BioSocieties (2006), **1**, 71–90 © London School of Economics and Political Science 2006
doi:10.1017/S1745855205040081

Embryonic Economies: The Double Reproductive Value of Stem Cells

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Abstract
Human Embryonic Stem (hES) cell research has met with a mixed reception internationally, but in the UK remains a significant national priority. Management of what is called the 'national embryo supply' in the UK involves new forms of governance at the 'IVF–Stem cell Interface', where questions about the provenance of donated embryos, including the ethics of their sourcing, are at a premium. This article explores the question of embryo donation to stem cell research from the perspective of the increasing proximity of IVF and hES cell derivation, using a model of 'double reproductive value' to explore what forms of exchange and flow are occurring, and how these are defined and negotiated in the context of a national hES cell coordination network of practitioners.

Keywords Embryo donation, IVF, Stem cells, Informed consent, Reproduction

It is a notable feature of the field of reproductive biomedicine that its development is characterized by distinct national profiles, or what Jasanoff describes as 'styles of governance' (Jasanoff, 2005). Even within Europe, the divergences between these styles are striking, and, as Rabinow (1999) has chronicled in his account of 'French DNA', they are also complex in their formation. As the case of the United States has shown, these 'styles of governance' can have significant effects on emergent fields of biomedical innovation such as stem cell research. These differences in the profile of reproductive biomedicine in Europe and elsewhere have direct implications for the shape and contours of scientific innovation, and are thus a prominent reminder of the ways in which even the 'hard' sciences are powerfully shaped by social and cultural factors. They also demonstrate the extent to which both public and political support are necessary for certain areas of the life sciences, most prominently the derivation of human embryonic cell lines, to become scientifically or economically viable. Uniquely, this field also depends on a reliable supply of embryos donated to research from assisted reproduction clinics. This question, of what in the UK is called the 'national embryo supply' and its source in what I call 'the IVF–Stem cell interface', comprises a crucial, but under-researched, dimension of hES cell derivation and its economies, including the sourcing, distribution and management of valuable research embryos, and the question

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of what reciprocities will 'return' from these donations, either to specific individuals or in the form of a more diffuse idea of 'common good'.[1] In addition, this interface, between the context of assisted conception and human embryonic stem cell derivation, is a microcosm of wider issues we often understand in terms of science and its 'publics'.

In this article I am building on the work of several other scholars who have begun to examine the increasing proximity of hES cell derivation to IVF in terms, for example, of patient perceptions of embryo donation to stem cell research (Koch *et al.*, 2005; S. Parry, 2005; see also note 4), media representations and public concern about embryonic stem cells (Döring and Zinken, 2005; Kitzinger and Williams, 2005; Williams *et al.*, 2003) and the wider implications of these issues (Cohen, 2000; Dickenson, 2005; Ganchoff, 2004; Hogle, 2003; Holm, 2002; Liddell and Wallace, 2005; B. Parry, 2005; Rapp, 2003; Salter, forthcoming; Sperling, 2003; Squier, 2004; Waldby, 2002; Waldby and Squier, 2004; see also Franklin, 1999a, 1999b, 1999c, 2001a, 2003b,c, 2005). The approach here focuses on the IVF–Stem cell interface, the question of the 'national embryo supply, and the 'double reproductive value' of hES cells in order to more precisely model the transitions in meaning, value and form that characterize this emergent and contested field of intertwined biomedical and biosocial investments.

A 'special case'

The value of embryos within the UK context of hES cell derivation is complicated, paradoxical and over-determined: they are extremely valuable but cannot be sold, and are instead often categorized as 'gifts' (Waldby, 2002); they are of variable quality and many are not viable for clinical purposes—some are potential offspring and others are dead (Franklin, 1999a); they are both alienable and inalienable and are 'related' to their donors by ties of reproductive substance, making of them a 'special case' of body tissue (Morgan, 2003), which may be uniquely fungible (Konrad, 1998, 2004), and which has a distinctive political history (Franklin, 1997, 1999b; Mulkay, 1997). Above all, they are valuable because they are seen to have *unique reproductive potential*, and it is this that defines them most prominently both in the context of assisted reproduction and in the context of stem cell derivation *but differently in each case*. HES cells are multiple and complex in their reproductive value because they are not only reproductively valuable in themselves, *but because they come from a context of reproductive labour* (Cussins, 1996; Thompson, 2005). Although in the future it may be possible for hES derivation to be undertaken without embryos from IVF programmes (for example, by using artificial gametes or parthenogenic development), this field at present depends almost entirely on embryos donated by couples who give their explicit consent for them to be donated to embryo research in general, or stem cell derivation in particular.

This means the embryos that form the basis for hES derivation and banking have a *dual reproductive identity*: their reproductive past, or pedigree, is determined by their production

1 The research on which this article is based was funded by the Economic and Social Research Council, the Medical Research Council and the Wellcome Trust. I am grateful to my colleagues at the Guy's, King's and St Thomas' Stem Cell Consortia, including Peter Braude, Sue Pickering (now at Leeds), Minal Patel, Stephen Minger, Glenda Cornwell and Alison Lashwood. I would also like to acknowledge the contributions of Celia Roberts (Lancaster) and Karen Throsby (Warwick) to the research on patient attitudes toward embryo donation reported here.

in the context of the highly emotive and labour-intensive process of IVF–a procedure that usually fails.[2] Their reproductive future, or potential, lies in the capacity of science to transform the vital power of individual cells into colonies of regenerative cells. Significantly, what unites these realms is what we might call 'reproductive hope'.[3] Thus, the following account of the 'embryonic economies' underlying hES cell derivation explores the meaning and sociological implications of the 'double reproductive value' through which I suggest the 'embryonic economies' based on the reproductive value of stem cells 'in themselves' *both can and cannot be separated* from their reproductive value in the context of assisted reproduction, where they embody a different domain of reproductive potential (Konrad, 1998, 2004). It is the mechanisms through which a negotiation of these two forms of reproductive value is framed, articulated and managed, as well as the social and political stakes of different models of embryo donation, that are the subject of the discussion and analysis presented here.

