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Creating Donors: The 2005 Swiss Law on Donation of ‘Spare’ Embryos to hESC Research

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Abstract In November 2004, the Swiss population voted to accept a law on research using human embryonic stem cells. In this paper, we use Switzerland as a case study of the shaping of the ostensibly *ethical* debate on the use of embryos in embryonic stem cell research by legal, political and social constraints. We describe how the national and international context affected the content and wording of the law. We discuss the consequences of the revised law’s separation of stem cell research from other forms of embryo research, its definitions of embryo and of spare embryos, and the introduction of donorship into the Swiss ethical debate on IVF. We focus on the exclusion of the potential embryo donors’ voices and perspectives from the debate, and consider the effects of this exclusion on ethical discourse and the political process.

Keywords Embryo · Stem cells · Oocyte donation · Public policy · Switzerland

Introduction

Lying at the interface between reproductive biology and genetics, stem cell technology offers – it is claimed – future therapies for devastating human diseases. The excitement generated by the scientific promise has nevertheless been tempered by serious ethical concerns. These concerns have predominantly focussed on the ethical legitimacy of destroying embryos in the course of obtaining stem cells, but questions have also been raised about ‘research tourism’, the potential commodification of human tissue [26], and the instrumentalisation of women as sources of human embryonic stem cells (hESC) [16, 17].

In this paper we want to look at the recent debate in Switzerland prompted by the introduction of a draft law on research using hESC. In countries around the world the regulation of stem cell technology negotiates a difficult path, trying to combine consistency with existing laws, fidelity to the community’s moral values, and openness to the continuing demands of research. The difficulty is exacerbated when legislation has to keep pace with a rapidly advancing technology, the technology is complex and unfamiliar, and the medium to long-term outcomes of a decision may be unexpected – as with stem cell technology. The use of hESC has legal, political, economic and social implications, and so generates discussions in all these areas in addition to discussions about ethics.

But the ethical discussion itself is also moulded by the wider social context in which it takes place. In the first part of the paper we show how political and cultural elements affected the drafting of the Swiss law, and how this in turn structured the terms of professional and popular ethical analysis. We identify some ethical issues that were created, obscured or skewed by social or legal framing, without at

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this point exploring the associated ethical arguments. In the second part we turn in more detail to one particular feature of the professional and public discussion of the law – the invisibility of the potential donors of 'spare' embryos for stem cell research. Arising out of cultural and legal precedent, the absence of the donors' perspective has significantly shaped the ethical discussion of the law.

The Context of the Swiss Discussion

Switzerland is a small country (population 7.4 million in 2004), with four official languages (German, French, Italian and Rumantsch) and a history and culture shaped by its location in the centre of Western Europe. The Swiss are conscious of these influences, while also wanting to assert Switzerland's distinct national identity. For instance, the Swiss media and parliamentary discussion of stem cells frequently referred to Germany's regulations governing embryo research, and despite the closeness of the two countries the Swiss assessment was not uncritical. Newspaper articles (e.g., [30]) regularly positioned the German regulation at 'one end of the spectrum' of permissibility, and suggested that Switzerland's preferred position might be distinct from it.

During 2000 and 2001 there was mounting pressure from the research community in Switzerland for clarification of the legal position on hESC research [18]. Biomedical research is a major political and economic power in Switzerland: chemical and pharmaceutical companies form the country's second largest industry, providing 3.3% of GDP in 2003 [41]. Neither the Federal Constitution nor the 1998 Federal law on reproductive medicine that came into force on 1 January 2001 (*Bundesgesetz über die medizinisch unterstützte Fortpflanzung*, or *Fortpflanzungsmedizingesetz*, LRM)[1] explicitly regulate the handling of hESC, but they contain a ban on the separation and investigation of cells from an embryo — a formulation intended to prohibit preimplantation genetic diagnosis but which could also be applicable to stem cell harvesting. According to the Federal Constitution, embryos can be produced *in vitro* only to overcome infertility or to avoid the transmission of a severe illness. They cannot be produced for the purpose of research. Both the Constitution and the LRM stipulate that IVF must only produce as many embryos as can be *immediately* transferred to the woman. Cryopreservation of embryos is forbidden, whether for transfer at a later date or for any other purpose. The original aim here had been to prevent embryos being generated *in vitro* for 'unacceptable' uses, suggesting that some uses of embryos *are* ethically acceptable but that donation of embryos, for whatever purpose, is not one of these.

On 29 September 2001 the Swiss National Science Foundation (SNF) made a landmark decision to fund a research project at the University of Geneva using hESC originally derived from a spare embryo and imported from the US. This decision was close to (but less restrictive than) the compromise in the German law. Note that the implication of the criterion that only spare embryos be used, in this decision and in German law, was that it is ethically permissible to treat these spare embryos differently from other embryos. Legal counsel had concluded that this solution did not contravene the existing Swiss legislation. Nevertheless, enough people argued that forbidding the derivation of hESC within the country but allowing them to be imported was an unacceptable ethical double standard, for further legal work to be encouraged.

