and clear. If all the women whose placentas were 'harvested' had to be compensated or indeed acknowledged, that would be quite a disincentive.

Near where I live, a motorway was planned to cut through an area where rare butterflies abounded, 'Alice's Meadow'. Hundreds of local people each bought a one-metre square of the meadow, and all their claims had to be adjudicated before eminent domain could be given. The motorway went elsewhere. It's a thought, isn't it?

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