In making this argument I hope to build on the work of other scholars who have examined the 'economic' aspects of donation of embryos, and other tissue, such as blood, organs, genes or other body parts, by examining how the reproductive capacities of cells become invested with particular kinds of value, and how these are linked *and uncoupled* in the context of hES cell derivation and banking. In so doing, the aim is to extend the various models that have been put forward of what is both the same and different about the 'bioeconomies' of practices such as hES cell derivation, 'banking', distribution, ownership, donation, circulation and exchange. As numerous scholars have pointed out, such forms of 'trade' (B. Parry, 2003, 2005) raise wider sociological, ethical and political issues that require further definition and analysis (Dickenson, 2005; Liddell and Wallace, 2005; Lock, 2002, 2003; Nelkin and Andrews, 2002; Rose, 2001, 2006; Scheper-Hughes, 2003, 2004; Scheper-Hughes and Wacquant, 2002; Thompson, 2005; Waldby, 2002; and see esp. Tutton and Corrigan, 2004).

The UK Stem cell Initiative

The question of what is at stake in the new 'embryonic economies' of hES cell derivation and banking is of particular significance in the UK, which is widely acknowledged to have one of the most extensive regulatory frameworks for governance of assisted reproduction and embryo research anywhere in the world (Gunning, 2000; Morgan and Lee, 1991; Mulkay, 1997). It is also often noted that this widely emulated system, while highly bureaucratic (it operates through a licensing body) and strict (it is backed up by criminal law), is also one of the most tolerant, progressive and 'liberal' towards embryo research, and, more recently, hES cell derivation (Jackson, 2001). In the latter context, the UK is also advantaged by both a national healthcare system and a comparatively 'joined up' climate of academic research, funded in large part by the national research councils, and

2 For additional literature on IVF see Becker (2000), Cussins (1996), Franklin (1997), Sandelowski (1993), Thompson (2005) and Throsby (2004).

3 The importance of the work of hope to the field of reproductive biomedicine is substantial and combines several dimensions. IVF, for example, can be described as a 'hope technology' (Franklin, 1997), while the debate about embryo research can be analysed in terms of the 'rhetorics of hope' suffusing it (Mulkay, 1993, 1994) and 'hope vs hype' is a predominant theme in the analysis of stem cell science (Braude *et al.*, 2005).

the Wellcome Trust, the world's largest charity and a major donor of research income to UK universities. Embryo research in the UK is thus protected by a stable regulatory environment and a strongly positive government policy of support, which in turn are directly linked to promoting UK leadership in the 'knowledge economy' of the biosciences, where scientific achievement and research investment are considered to be a vital matters of national, commercial and political self-interest (Franklin, 2001, 2003b).

Following in the wake of a number of distinctive UK 'firsts' in the fields of reproductive biomedicine, embryology, developmental biology and genetics—including the discovery of the structure of the double helix (1953), the first embryo transfer and biopsy in rabbits (1967), the first test-tube baby (1978), the first hES lines in mice (1983), the first successful preimplantation genetic diagnosis, or PGD (1990) and the first successful cloning of a mammal from an adult cell (1996)—it was clear that the UK would enjoy an 'indigenous' advantage in the field of hES cell derivation—the first major post-genomic industry to galvanize into a global 'race' for clinical and commercial success since the completion of the draft sequence of the human genome map in 2001 (Edwards, 2001, 2004, 2005). Since the late 1990s, it has been the official policy of the UK government to promote hES cell research, and in order to further this priority the government has both increased research funding to this area, and supported the commissioning of the world's first National Stem Cell Bank to make the UK a world hub of hES cell science (House of Lords, 2002).

Funding for the bank was secured in the first quarter of 2003, and construction work began immediately on a state-of-the-art modular facility, built off site by a specialist biomedical engineering firm. By the end of the year a so-called GMP (Good Manufacturing Practice) standard, or highest quality, 'ultra-clean' research facility had been delivered and installed at the National Institute of Biological Standards and Control in South Mimms, near Potter's Bar, just outside the M25 ring-road around London. In spring 2004 the facility completed its rigorous and exhaustive testing, validation and accreditation process, and began to devise and implement its equally laborious and exacting accession protocols. The first UK hES line, WT3, made by Susan Pickering, Peter Braude and Stephen Minger at King's, was banked in January 2005. Later that spring the bank's steering committee approved 22 additional lines for accession, including 17 from overseas.

The mission statement of the UK stem cell bank is to 'work with the scientific and clinical community to assure the quality of human stem cell lines used in research and therapy'. Its four main aims are to:

1. produce, test and release well-characterized seed stocks of adult, foetal and embryonic stem cell lines within a stringent quality framework;
2. promote basic research in the UK and abroad through the provision of 'Research Grade' cell banks;
3. provide stringently tested, safe 'Clinical Grade' cell banks under EU cGMP conditions as starting material for therapeutic uses;
4. work with the scientific and clinical communities, commercial organizations and regulatory agencies to assure the quality of human stem cell lines used in research and clinical therapy and disseminate best practice.

The bank is a public, non-commercial facility that will provide a major resource for the global biotechnology community, including the commercial sector. The cell lines that are banked and exchanged through the new facility are intended to comprise a unique population, which acts as a vital repository for an emergent form of reproductive value that literally fuses social technologies of regulation and consent together with biological techniques for cellular control and management, and medical and social aspirations for scientific progress. In addition to the quality and stability of lines that are adequately characterized to be banked, the new stem cell facility will be responsible to guarantee the provenance of any lines it accepts—a procedure that has required devising new protocols for informed consent to donate embryos to stem cell research (as we shall see further below).

With the bank as its hub, a national system of human embryonic stem cell derivation, characterization and banking has been developing rapidly since the first UK lines were successfully derived at King's in 2003 (Pickering *et al.*, 2003). Two of the most important components of the UK stem cell network are the connections between and among the various centres (the added value of national scale), and the interface between stem cell derivation laboratories and IVF clinics (which are in many cases literally being merged into a single facility).