The Swiss administration first aimed to clarify the legality of hESC research within the framework of a wider law covering all research on embryos and stem cells (*Bundesgesetz über die Forschung an überzähligen Embryonen und embryonalen Stammzellen*, LER). The LER would in turn be integrated into an umbrella law covering all forms of research on human subjects, including embryos and foetuses: this latter law has just (in 2006) been presented in draft. Not surprisingly, reaching agreement on such a diverse and ethically contentious area as embryo research proved difficult. At this point the perceived special urgency around stem cell research became an important factor. Such urgency did not apply to research on embryos in general. The stem cell law was needed, as Ruth Dreifuss, then Minister for Health, said, 'because [stem cell research] is a burning question right now' [21], driven by the needs of research. In line with

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[1] The following abbreviations are used for the laws referred to in this paper:

LRM, Federal law on reproductive medicine (*Bundesgesetz über die medizinisch unterstützte Fortpflanzung*, or *Fortpflanzungsmedizingesetz*, official abbreviation FMedG)
LER, Federal law on research on spare embryos and embryonic stem cells (*Bundesgesetz über die Forschung an überzähligen Embryonen und embryonalen Stammzellen*, official abbreviation EFG)
LSCR, Federal law on research with embryonic stem cells (*Bundesgesetz über die Forschung an embryonalen Stammzellen*, official abbreviation StFG).

this, in April 2002 the Basel-based pharmaceutical company Novartis announced that it was going to enter the field of stem cell research. The 'pace maker' here was described in the weekly news journal *FACTS* as the reports of advances in international stem cell research that came out 'almost weekly' [19]. As a result, it seems that the media and parliamentary discussion about the stem cell law rapidly moved into a phase in which the ethical question 'Should stem cell research be done?' appeared to have already been answered.

After a public consultation period, the draft law was passed to the Council of States (*Ständerat*) in mid-November 2002 for discussion. At this point the law's scope was significantly cut back. In revision, it was argued that more time was needed for a full discussion of the ethical and social consequences of embryo research as a whole. The law was therefore restricted to research on hESC only. Clearly, this was felt to be something that the population *could*, just about, agree on.

But this step was also significant in another way. The reduction in scope did not simply alter the focus of the law's attention; by removing the question of embryo research it altered the framework within which the law was read. It meant that the ethical issue of obtaining hESC was translocated from the broader setting of embryo research to the more restricted one of regulating a novel technology. When an issue is debated in the form of the question 'What can we do with embryos?' it inevitably comes with a background of certain assumptions and associations; when the question is 'How can we best regulate this technology?' some quite different assumptions and associations are mobilised. The first question is 'about' ontological beliefs concerning the early embryo, and moral relationships with it. The second is 'about' the technology's goals, the need for it, its risks and safety. The question of the right handling of embryos in a wide range of research settings can also leave open for discussion whether it is actually morally permissible to treat embryos as the raw material of hESC technology like this; focussing the discussion on the right regulation of the technology gives the impression that the issue of moral permissibility has already been answered, and that all that is left to talk about are the details.

The New Law on Stem Cell Research

The final parliamentary vote in December 2003 therefore accepted a law now called the Federal law on research with embryonic stem cells (*Bundesgesetz über die Forschung an embryonalen Stammzellen*, LSCR). The new law had to harmonise with both the Federal Constitution and the 1998 LRM, which meant it had to be in line with statements that had been drawn up before stem cell research existed and that reflected the scientific knowledge, technical possibilities, and ethical discussions of an earlier time. Skilful, and sometimes strained, interpretation was necessary to figure out what was and was not consistent with existing legislation. The new law had also to work within the definitions and distinctions given in earlier laws, including the definition of the embryo and the distinction between embryos and fertilised eggs. We discuss the effects of this later.

The key innovation of the LSCR is that it allows hESC to be obtained from *überzählige* (spare) embryos. The earlier LRM does not discuss spare embryos directly, only *indirectly* via the provisions that cryopreservation of embryos and donation of the embryo to another couple (for 'adoption') are both forbidden. These two restrictions led the *Botschaft* (explanatory report) to the new law to conclude that any embryos that are spare in the sense of the law can only be 'allowed to die' (*absterben lassen* in German, *laisser détruire* in French [4]). The stem cell research law defines spare embryos as those generated *in vitro* with the intention of being transferred to the uterus, but for which transfer turns out to be impossible. The possible reasons for transfer not taking place are given in the *Botschaft* as:

(1) the embryo is not of good enough quality to transfer,
(2) the woman becomes ill, has an accident, or dies, or
(3) the woman or couple change their minds about transfer.

However, although the earlier laws were clear that appropriate protection of the embryo includes protecting it from being used in research, they had nothing to say about 'spare' embryos. By introducing the category of 'spare' embryos, the new law appeared to create a type of embryo whose status was not clearly covered by precedent.

Other IVF embryos in Switzerland do not fit into the category of 'spare' as defined in the new law. When the LRM came into force in 2001, forbidding the cryopreservation of embryos, there remained numerous embryos that had already been frozen. The *Botschaft* estimated there were about 1,000 of these 'old law' or *altrechtliche* embryos stored in IVF centres around Switzerland [5]. Article 42 of the LRM contains a transitional provision: these embryos could be stored for up to three years (to the end of 2004), after which any remaining were to be thawed and disposed of. In the final version of the stem cell law and following extensive discussion in Parliament and lobbying by a group representing the parents of these cryopreserved embryos, *Verein Kinderwünsch*, who wanted to be able to store them for longer, the time limit for cryopreservation with the aim of *producing a pregnancy* was extended to the end of 2005. If the embryos were being stored for *donation to research* the limit was extended to 31 December 2008. The practical effect of this was to make it possible for these *altrechtliche* embryos to be donated to stem cell research as an alternative to being disposed of.

Its effect on the ethical construction of the debate is more complex. Extending the time limit enabled parents of these embryos to opt for another pregnancy or disposal (as the vote on the new law was not until November 2004, a deadline of 31 December 2005 gave parents just over a year to make this decision). But extending the deadline by a further three years for donation to research suggests that there are no *a priori* reasons why embryos should not be used in this way. It means that after 2005 parents of these embryos will have only two choices: to destroy the frozen embryo or to donate it to research (which of course also involves its destruction). One concern here is whether this generates something like the ethical equivalent of an optical illusion, where the foreground figure changes according to the background it is viewed against: having only the two options of destruction versus research plus destruction makes donation to research appear ethically more acceptable than if it were offered against a background of other non-destructive options, such as donation to other couples.

Definitions and Distinctions: Some Ethical Consequences

In this section we look at the distinctions and definitions that were developed in the evolution of the law. These distinctions and definitions are pivotal because they provide the component concepts, entities and issues used in the ethical debate.

Distinguishing Between Embryo and Stem Cell Research

The law was prepared against the perception that there was a pressing need to clarify the rules on research with hESC. Partly because of the heterogeneity of what is collectively called 'embryo research' (a term covering a wide range of procedures including 'knock-out' experiments, parthenogenesis, somatic cell nuclear transfer [SCNT], the production of chimera, and noninvasive observation[2]), and partly because it was felt a comprehensive discussion of embryo research would take too long, a decision was made to address stem cell research alone, leaving other kinds of embryo research to a later date.

Practically, the change in substance and title of the law allowed the crafting of legislation to be speeded up. Conceptually, it inserted a gap between issues to do with *stem cells* and issues to do with *embryos*. The law that the public finally voted on in November 2004 has a revised title and the bulk of the text now covers the experimental use of the hESC once they are obtained. The separation thus shaped what types of moral issues were seen to be at stake. Stem cell research sits at a complex interface in which it can be viewed by philosophers or the public as (a) research that might lead to new therapies (which most people are likely to consider a moral good); (b) reproductive medicine that helps infertile couples to have children (again, most people would probably think of this as a good, with some reservations about resource allocation or the effect on traditional family relationships); or (c) research that might lead, through the use of the SCNT procedure, to a form of cloning (which majority public opinion finds morally questionable if not downright wrong: see for example the meta-survey by the Center for Genetics and Society [15]). Which area stem cell research is predominantly associated with will determine whether it is popularly seen as being about developing beneficial therapies, about helping people

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[2] 'Knock-out' mice have specific gene sequences removed, so that their normal function can be deduced by whatever goes wrong in the mice lacking the sequences. In parthenogenesis an unfertilized egg is stimulated to undergo further development. In somatic cell nuclear transfer (SCNT) the nucleus of a somatic cell (i.e., not an egg or sperm) is used to replace the nucleus of an unfertilized egg cell. Chimera are organisms composed of genetically distinct tissues, e.g., if cells from one embryo are mixed with those of another.

have babies, or about mad scientists creating clones. We suggest that the change in name and scope of the law favoured an association with medical therapies, and so facilitated the perception of those ethical issues that are primarily to do with regulating a novel technology: for example, the level of risk tolerable for an unknown therapeutic gain. Questions about the ontological status of the embryo, or more wide-ranging questions about tissue commodification or instrumentalisation, did not entirely disappear but they became considerably more peripheral. Yet despite the change in name and content, the law *does* still concern embryos, as the source of hESC.

Distinguishing Between Fertilised Eggs and Embryos

According to both the Federal Constitution and LRM, IVF must produce only as many embryos as can be immediately transferred for the purposes of pregnancy, and hence embryos cannot be cryopreserved [11]. But the LRM also introduced a distinction between embryos and what are termed in the law ‘fertilised eggs’ (in reproductive medicine these are usually called pronuclear stage embryos). The embryo is defined as existing between nuclear fusion (*Kernverschmelzung*) and the end of organ development. Before nuclear fusion what exists is not an embryo, but a fertilised egg cell. The biological distinction is that in the pronuclear stage, the nuclear material of the separate egg and sperm cells have not yet merged.