Visiting WT3

Through my work as a social scientist/ethnographer working with the Guy's, King's and St Thomas' (GKT) IVF, PGD and stem cell teams since 2000, I have had the opportunity to pursue the famously imprecise anthropological methods of 'hanging out', 'writing field notes' and 'following things around' for several years in both the clinic and the laboratory. One of the most striking observations during this period was the complex 'choreography' (Thompson, 2005) linking these various sites, as clinicians, scientists, equipment, documents, embryos, feeder cells, Petri dishes and myriad other entities criss-crossed back and forth in the complicated traffic necessary for deriving 'successful' lines. These movements are frequent but take a variety of forms: they are at times hurried, purposeful, urgent, spontaneous, delayed and otherwise caught up in the complex dynamics of medical-scientific research—which are always highly regulated and under-resourced. This to and fro is part of an increasing proximity between assisted reproduction (in particular IVF) and hES derivation that indexes the increasing dependence of hES cell derivation on an organized interface with IVF—and it is at this interface that I am arguing many wider sociological dynamics come into focus in discussions about embryo donation to stem cell research.[4] I have been part of this widening traffic myself since 2002, when I was invited to become a member of the Guy's, King's and St Thomas' Stem Cell Consortium, in recognition of the complex social and ethical issues raised by hES cell derivation, and in particular the

4 The effort to characterize these wider sociological dynamics in the context of embryo donation to biomedical research is part of ongoing research and a full exploration of this issue is beyond the scope of the present article. There is a growing literature on embryo donation in which such dynamics have begun to be explored (see Bangsbol *et al.*, 2004; Bjuresten and Hovatta, 2003; Burton and Sanders, 2004; CHILD, 2002; Choudhary *et al.*, 2004; Newton *et al.*, 2003; Kovacs *et al.*, 2003; Laurelle and Englert, 1995; Lornage *et al.*, 1995; McMahon *et al.*, 2003; Moutel *et al.*, 2002; Soderstrom-Antilla *et al.*, 2001; Svanberg *et al.*, 2001; Van Voorhuis *et al.*, 1999; Westlander *et al.*, 1998; on the ethical dimensions see Magnus and Cho, 2005; Robertson, 1995).

importance of securing adequate consent for donated embryos.[5] In the following three sections, I have drawn on these experiences to sketch out briefly (1) seeing for myself the 'special' reproductive value of stem cells 'in themselves', (2) considering how 'reproductive value' is defined at the IVF–Stem Cell Interface, and (3) participating in the current effort to create national standards for embryo sourcing, distribution and use in the context of hES cell derivation. Although clearly a preliminary and qualitative glimpse of what is at stake in the emerging 'embryonic economies' linked to hES derivation and banking, this account is offered as a means of beginning to calibrate and assess some of the questions of 'reproductive value' that arise in the context of stem cell derivation, where it may prove impossible fully to separate what is 'strictly biological' or 'purely commercial' from the social, familial, and personal ties that ensure embryos continue to 'reproduce relationality' in perpetuity.[6]

New worlds

I visited the first UK cell line shortly after it was announced to the press in 2003, just as I was beginning to research patient attitudes toward embryo donation in the clinic. It was difficult to find a time to visit the lab, as I was living quite far away from London, and the lines were often unpredictable in terms of when they needed to be tended, and by whom, as everyone was completely overstretched with other duties. The building in which the derivation lab was housed was high security, so visitors needed to be personally accompanied from the lobby through the labyrinthine corridors of the Dorothy Hodgkin building on the Guy's Hospital campus. The following are extracts from my field notes from August 2003 on the occasion of my first visit to 'WT3', the UK's first 'home-grown' cell line. The week before I wrote these notes, the King's lines had been announced in the press with much fanfare and the usual tabloid embellishments: 'Scientists grow new heart cells in test-tube' proclaimed the *London Evening Standard* in the week before my visit. Embryologist Sue Pickering and neurobiologist Stephen Minger had been highly successful in making human embryonic stem cells, using blastocysts donated from Professor Peter Braude's Assisted Conception Unit (ACU) at Guy's Hospital for over a year. Pickering was granted one of the first two UK licences to make human embryonic cell lines in February 2002, by the Human Fertilization and Embryology Authority, which has overseen and regulated all embryo research in Britain since it was established in 1990.[7]

5 GKT is one of only two Stem Cell Consortia in the UK formally to include social scientists on their team. The other is at Newcastle where Professor Erica Haimes, a sociologist and director of the Policy, Ethics and the Life Sciences Centre, is part of the medical-scientific consortium.

6 For example, under existing EU legislation it will be required that all embryo donors to stem cell research be traceable, in the event a major health issue, such as detection of the presence of human form BSE prions in a tissue sample, can be managed most effectively. This means anonymization of all samples must be reversible, and therefore partial. The moral concern surrounding use of embryos for research is another reason this field must work harder to 'keep in step' with public opinion than less controversial fields.

7 The press was responding to an article about to be published in Robert Edwards' journal, *Reproductive BioMedicine Online*, the abstract of which had been available since late July on the Internet. The article was not even published, but the news was out, confirming Britain's much-heralded scientific potential in the field of hES cell derivation (see Pickering *et al.*, 2003, 2005).

When I met Sue Pickering on the Tuesday following the announcement she was not happy about all the media publicity: 'I hate all this press stuff,' she said. But she was very happy about the cell lines: there were more and more coming on very nicely in the lab.

Tuesday 19 August 2003, London

Sue took me over to the Hodgkin building at about 3:30 to see the stem cells. We walked past the porters at the main entrance and through three sets of security doors before we got to the lab on the second floor. Nothing looks very 'state of the art'—indeed some of the cracks in the old lime green terrazzo floor are as wide as a 5p coin.