The LRM stipulates that only as many fertilised eggs may be developed further to embryos as can be transferred within one cycle, in any case a maximum of three. Unlike embryos, however, the LRM permits the cryopreservation of *fertilised eggs* with the aim of producing a later pregnancy in the same parent [12]. The definition of the embryo as the biological entity that exists from the point of nuclear fusion until the end of organ development was a deliberate compromise to block the freezing of embryos (considered undesirable as we saw because of the possible unacceptable uses to which frozen embryos could be put), but to avoid a situation in which women are forced to undergo repeated hormonal stimulation and oocyte retrieval at every IVF cycle. The law’s definition of embryo allows the stage that exists after penetration of the ovum by the sperm head, but before nuclear fusion, to be frozen. On thawing, development continues as normal, giving rise within around 12 h to the entity defined under Swiss law as an embryo. The cryopreserved, fertilised egg can be stored for up to five years, or until withdrawal of consent to storage by either parent, after which it must be disposed of (*vernichtet* [13]).

Since 2001, IVF centres in Switzerland have largely adopted the cryopreservation of fertilised eggs. It is now standard practice for six or so eggs to be fertilised, and two or three of these to undergo further development *in vitro* until ready for transfer while the remainder are cryopreserved for use in a later cycle if need be. In practice the situation is much as before the LRM: couples undergoing IVF freeze the product of the IVF for later use if desired. The only difference is that, because the LRM made it illegal to freeze embryos, the product frozen is not what the law calls an embryo, but the stage before. In research interviews with IVF specialists (carried out as part of the research project funded by the Swiss National Science Foundation, described later) we have been told that the original strategy to avoid a legal restriction turned out to be a blessing in disguise, because the success rate of thawing from the pronuclear stage is greater than from embryos.

Nevertheless the distinction raises at least three points of difficulty:

(1) There is no clear basis in either ethics or biology for giving this difference the significance it has. The breakdown of the pronuclear membranes and establishment of a single diploid nucleus within a bounding nuclear membrane is an observable biological phenomenon, and its endpoint can therefore act as a useful marker in the ongoing process of development. But it marks no change in biological properties that can easily be correlated with an equivalent change in moral status of the entity. The distinction between fertilised egg and embryo exists in law to facilitate clinical practice while simultaneously blocking undesired abuses, but the side-effect is to imply that this is a key transition point in the moral status of the embryo.

(2) The choice of marker is therefore also an instance of what we call ‘DNA centrism’. The makers of the law had to define a point during embryogenesis at which an entity exists that has moral value great enough to require this level of protection. They could have chosen some other developmental event: for example, the end of the first cleavage

stage, or the moment of successful implantation. By selecting the point at which a new kind of DNA organisation appears as the marker of this change in legal status, they make the implicit claim (which is not easy to justify on either biological or ethical grounds) that there is a significant link between the DNA arrangement and the kind of protection that is morally due to the biological structure that contains this DNA. The standard explanation given for this choice is, of course, that the new DNA organisation represents the start of an individual human 'genetic program' that justifies protection of the entity carrying it (for a recent discussion see [22]). But this conclusion would be contested by other theoretical approaches to organismic development that do not make genetic information the central organising principle [9, 35, 36].

(3) The realities of today's healthcare provision in Switzerland mean that couples undergoing IVF have a counselling/information session of less than an hour, during which they are taking in a huge amount of information. Some patients will have had little or no biological education, and for some the session will not be conducted in their mother tongue. So a further ground for concern is that patients may not understand *why* a very early product of IVF is labelled a fertilised egg cell, while at a slightly later stage it is called an embryo. This is more than a worry about the public understanding of science. Some of the medical procedures to which patients must consent, and some of the choices they have to make or, indeed, are unable to make, are there because of this legal distinction that may not be understood and, even if understood, may not be accepted as morally important, by the people the law affects most directly.

There is a deeper issue here about *epistemological privilege*, which in our opinion has yet to be adequately addressed in biomedical policy. How should societies regulate a technology that is complex, ethically contentious, and yet has become so 'everyday' that it presents ordinary people with moral conundrums on a daily basis? One approach – the one generally taken, and taken by this law – is to base policy on distinctions that are valid in the light of a particular biological theory (in this case, of the role of the genome as genetic program [37]) even if the theory is disputed among specialists. An alternative approach would be to base it on the everyday understandings that may make sense to the women involved, or may be culturally acceptable, but that from an expert point of view are flawed or inadequate. While the first approach is ethically and politically questionable, the second is, in its own way, no less problematic.

Creating the Category of Spare Embryo

The concept of the 'spare' embryo is a recent one: the term *überzählig* (in German) or *surnuméraire* (in French) is not used in either the Constitution or LRM. It appears to have emerged in the discussion of LRM, and by 2001 had become established enough that the draft LER was called a law on *überzähligen Embryonen und embryonalen Stammzellen*.

The *Botschaft* to the LER drew on a paper on embryo research prepared by the National Ethics Commission in 2002 [33], which gives three ethical models for evaluating the *Schutzwürdigkeit* (the protection morally due) of the embryo. This paper concluded that respect for the dignity of the embryo requires that the use of embryos as a source of stem cells must be restricted to those (spare) embryos that could not otherwise be transferred to the uterus (if the parents gave free and informed consent and if certain other conditions are also met). This is the ethical basis on which the law was able to move from its previous position of a complete ban on doing anything with any IVF embryos other than generating a pregnancy. So being designated spare in the LSCR effects an important change in the possible futures legitimately open to an embryo. It means it can be used for a purpose that otherwise it could not – as source material for hESC.