Sue introduces me to both of the lab assistants as we go in to what seems like a tiny room. They are wearing white coats and I am fitted with one of Stephen's extras from the back of the door. The lab is very 'understated' and could be an undergraduate teaching facility it is so basic. Minal, one of the researchers, has a square covered tray containing four sealed wells of stem cells under the microscope. She's new to the lab, and is quite pleased with the colony she has put through four passages successfully. It's from ESI, Alan Trounson's Singapore unit. A small vial of six colonies costs £6,000. It has been through 84 passages without differentiating and is being grown on an equally carefully characterized bed of mouse feeder cells (£300 per vial).

I have to put on white latex gloves and rinse them with disinfectant before I can approach the microscope. Sue does the same, expertly snapping her gloves up over the ends of her lab coat sleeves, which I imitate somewhat clumsily.

I have a look through the viewfinder and it is immediately obvious which are the stem cells, as they look like a flat bed of round amber pebbles surrounded by the stringier, more brachiated feeder cells. The surface of the stem cell colony is very uniform in colour and texture, which is what makes it clearly 'characterized' or differentiated. It has a unity distinct from its surrounding cells, and appears a bit like an island floating in a feeder sea. I can see at once why Minal is happy, and why this is a 'successful' colony.

Sue shows me one of the lines they have made themselves, which looks quite similar, except that it has a kind of brown, furry mound in the middle. It is unattractive and looks like mould. Sue explains this is what she calls 'the dog's dinner phase', during which the colony forms a kind of brown scum on top. She calls it a 'button', but it looks more like a smog cloud, which, apparently, later disappears.

As I have experienced before in visits to the lab with Sue, it is striking what a difference it makes actually to see something for oneself (Franklin, 2003a). My first thought was that the word 'line' is very much at odds with what you see when you look at one. They do not look like 'lines': they look like ponds or landscapes. They look a little bit like the skin on the back of your hand when it is magnified, except there is no grain or apparent organization among the cells, which appear instead to be randomly strewn together, albeit with an overall coherence of form, shape and colour.

In my field notes I recorded my initial reactions to witnessing stem cells in person:

Looking at a stem cell colony, you can see immediately what is changing about the 'new biology'. It is not about development and form in the older sense of the whole organism, but about parts. This is a biology that is about multiplication and reassembly. It is about using the logic of the system or totality, but applying it to parts, which

> in turn are being used to make new 'wholes'. It is very important that the stem cell colony has a systematic integrity, that it is clearly differentiated, and well characterized. This stability and uniformity is 'good form and function' for a cell line. But it must be singular and identical, and not developing new parts. It must be almost the opposite of the old developmental biology in that it should be both growing and static. It should be continuously reproductive, but non-differentiating. Separating reproduction from development in this way is the most important form of biological control now, at the outset of stem cell propagation. And later, being able to direct the cells to differentiate 'to order' will be the prize of this new field. Consequently, the cells in the colony are being made to work by having their reproductive power redirected, re-instructed, re-deployed. The total assemblage, of human cells, mouse feeder cells, plate, microscope, lab, scientists, university, etc. fuses cellular matter with all of the culture ingredients needed to sustain it as a productive, generative, system.

Later, writing up my notes for an academic paper I thought more about the relationship between the idea of the colony and the idea of the line. Both of these, and the ubiquitous presence of agricultural analogies, made me think that stem cells are not only about the 'new' biology, but about how much it has in common with some of the oldest meanings of the biological, especially where it intersects the horticultural, as in its references to propagation, culturing, tending and 'seeding' a new line. In this context too, reproduction was both a source and a mechanism for a crucial expansion of scale, leading Marx to conclude it was the primary condition for the emergence of modern industrial capital (Marx, 1972 [1894]: 676; and see discussion in Franklin and Lock, 2003b).

Biological colonies

Traditionally, the idiom of the biological line conveys the path of descent—it provides the vertical axis of the post-Darwinian biological model of genealogical connection through shared reproductive substance, bilateral inheritance and irreversible continuity. The idea of the colony, by contrast, depicts the vertical spread of settlement by a community, a population or group that is linked by origin to another place, such as a 'mother country', from which they have migrated. According the first definition of 'colony' from the *American heritage dictionary*, it is 'a group of emigrants or their descendants who settle in a distant territory but remain subject to or closely associated with the parent country'. The second definition emphasizes political control and subjugation: 'A region politically controlled by a distant country: a dependency'. This definition is much more hierarchical than the biological definition of 'colonial', which simply means: 'living in, consisting of, or forming a colony', for which the example is 'colonial organisms'. Sue's lines epitomize the definition of 'colony' from microbiology: 'a visible growth of micro-organisms, usually in a solid or semi-solid nutrient medium' (*American heritage dictionary*, 1992: 374).

Significantly, the term 'colony' derives both from the Latin *colonus* for settler, and *colere*, for cultivate. Colony in its biological sense thus refers to controlled reproduction of a part from a whole, through culturing it, or, to use a closely related word that is virtually synonymous with stem cell passaging: propagation. Propagation provides the horizontal axis of stem cell growth, or culture, in that the basic idea is expansion or spreading out.

'Propagation' is defined as 'multiplication or increase, as by natural reproduction. The process of spreading to a larger area or greater number. Dissemination' (*American heritage dictionary*, 1992: 1452). Successfully propagated stem cells are ideally, then, both singular and multiple, individual and derived, and distinct but sharing a common origin in their 'parent', so that the uniform singularity of their inheritance, or lineage, is preserved as they multiply or spread, and can be transported to create new populations that will similarly thrive and reproduce.