In English, the term 'spare' usually implies something being kept aside for use as a replacement when necessary, which is precisely *not* what these 'spare' embryos are used for. (The pre-2001 frozen embryos were closer to this meaning of 'spare'.) The term in the LSCR that is translated as 'spare' (*überzählig*, *surnuméraire*) implies that there are now *more embryos than there should be*, which is equally not what it really means. For example, if a woman after IVF becomes too ill for transfer to take place, it is not the case that before she came down with (say) appendicitis there were the right kind and number of embryos, but because she is now complaining of abdominal pain there are suddenly too many. We might instead think of 'spare' as meaning 'excess to requirements' or even more precisely, if more clumsily, ‘excess to present possibilities’. And the present possibilities are contingent. At least in those cases where the embryo becomes spare because of something like death, illness or a change of mind, it is not some intrinsic characteristic of the embryo that has changed, but the external circumstances, in such a way that one of the embryo’s possible *futures* (being transferred) can no longer happen. The morally permissible fate for an embryo, in this very specific situation, is therefore entirely dependent on the altered external circumstances. That this is the case is obscured by the designation of ‘spare’, a new label that gives the impression that we are now talking about a morally distinct kind of entity.

In tracing how the legal categories influence the ethical terms of reference we are not trying to suggest that there were deliberate attempts to manipulate the moral acceptability of the proposals. We do not believe, for example, that the legal category of spare embryo was introduced *in order to* change its moral status. It is not the job of the law to *define* the moral status of embryos at different stages of embryonic development and under different conditions, but rather to reflect society’s moral consensus on these issues. The government *Botschaft* to the original version of the new law makes clear that it will not attempt to reach any conclusions on moral status. It states that the ethical permissibility of using embryos for research depends on ‘whether – and if so, to what extent – protection-worthiness *[Schutzwürdigkeit]* can be attributed to the embryo’ [6]. The rest of the discussion of the ethical basis of the law is about how the entity called an embryo can be protected, without actually specifying what moral status this entity has. But just as ethics influences the law, it would be naive to think that the language and strategies of the legal discussion of hESC did not in turn subtly interact with the ethical discussion. Furthermore the implementation of the law in everyday life is also subject to a hermeneutical transformation. When put into practice, the law’s provisions acquire an everyday meaning that may not be exactly in line with its original intentions. Whatever the legal intention in creating the category of spare embryo, simply having the category available readily leads to the deduction that this new identification really does change the embryo’s moral status or its *Schutzwürdigkeit*.

It also needs emphasising that these ‘kinds of embryos’ [23, 24], and the things that can ethically be done with them, are creations of the legal framework as much as they are the consequence of biology or moral status. It is not a biological limitation that prevents embryos being frozen or donated to a third party, but a legal one. Speaking of the pre-2001 (*altrechtlich*) frozen embryos, the LRM *Botschaft* said, ‘When eventually it is clear that there is no possibility of transfer for an embryo, the *Keimling* [literally, seedling] is to be left to its fate’ [8]. The wording seems intended to mean something like ‘letting nature take its course’, but what is obscured is that the frozen embryo’s ‘fate’ is not a result of any intrinsic property it has: it is due to the stipulations of the law (because of the ban on donation to research or for adoption). At the very least, the embryo must be removed from cryopreservation and thawed out in order for it to die. Its fate, then, is not the result of nature taking its course but the combined effects of (a) the technology that brought it into being, (b) its status according to the law, and (c) a contingent interpretation of that law.

The Emergence of Donation

Introducing the possibility of donation for research purposes is an innovative move in the light of the previous ban on donation of eggs or embryos for any purpose (sperm donation is legal). The *Botschaft* on the LER notes that the Federal Constitution and the LRM both forbid embryo donation (*Embryonenspende*), but then goes on to state without further explanation that ‘The prohibition refers to the donation of embryos for reproductive medical purposes and not to the “donation” [quotes in original] of spare embryos for research purposes’ [7]. In fact neither the Federal Constitution nor the LRM felt the need to be explicit about what the prohibition referred to. Formerly, the term ‘donation’ had not been used in connection with the handling of fertilised egg cells or embryos: donation has simply not been within the range of possible futures for these entities. The donation of spare embryos for stem cell research can thus be seen as opening up a way of thinking the (previously) unthinkable. The LSCR does something very new by introducing the topic of donation of embryos in Switzerland into serious ethical debate.

The LSCR permits the donation of IVF embryos to stem cell research as an alternative to their destruction when they cannot be transferred. But where will these spare embryos come from? With the IVF procedures in use in Switzerland today, the only situations in which truly untransferable embryos are produced are uncommon: where development after fertilisation has carried on *in vitro* to the blastocyst stage, and then the resulting embryo turns out to be unsuitable for transfer, or the woman is ill, has an accident, dies, or changes her mind. There is considerable discrepancy in the estimates of the number of embryos that are spare according to these criteria, ranging from the Ministry of Health in 2004 which gave a number of around 200 per year [10], to IVF specialists interviewed for a *FACTS* report, who offered a much lower figure [44].