The propagation analogy becomes more 'experience near' when Sue shows me a large piece of the inner cell mass of a blastocyst donated by a woman patient at the weekend from the ACU. Looking through the microscope, she shows me how the plump cell is literally seeded into the feeder bed, which provides the 'soil' to support its growth. Nothing appears to be happening right now, but in theory this is the beginning of a new colony, or line. Sue is widely praised among the scientific community for her 'green fingers'—a variant on the ultimate laboratory compliment of having 'good hands', referring to her proven talents at growing stem cells.[8]

The resonances with agriculture and colonialism do not seem at all out of place here in the lab at one of Britain's leading scientific universities, where the UK's ongoing ties to its commonwealth partners continue to be based on strong links established through agriculture, engineering, and science, as well as economic trade.[9] From this perspective, Marx's early accounts of agriculture could be used to describe stem cells as a form of 'primitive biocapital' that, like the fertility of the soil, became an enabling reproductive condition for whole new industries, or lines of commercial exchange—such as cattle, wool, cotton, corn and tea. Similarly, the idea of 'extracting' value out of specially cultivated cells could be compared to the importance of control over the germplasm to 'add value' in the production of 'live stock', for example through selective breeding and the use of pedigree to create what Harriet Ritvo describes as 'genetic capital' (Ritvo, 1995; and re biomedicine see Franklin, 2000, 2001a, 2003b, 2006). These forms of value—the value of hES cells uniquely to be able to reproduce themselves in perpetuity, *and for this reproductive potential to be harnessed, channelled, redirected, etc.*—is one sense in which these cells belong to a 'mode of reproduction' in which 'reproductive value' can be described as the capacity to be multiplied in perpetuity while preserving totipotency.

The IVF–Stem Cell Interface

However, it is also the case that new biological relations are created through stem cell derivation that complicate their ability to be considered entirely, or 'strictly', separate entities.

8 The reference also indexes the importance of unknown factors in science, such as why some lines develop and thrive, and others never get off the starting blocks, or suddenly cease to thrive. Whereas some of the leading stem cell laboratories in Britain have used hundreds of embryos without creating a single successful cell line, other practitioners, such as Sue, are able to 'coax' their lines to grow successfully.

9 It is no coincidence the 'control' cell line is from Alan Trounson's lab in Australia, via Singapore, thus being itself a produce of the world-wide scientific web that has its base in Cambridge, where Trounson completed his postdoctoral work among many of the scientists who would later be responsible for IVF, PGD, cloning and stem cells also received their training (Franklin, 2006). Moreover, because King's is a research training facility, and has a typically transnational postgraduate population working in the labs, it is linked into global networks of scientific exchange and their 'reproduction' in the future.

For example, there is a local character to the transactions necessary to create stem cells in that they derive from a context of clinical practice, where couples may experience intense attachment to their embryos, and for that reason may, or may not, want to give them to scientists who can make use of them if the embryos are unsuitable for clinical use. Such a context thus creates new forms of attachment and belonging through the donation of 'special' reproductive substance, *whether this substance is given away or retained*.

The factors that influence couples' decisions to donate embryos to stem cell research, or not to, vary and are not well understood (see note 4). Some couples may be particularly keen to donate their embryos to stem cell research as a result of the publicity and excitement surrounding this field, whereas for others such publicity may arouse suspicion. For many patients, hES cells have accumulated symbolic capital or worth as 'investments' (Becker, 2000), and this can find expression as a desire to donate embryos in hope of contributing to new treatments for disease, or new life-saving therapies, much as the new reproductive technologies that preceded them were seen to offer 'hope for a miracle cure' (Franklin, 1997).

Embryo donation rates in the UK are high, and this is often correlated in studies of donor motivations to a sense of obligation to 'give something back'. A research project undertaken at the Guy's and St Thomas' Centre for PGD to find out more about factors affecting patient perceptions of embryo donation to stem cell research which ran from 2002 to 2005 identified a 67% rate of willingness to donate, of whom more than 80% expressed a desire to 'give something back' (Franklin *et al.*, 2005).

Such high levels of willingness to donate embryos to research may appear to indicate approval for stem cell research, but preliminary evidence does not confirm the latter (Franklin *et al.*, 2005). Indeed, in the GKT study of patient motivations to donate embryos to stem cell research (for which final results are forthcoming) the findings showed no correlation between willingness to donate a positive ['yes'] answer to a closed question 'Do you know what a stem cell is?'[10] This has several consequences for one of the most important sites of the IVF–Stem cell interface, which is the process of informed consent. The ethics of embryo donation to stem cell research are of concern to both scientists and clinicians alike, and are complicated both by the novelty of this area and by some of the 'special considerations' it raises, for example that donors must remain traceable and that the lines potentially exist in perpetuity. 'Good consenting practice' for stem cells is thus crucial to their utility and value—once again demonstrating that it is not only their power of reproductive biology 'in themselves' that matters, but the ability of this to be combined with social technologies such as patient information, informed consent, willingness of couples to donate and other aspects of what might be called 'biological citizenship' (Petryna, 2002) or 'the politics of life itself' (Rose, 2001, 2006). Indeed the ethical provenance of stem cells is not only a matter of their 'bankability', but a factor which can directly affect the rise and fall of national reputations, scientific prestige, the ability to attract and retain research and development (R&D) investment, and thus economies of knowledge, prestige and credibility, as well as goods and trade. As in the case of both genomics and reproductive

10 In fact, twice as many respondents who could answer this question were unwilling to donate as compared to an inverse proportion of those willing to donate who could not provide any answer, clearly indicating a lack of any correspondence between knowing what a stem cell is and being willing to donate embryos to that branch of science (Franklin *et al.*, 2005).

biomedicine, the need not only to be ethical but *to be seen to be ethical* has become an increasingly prominent feature of both scientific practice and scientific publishing, as well as of national and international diplomacy concerning controversial issues such as reproductive cloning (Franklin, 2001, 2003b). Increasingly, a dimension of hES cells that has consequences for both their social and economic value is thus their ethical status—currently the subject of much international dispute (Jasanoff, 2005).