The other potential source of hESC is the *altrechtliche* frozen embryos. These will only be available for donation to stem cell research until the end of 2008, however, and it is not clear how many of them will then still be technically suitable (about half of thawed embryos do not thaw successfully, and not all of those that do will then develop normally). Nor is it clear how many of their parents will be willing to donate them at this stage. A Danish survey of parents of cryopreserved embryos concluded that the pool of available embryos would need to be 100 times larger than it was to service stem cell research in that country [1]. It is not known if the same will apply in Switzerland.

Permitting the donation of spare embryos to stem cell research undermines part of the rationale for prohibiting donation to other forms of research, or to infertile couples. Even when the LSCR was under discussion, the oddity of permitting embryos to be donated to stem cell research (so they are destroyed) but not to 'adoption' (so they have a chance of life) was acknowledged. In a news journal interview, the then Minister of Health, Ruth Dreifuss, was asked, 'Is it not a contradiction to permit research on embryos but not let infertile couples have them for adoption?' Her reply was that if there is no 'biological connection' between parent and child anyway, then it is preferable to adopt a child than to adopt an embryo [20]. This is a puzzling answer, since it suggests that if there *were* a biological connection (if the donor were related to the recipient, for example) things might look different.

Input into the Debate

We will now examine how the debate about the ethics of stem cell research was constrained by features of the public input. Serious attempts were made by the Swiss government and other bodies to encourage widespread participation. One example was the recommendation in 2001 by the then newly established Swiss National Advisory Commission on Biomedical Ethics (*Nationale Ethikkommission im Bereich Humanmedizin*, NEK) that the decision on the use of imported stem cell lines by the SNF should be postponed, to give time for more thorough public and parliamentary consideration of the use of spare embryos *per se* [34]. In spring 2002 the Federal Council commissioned the organisation *Science et Cité* to hold public events around the country to discuss the stem cell issue.

In the Swiss legislative process, draft laws undergo a public consultation (*Vernehmlassung*). The consultation on the LSCR drew about 120 replies. Respondents included the regional governments of 26 cantons (states), 12 political parties, five business organisations, 11 church organisations, eight women's organisations, and 10 medical or pharmaceutical organisations. The main reservations expressed by both groups and individuals concerned the law's possible inconsistency with the Constitution and/or the LRM; concern about the instrumentalisation of human life (that of the embryo – only three organisations, two of them representing women's interests and one human rights organisation, referred to the possible instrumentalisation of the women providing the embryos); or the fear that the provisions of the LSCR were the start of a slippery slope towards permitting other procedures, for example the creation of embryos for the purpose of research. Notably absent was a collective response representing IVF patients, the potential sources of spare embryos. Public discussion of the law was also encouraged in December 2003 when three groups opposed to hESC research (two 'right to life' and one broadly critical of gene technology) collected enough signatures to force a referendum on the proposed law. Such referenda will often act as catalysts for public discussion, as both the government and their opponents launch information and public relations campaigns to convince voters to agree with them.

Despite these and other efforts, throughout this period there was a growing sense that contributions were coming from a limited range of constituencies: the media, the academic world, groups with a vested financial or professional stake in promoting stem cell research, and pro-life groups. The opinions of the wider lay public were much less visible. Although it is hard to quantify public engagement in a form that allows comparison over time or between countries, it would not be unexpected if the public were reluctant to engage with the stem cell debate, for example due to lack of confidence in tackling a technically daunting subject. This may have been exacerbated here by the modification, described earlier, that meant the new law was not concerned with embryos but with details of biology outside the experience of most non-specialists (such as the difference between an impregnated egg cell and an embryo). The resulting switch from embryo to stem cells as the focus was also a switch from an entity for which some shared discourse already exists, to objects about which there are as yet few culturally shared moral intuitions. In addition, few people are as yet directly affected by either stem cell or embryo research, in contrast to debates about abortion for example, while the absence of hard evidence about the therapies supposed to come from stem cell research offers little purchase for factual debate.

The Silence of the Donors

Although the views of various interested parties appeared in the media (e.g., stem cell researchers, potential beneficiaries of therapies), in all the public and parliamentary discussion of LSCR we have not been able to find significant representation of the viewpoint of the prospective donors. As with the distinctions and definitions in the law, we are not suggesting there was some kind of conspiracy to exclude the voices of potential embryo donors, but with hindsight this seems an extraordinary omission. The absence of the IVF patients' perspective is not restricted to donation: although there is a vast professional literature on the ethics of reproductive medicine, until recently there has been little attempt to complement theoretical work with empirical research into the ethical concerns, priorities and values of people undergoing IVF. The tendency to invisibility may be exacerbated for potential embryo donors, in that their role in the IVF setting is less widely acknowledged because it is associated with reproductive failure. Yet those directly affected may perceive difficulties and risks, for instance in the processes of communication and decision making, that are considered trivial or are simply not noticed by those who do not go through the donor experience. These are the very features that, because they give this situation its particular vulnerabilities, need to be better understood for a comprehensive ethical account of embryo donation.

Apart from one paper demonstrating that couples' attitudes towards spare embryos range from quasi-parental concern to treating them as medical by-products [29], relevant studies have largely been quantitative surveys of donor intentions. A study of Australian couples with cryopreserved embryos suggested that 34% would consider donation of embryos for research [32] while another, also in Australia, found that 29% would donate a spare embryo to infertility research, 27% to stem cell research, while only 15% would consider donating to another infertile couple ('adoption') [14]. Sixty percent of couples in a Danish study were in favour of donation to infertility research, 57% for stem cell research, and 29% to another infertile couple [1]. Some unpublished data from Switzerland also indicate that parents of cryopreserved embryos are more favourably disposed to donation to research than to 'adoption' (Professor M Hohl, consultant, Cantonal Hospital Baden, personal communication). It is not clear if the couples in these studies would donate for research *in preference* to donation for adoption, if both options were available.

By their nature, quantitative surveys can make only a limited contribution to understanding the moral background to donors' choices. Ethnographic studies confirm that 'the IVF experience' is far from straightforward [2], and the ambivalence of the experience is likely to be even stronger in the particular case of donation of spare embryos, which (in the circumstances where it is allowed by the LSCR) will often be when IVF itself has failed. Women or couples who choose to donate spare embryos may be doing so because they understand fully the implications of their action and have come to a well considered decision, or, less happily, they may be unaware of the implications but feel obliged to donate because of external pressure or expectations. Those who choose not to donate may also have gone through well considered reflections but have come to the opposite conclusion from donors; this might reflect fundamental differences in the evaluation of key factors, such as the moral nature of their relationship to the embryo, or beliefs about the transcendent source of human life and the limits to human control, or could be primarily influenced by the individual life context of the potential donor. The roles played by these various factors may also vary according to whether the spare embryo has been newly produced or is a cryopreserved *altrechtlich* embryo.

Quantitative investigations therefore need to be complemented by a 'thicker' account of donors' beliefs, values, perceptions and judgements, in order for these lay moral understandings to be given serious normative scrutiny. After all, it will be moral considerations from the donors' perspective that determine the real-life fates of spare embryos. Donors' deliberations will take place within the ethical framework given by the law, and by social rules and institutions, but how donors interpret the framework within the context of their own values and moral priorities remains to be explored.

In April 2005 we began a study of the choices made by couples undergoing IVF in Switzerland, with a particular interest in seeing how the implementation of the LSCR (which came into force on 1 March 2005) affects the decision-making process and couples' attitudes towards, and beliefs about, their embryos. We hope this research will provide insight into the ethical and other grounds for the choices made by women or couples who find themselves in possession of a spare embryo and have to decide what to do with it. We want to find out which, if any, of the options now available corresponds to what the woman or couple might consider as their ideal: what they would *wish* to happen, when they are faced with an untransferable embryo. An empirical ethical analysis that goes beyond being purely descriptive is equally crucial to acquire information about the values on which couples base those choices, the process of moral evaluation they perform, and how moral understandings are affected by factors such as the language used (e.g., spare, surplus, excess, unwanted, untransferable) to describe the embryo, or the implicit and explicit procedures that accompany the making of these decisions.

There is ongoing debate within bioethics about how to relate empirical evidence of real moral behaviour to normative understandings of bioethical issues [3, 25, 27, 42, 43, 45]. How much can what people actually think and do, morally, contribute to theorising about what people *should* do (and even think)? We can do no more here than simply state our theoretical commitment that, although empirical data on moral life cannot in themselves be normative, the bioethical enterprise as a whole should be based on the widest possible knowledge of real moral understandings. This expanded database can challenge what is taken for granted as normative values or goals, and enhances the critical appraisal of assumptions about what constitutes good lives, and how to identify good acts. Such an empirically grounded and critical function of bioethics is especially needed in situations like stem cell research, where biomedicine, legislation and the social order together create novel moral entities (spare embryos) and social roles (the embryo donor) that lack normative precedents.

Does introducing the embryo donors' point(s) of view affect the normative evaluation of embryo donation? We believe that there are strong reasons to think that it will. First, it will increase our understanding of the elements that the donors themselves, rather than bioethicists or doctors, find morally salient in this situation. For a topic like this, some of the differences will undoubtedly be due to differential *understanding* of biological and ontological distinctions. But our previous research in other areas of bioethics [38–40] shows that there can also be substantial differences between the principles, values and actors that are prioritised in professional ethical analyses, and the priorities of lay moral evaluations. As an example, we noted earlier the potential difficulty in giving legal weight to the difference between fertilised eggs and embryos, when this distinction is not easily grasped by some of the people the technology is intended to serve, or when it may not be morally meaningful. Placing the donors at the centre of the moral account here will enable us to notice how useful they find this distinction; if they do not find it useful, whether this is because they simply do not understand the point or whether they have other, more cogent reasons; and whether their own reasons give good ethical grounds to challenge the key role given to the fertilised egg/embryo distinction in Swiss law on reproductive medicine.