Successful clinical introduction of stem cells and the emergence of international stem cell exchange and trade, as well as commercialization, will thus involve a combination of several components: they must be safe, regulated and standardized to an acceptable GMP standard; they must retain public confidence and support to become viable products on a significant scale; they have to work and be successful enough to be either clinically or commercially viable; and they must be seen to be ethically derived and subject to appropriate legislation. In sum, good governance of hES cell derivation, banking and manufacture will be essential to their potential clinical, commercial and social value (Banchoff, 2004; Liddell and Wallace, 2004; Salter, 2005).

The national embryo supply

The UK is currently one of the only countries to begin to attempt to develop national standards and regulation not only for hES cell derivation and banking, but also the ethical protocols for use in the context of IVF, where the embryos necessary for hES cell cultivation are sourced. A unique UK initiative launched in 2003 established a network of human embryonic stem cell coordinators (hESCCO), which is currently in the process of updating, improving, piloting and semi-standardizing a national protocol for patient consent and information materials for donation of embryos to stem cell research, as well as GMP and other derivation criteria.[11] This ongoing British initiative provides an unprecedented practical intervention into the practices and procedures that structure the 'embryonic economies' linking hES derivation to IVF, as well as an opportunity to sketch out some preliminary reflections on how these are beginning to be managed, standardized and regulated.

Based on my experience in hESCCO, the remainder of this article attempts to model hES cell futures from the perspective of participating in the effort to devise national protocols for hES derivation and banking in the UK, which involves implementing and testing practical protocols for everything from GMP to informed consent. From my experience of working with a national team of stem cell coordinators at 13 clinics nationwide over the past two years, I draw a contrast between two models of the 'embryonic economies' that underlie the emergent fields of hES derivation and banking. Crudely I refer to these as the 'one-way model' and the 'two-way model'—not so much in order to suggest that only one will prevail, but as a means of thinking through what kinds of reciprocities may be important

11 The seven units who bid successfully to the Medical Research Council in 2003 for funds to support appointments of stem cell coordinators were Aberdeen, GKT, Leeds, Newcastle, Roslin, Sheffield and York. A further grant proposal submitted by GKT provided funds for these and five additional units (Manchester, Birmingham, Bourn Hall, Nottingham and Oxford) to meet at regular intervals to coordinate activities and share information. The first network of its kind, hESCCO, the human embryonic stem cell coordinators group, was founded in June 2005 in Leeds with approximately 25 members.

to this field of medical scientific innovation as a means of characterizing their social and cultural dimensions.[12]

At the first meeting I attended, in 2002, to discuss what I have since come to describe as the 'IVF–Stem cell Interface' approximately 20 representatives of nine leading UK stem cell consortia were meeting to discuss a new issue of medical-scientific concern, namely 'management of the national embryo supply'. As one prominent physician described the situation at the outset of the meeting, concern had been expressed about a 'bottleneck' preventing sufficient numbers of embryos going into research, often caused by arbitrary bureaucratic, or unknown, reasons that led to what was referred to as 'wastage'.[13]

So-called 'candidate embryos' for donation to research are routinely described in a number of ways including 'excess', 'surplus', 'extra', 'spare', 'supernumerary' or 'leftover'.[14] In general practice, embryos donated for research must be clinically non-viable. If a couple has 'surplus' viable embryos (which is common because only two can be implanted in any single cycle to minimize the risk of multiple birth), they are frozen for future use, donated to another couple, or discarded if they are considered to be of poor quality. Some embryos are considered unsuitable for freezing if they appear to be non-viable, for example if they have stopped dividing, or show uneven or fragmented development. Technically, however, it is not possible to tell precisely which embryos are viable and which are not. Some 'top grade' embryos, which are judged by their morphology to be the 'best' for selective re-implantation, may have invisible but lethal genetic or chromosomal defects that mean they are clinically useless—but no one can tell this 'just by looking'. Other embryos that 'look like crap' may be implanted in the absence of any others as a default path of last resort and sometimes, surprisingly, against everyone's predictions, these turn out to be perfectly viable and produce offspring, revealing that 'what you see is not always what you get'.

Whether they succeed or fail at IVF, it is not unusual for couples to have embryos in storage they are uncertain whether they will use. After five years, the couple must decide whether to allow the embryos to perish, to donate them to research or, exceptionally, to preserve them for another five years on an extension.[15] However, unless a couple sign a consent

12 In what might be described as the 'Alder Hey' or 'Jesse Gelseimer' scenarios, public confidence in stem cell science is weakened by an event which leads to diminished public trust in science. The 'Monsanto' version of this would be an attempt to 'force' a product onto the market without sufficient public consensus. In what, by contrast, might be described as the Richard Titmuss, or blood-as-gift scenario, hES cell banking, commodification and trade enables a new form of public-private 'market' in which a sense of common good and mutual benefit is reflected in confidence that a donation of bodily tissue is reciprocated by a flow of benefits back to the donor, such as improved healthcare, or even purely the satisfaction of 'trying to help'.

13 Between 1991 and 2004, 1,950,757 embryos were created in the context of assisted conception under licence from the HFEA. In the same period, 78,505 of these were donated for research. An unknown number were discarded, and among these might be some that could have been 'salvaged' for research purposes, including hES cultivation.

14 These were the terms used by the physicians and clinicians who were present at the meeting I attended and can be considered common 'terms of use'.

15 Given the physically and emotionally arduous, and often unsuccessful, nature of IVF, it is not surprising that many couples temporarily drop out of IVF programmes, and may no longer be in contact with the clinic by the time of the five-year limit's expiration. Indeed, it is not uncommon for large numbers of couples not to respond to the clinic's, often repeated, requests to decide the fate of their frozen embryos. More research could usefully be done on this phenomenon, but it is not difficult to imagine that the need to decide the fate of frozen embryos in storage may raise unwelcome, intrusive and possibly disturbing issues for couples, whether they have been successful in previous attempts at IVF or not.

form to donate their embryos to research, or to prolong their storage period, the embryos must be destroyed, or, in the language that is most often used, 'allowed to perish', meaning they will be removed from storage, allowed to thaw and thrown away. It is the consequent 'wastage' of 'perfectly good' embryos that causes concern among parts of the scientific community, and it is this possibility—that valuable embryos that could be used for research are being lost due to 'gaps' in the administrative process—which led to a call for greater coordination.