On a theoretical level, introducing the embryo donors' moral perspective challenges the way that bioethical questions (particularly those dealing with embryos) are framed, both within the professional domain and, as bioethical issues become integrated in everyday life, within popular discourse. Taking its cue from philosophy, bioethics conventionally privileges deductive approaches to situations of moral difficulty, and deductive approaches work against sampling a plurality of experiences, or the inclusion of moral viewpoints (like that of the donors) that may not be immediately transparent to professional bioethics or medical ethics. The deductive approach is appropriate to societal decisions on the rules that set limits to individual choices, but does not necessarily hold for the individual decision taken within the framework of the law. Here, other criteria of reasonability can also be used — criteria that have less to do with rights, duties, norms or moral status and are more concerned with virtues, the quality of communication, or the maintenance of relationships.

Other conventions of bioethical analysis also determine how moral issues are framed, who or what is seen as the most relevant factors to be taken into account, and how they are weighted [22, 28, 31]. For example, many bioethicists would consider that the key question being asked in the Swiss stem cell debate was, 'What is the moral status of the embryo?' Structuring the debate around the embryo's moral status inevitably makes the embryo the key figure and decontextualises it. What slips from sight is the moral significance of the relationships between the embryo, its mother, father, and other persons, the place of care owed to the existing or potential offspring, or the interweaving of multiple responsibilities through a person's social and familial roles. From the point of view of a potential donor the key ethical question might be, 'Given that I hoped this embryo would turn into a child for me, but now it never can, what is the right way for me to treat it?', or 'What kind of person am I if I decide not to donate?' or 'Who else might be harmed by my decision, and what is my responsibility to them?' These questions are all different, both from each other and from the question of moral status. They are also linked to different sets of assumptions and lines of argumentation.

Similarly, describing the stem cell law as being about *donation* turns it into a question about the ethics of an abstract, decontextualised act, one that has parallels with donor acts in other areas of medicine. Describing it as being about *donors* and the decisions they can make, on the other hand, brings previously obscured areas of moral life to the fore. This is particularly important in this case because with the innovation of permitting donation of spare embryos to research, a new social role has been created: the embryo donor. In Switzerland at least there is no precedent for this role and hence no collective knowledge of how to *be* an embryo donor. Likewise, there has so far been no exploration of the ethical issues faced by the person in this role, the problems and priorities encountered, which ethical approaches provide the best guidance, and so on. This means that as yet, there is no individual 'feel' for how to be a good embryo donor. In principle the idea of donation might have some overlap with, for example, the role of living organ donors, but there are equally obvious differences between the experience of a woman donating an untransferable blastocyst to research, and that of a man donating a kidney to his mother.

One of the most crucial differences here is gender. The law refers almost exclusively to couples, largely because IVF is not legally available in Switzerland to single people. It is not until we focus on embryo donors rather than embryo donation that the complexly gendered nature of the process becomes clearer. Many feminist ethicists would argue that the gendered differences in the physical cost of invasive IVF procedures, and later of childcare, need to be incorporated in any ethical account of embryo donation to research. A feminist ethics of embryo donation might claim the right of a woman to dispose of her blastocyst as she herself determines, but it might also want to take seriously the ambivalences, ambiguities and conflicts around the enacting of that right in real life. Moreover the socially recognised pattern for 'how to be a good embryo donor' is likely to look quite different for women and for men, and this difference itself should draw ethical attention.

Concluding Comments

In this paper we have used Switzerland's discussion in 2002–2004 of its draft law on stem cell research to show how the existing laws, available political processes, and dominant social structures can modulate an ethical debate by determining the questions considered worth asking, the concepts and entities used for discussion, which concepts or entities are given priority, and whose opinions are invited and heard. In the Swiss case, reaction to legislation in neighbouring European countries, and the drive for biomedical research by economically important local industries, were among the features that shaped the political response. The practical demands of the parliamentary process later led to the separation of stem cell research from embryo research with a concomitant shift in the ethical background, while work within the legal framework meant that legally defined entities, such as fertilised eggs and spare embryos, acquired new ethical importance. The media discussion was characterised by the absence of representation of potential embryo donors, and we indicated above how we think their presence could have fundamentally altered both ethical discourse and political process.

It goes without saying that the interactions between the legal, political, social, ethical and other domains are not straightforward, and any real-life bioethical controversy will be unique in detail. Nevertheless, understanding how these parameters interact with ethical analysis in specific cases is likely to lead to insights that are more broadly applicable. The examination of the Swiss case suggests to us that the ethical discussion of a socially embedded practice such as research on hESC not only *should* not, but actually *cannot* be carried out in isolation from the social setting in which it takes place. To have these multiple interactions teased out is *ethically* helpful – certainly to clarify ethical analysis, but also to achieve the goals of fostering informed public debate, and helping couples undergoing IVF comprehend the rationales behind what they can and cannot do, legally and morally, with their own embryos.

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