The IVF–Stem Cell Interface revisited

Two aspects of the IVF–Stem Cell interface become important at this juncture. One is the extent to which research on IVF-derived embryos will feed back into IVF in the form of potential improvements in embryo culture etc., and the other is the actual, physical interface between IVF and stem cell research. The former raises the issue of the principles and reciprocities that will define this unique area of tissue donation, while latter takes many practical forms—including everything from an actual door connecting the IVF surgery to the derivation laboratory in one of the many new facilities being built in the UK and elsewhere to bring IVF and hES derivation physically closer together,[16] to the informed consent forms and the patient information literature, which may or may not provide details about specific research projects.

A key question for any version of the IVF–Stem cell interface is what kinds of flow, exchange, connection and separation will exist between the clinical realm of IVF and the scientific context of hES derivation? For some scientists, the interface should be nothing less than a 'firewall': once an embryo crosses the threshold from clinical use to research object, it becomes an entirely 'new' object from which nothing can 'travel back'—and this sets a strong 'one-way' flavour to the process of embryo donation.[17] For others, and perhaps in particular clinicians, who often work on 'both sides' of the IVF–Stem cell interface, it is imperative that some benefits not only flow back into IVF, but are seen to improve treatment, as a kind of 'return' on donors' contributions. These benefits could take the form, for example, of making improvements to IVF by using some of the knowledge about embryo morphology gained by growing blastocysts past the normal time of re-implantation—to see if additional 'markers' of viability could be identified. If there is something about a blastocyst that could be linked to its ability to produce successful cell lines, perhaps more could be learned about which embryos produce successful pregnancies.

In sum, there are divergent views among medical scientists about the practical and ethical issues raised by the IVF–Stem cell interface, and these reference different models of embryo supply, gift, donation or exchange—as well as of consent procedures, patient information and protocols for feedback. For some, the language of a 'firewall' is used to depict an almost fortress-like separation between scientific research and clinical practice.

16 The five units that have received MRC grants to become single-facility IVF and hES derivation centres are GKT, Newcastle, Manchester, Roslin and Sheffield.

17 While it is a legal requirement that once an embryo has been designated for research it cannot, as it were, return, this does not mean that all ties need to be severed. For example, questionnaire evidence from embryo donors at several UK clinics indicates they would be likely to 'keep in touch' with UK research on hES cells, potentially derived from their embryos, via a national website or newsletter (Franklin, 2005).

This model is not inconsistent with UK policy and best practice, which tries to protect patients against being asked to donate tissue by someone who may have a scientific interest in it, but the 'firewall model' may still appear to engender a very 'one-way' model of transfer, with the single goal of getting as many embryos as possible with the least amount of interference from complicated consent procedures or follow-up. Among other researchers, the prospect of carefully negotiated consent to donate embryos to research, underwritten by the potential of reciprocal benefits for future IVF patients, suggests a donation model that works 'both ways', evoking Richard Titmuss's famous depiction of the 'public good' that is 'returned' to donors in the context of voluntary blood donation (Titmuss, 1997; see also Fontaine, 2002). As sociologist Richard Tutton (2003) has noted, this two-way, reciprocal model, whereby benefits return to patients and the act of donation affirms a greater sense of social solidarity, is often offered as an antidote to concerns about reportedly declining levels of public trust in medical and scientific expertise.

While efforts are being made in conjunction with the UK stem cell bank to develop semi-standardized national protocols for GMP and relevant aspects of derivation, such as culture medium requirements, the primary outcome of the hESCCO initiative has been the determination of practical, legal, up-to-date and agreed-upon criteria for informed consent, as well as a new four-page consent form that is being piloted at the time of writing, in late 2005. The form is the outcome of an extensive, time-consuming and laborious consultation process involving representatives from the HFEA, the Bank, the National Blood Service, the Department of Health and the MRC. The form awaits the final adjustments pursuant to the initial pilot, but it is expected to become the basis for wider standardization of procedures, including patient information, traceability, feedback and documentation of the national embryo supply.

Another hESCCO priority is national data collection on patient perceptions of stem cell research, informed consent procedures and attitudes toward donation of embryos for hES derivation. Increasing information about this difficult-to-research area will be used to provide more of an empirical basis for evaluating best consenting practice, as well as issues such as patient expectations of hES research, and/or particular kinds of feedback.

The construction of two hESCCO websites—one that is publicly accessible and the other for members only—will provide a means of increasing public and professional participation in the regulation and governance of hES cell derivation. Especially in light of recent specialist commentary that suggests hES derivation adjacent to IVF provision may involve modifications to IVF protocols that are potentially in tension with best clinical practice, it will be essential to provide evidence that the importance of IVF as a source of embryo donation is viewed in terms of its risks as well as its benefits (Mortimer, 2005).[18] The gender imbalance of the labour and risk involved in embryo donation, in the form of the disproportionate burden it imposes on women's health, and the potential exploitation of couples who

18 As David Mortimer notes of the conflict of interest between IVF and hES derivation in his evaluation of the recommendations put forward in the 2004 EU Tissue and Cells Directive, 'Put simply, any requirement for a specific background air quality that requires clean room standards for an IVF laboratory will create a situation that is impossible to reconcile with best [clinical] practice, when considered in terms of the medical, and moral, obligation to perform IVF to the highest standards that will maximize the patient's chance of a successful outcome' (2005: 172).

may be induced to exchange embryos for free IVF treatment due to reduced financial circumstances, are the kinds of risks to which the IVF–Stem cell interface is prone, as it intensifies in significance.

Double reproduction

There are thus two main, concluding, questions that emerge surrounding stem cell research and the embryo supply that is necessary for it to develop in the near, and possibly distant, future. One concerns the reproductive qualities of hES cells in what is often described as a 'primitive' or 'strictly biological' sense—such as which ones are high quality, how to propagate them successfully and so forth. And the other question must address the biologically reproductive qualities of these same cells that give them social value, through attachments of shared bodily substance, genetic identity or biological ties, to particular people and their 'biological relations' (Edwards, 2000; Strathern, 2005). What I am suggesting is that, in contrast to the view that these are two distinct modes of value, it may be more useful to acknowledge the extent to which these two biological dimensions of stem cells are inextricable in the context of devising proper means by which these 'special' cells can be donated to research. This is not to say that what might simply be called the biological value and the social value of embryos cannot be uncoupled, which could be argued either way, but rather that how these two forms of value are combined, and then potentially recombined differently, is a defining feature on both sides of the IVF–Stem cell Interface.

What has become increasingly clear is that Good Consenting Practice, like Good Manufacturing Practice, will need to attend to both 'sides' of this duality through management of two different versions of the same 'scientific facts' of biological reproduction, or 'facts of life'—the one that determines how cells reproduce other cells, and the other that links these 'special' cells to the people who donated them. Biological reproduction is, in this sense, inherently split in its significance between what it means in 'strictly scientific' terms, and the fact that it can never *only* be 'strictly scientific', any more than genetic identity can (Franklin, 2003a; Rapp, 1999, 2003). This doubling of biological reproduction may help us to extend Charis Thompson's model of the biomedical mode of (re)production (2005) if we think again about how not only production and reproduction are being managed in this new economy, but also how labour and body parts are *and are not* being alienated. It is not just that reproduction is becoming more productive, or that it is reproductive power that is being extracted from cells, or bodies (instead of labour or productivity), but that some kinds of labour are undergoing a transition from the context of what Thompson calls 'making parents' to another of 'making health', or even, uniting them both, of 'making hope'. In this process, the intense amount of labour involved in IVF in pursuit of a personal goal (a child of one's own) is, for a majority of couples, redirected into public goal (improved national health), along the same path of hope in scientific progress to alleviate suffering in the name of an improved future. While it is probable that high levels of embryo donation in the UK exist will be retained, it is nonetheless prudent to find out more about what kinds of ideas, intentions, obligations, uncertainties, ambivalences, hesitations or responsibilities are at work at this crucial juncture.

After all, embryos are the objects of significant moral, social and regulatory investment for *the same reasons* they are the objects of so much scientific research investment: *because they are biologically reproductive*. It is the same biological capacity (totipotency) that enables an *internal* system of generativity, which is seen inevitably to create *external* social connections (much as these can be denied, severed or forgotten, they are rarely seen not to exist at all).

A simple consequence of this, or even a sociological effect, is to point out that as reproduction, in the sense of reproductive 'potency', has become more important in the biotech economy, it has simultaneously also been split, doubled and troubled, in its significance—as the figure of the embryo demonstrates most powerfully. The significance of reproduction as a source of *biological* productivity, or multiplication, has increased, while the *social* significance of reproductive ties, as forms of connection, has both been reinforced and challenged by, the emergence of new reproductive technologies, through which, as numerous scholars have shown, whole new versions of 'biological relatedness' can be forged through procedures such as surrogacy, donor insemination or, as we have seen more recently, cytoplasm transfer (Franklin, 2001b; Haraway, 1997; Hayden, 1995; Ragone, 1994; Thompson, 2005).

Conclusion

It is for precisely this reason that in Britain the pursuit of ever-increasing biological control over embryos has resulted in ever-increasing government regulation of this kind of research. *Indeed, it is this combination of biological control and government regulation which is seen to provide Britain with the most favourable economic for stem cell research in the world.* A stable regulatory structure is deemed desirable for both public- and private-sector investment in stem cell research, because of the decreased risk of public disapproval, or governmental interference, disrupting long-term research strategies. The United States and Germany are frequently referred to as examples of countries that could have much greater scientific investment in hES derivation, were not public and governmental opposition to embryo research so prominent. Similarly, China, India and South Korea are often hailed as burgeoning arenas of stem cell science, but are seen to be vulnerable to a lack of clear regulatory strategies, the absence of which could exclude them from full participation in the future in what is potentially an important global market. The Commonwealth countries Canada and Australia, and the Scandinavian nations, such as Sweden, Denmark and Finland, have become key partner-countries to Britain both in terms of scientific collaboration, and in terms of developing regulatory guidelines that closely resemble those in the UK.

In vital economies such as stem cell research, reproductive substance can never be fully de-differentiated from social definitions of obligation, responsibility, equality, or health and well-being. While this has also been shown to be more true of organ donation than might have been imagined (Kauffman, 2000; Sharpe, 2001a, 2002; Lock, 2002, 2003; Kauffman and Morgan, 2005), the alienability of the embryo in the context of hES cell derivation is rightly described as posing a unique context of personal tissue donation.

Thompson's distinction between harnessing productivity, through the labour supply, and harnessing reproductivity, through the embryo supply, can thus be taken through

another turn, by pointing to the contested alienability of reproductive cells. This exemplifies Nikolas Rose's suggestion that: 'our very biological life itself has entered the domain of decision and choice [and] we have entered the age of vital politics, of biological ethics and genetic responsibility' (2001: 22). However, it also raises the question of whether a slightly less modern set of conventions, namely those associated with blood, descent and kinship, may turn out to be in new hybrid formations with the genealogies of future stem cell lines (Strathern, 2005).

The decisions and choices that are being made about embryo donation have begun to be analysed, and already yield significant questions about patients' understandings of their actions (Parry, 2005). These in turn reveal the degree to which the formations of value at stake in these choices invoke classical sociological questions about economy and society, both of which are being reconfigured in the name of national health through public initiatives such as the UK stem cell bank. What this reconfiguration suggests is that reproductive power is being harnessed within an emergent embryonic economy in which the biological management of cells is inextricable from social technologies of consent and regulation. As governance and regulation of the IVF–Stem cell interface becomes more explicit, it will prove to be one of the key windows into the workings of the biosociety.

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