

## COMMENTS

# Regulating (or not) reproductive medicine: an alternative to letting the market decide

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### **Abstract**

*Whilst India has been debating how to regulate 'surrogacy', the UK has undergone a major consultation on increasing the amount of 'expenses' paid to egg 'donors', while France has recently finished debating its entire package of bioethics regulation and the role of its Biomedicine Agency. Although it is often claimed that there is no alternative to the neo-liberal, market-based approach in regulating (or not) reproductive medicine - the ideology prevalent in both India and the UK - advocates of that position ignore the alternative model offered by France's tighter regulation, as well as its overarching concern with protecting the vulnerable and ensuring social justice. Whilst the concepts underpinning the French model of regulation also have their provenance in Western political philosophy and not in the developed world, they embody a very different attitude and suggest that there is indeed an alternative to letting the market decide. However, even in France that alternative is highly contested.*

### **Introduction**

Does India need a new independence struggle? If so, it would not be against British colonialism this time, but against the neo-liberal UK approach to regulating reproductive medicine. It is highly ironic that in its approach to encouraging commercial 'surrogate' motherhood and private IVF clinics, India seems to be following the same 19th-century liberal 'free market' arguments that have long prevailed in Britain and that are gaining further strength under the Conservative-Liberal Democrat coalition government (1,2). Despite the existence of a regulatory body, the Human Fertilisation and Embryology Authority (HFEA), 'let the market decide' often seems to be as much the order of the day in the UK today as in the time of the *Ragged-Trousered Philanthropists*. (3) But *laissez-faire* ideology is not the only available set of principles for regulating reproductive medicine-or, as *laissez-faire* would recommend, not regulating it.

Whilst India has been debating how to regulate 'surrogacy' and the UK has been undergoing an HFEA consultation on increasing the amount of 'expenses' paid to egg 'donors', France has recently finished debating its entire package of bioethics regulation and the role of its Biomedicine Agency. (I use inverted commas around commonly used key terms in the previous sentence because all three words are misleading:

the birth mother is the legal mother and not in any true sense a 'surrogate', the 'expenses' foreseen in the HFEA consultation border on 'wages', and paid egg 'donors' should more accurately be termed egg 'sellers'.) Although it is often claimed that there is no alternative to the neo-liberal, market-based approach in regulating (or not) reproductive medicine, which is the ideology prevalent in both India and the UK, advocates of that position ignore the alternative model offered by France's tighter regulation, as well as its overarching concern with protecting the vulnerable and ensuring social justice.

In this article I want to set out the underlying philosophical presuppositions of the British approach to regulating reproductive medicine and to contrast them with another set of attitudes: those embodied in the French debate on bioethics regulation in France's National Assembly and Senate. Whilst the concepts underpinning the French model of regulation also have their provenance in Western political philosophy and not in the developed world, they embody a very different attitude and suggest that there is indeed an alternative to letting the market decide. However, even in France that alternative is highly contested.

On June 23, 2011, the revised French bioethics bill was passed, resolving disagreement between the National Assembly and the Senate. Assembly deputies tried to reach a compromise between their preference for strict regulation and amendments passed by the Senate in its first reading, which would have overturned some aspects of the traditional strict regime. In its own second reading of the draft bill, the Senate accepted those compromises and retreated from its earlier more neo-liberal position. Nevertheless, even though the two chambers disagreed on particular issues, such as whether stem cell research should be permitted by default or only by a specific derogation, both legislative bodies adhered to a very different set of ethical principles to those dominating in the UK, suggesting that there is indeed an alternative to letting the market decide. For example, private umbilical cord blood banking will remain illegal in France, on the grounds that it takes away a valuable resource from the public banks, undermines solidarity and risks exploitation of parents at a vulnerable time. By contrast, in the UK private cord blood banking is permitted, although with some regulation by the Human Tissue Authority-but that body is soon to be abolished.

Whilst the Assisted Reproductive Technologies Regulation Bill, 2010, now before the Indian Parliament, is justifiably concerned with reducing exploitation of 'surrogate' mothers, it will also make commercial 'surrogacy' contracts legally binding, which the French bill explicitly rejects-just as it rejects markets in eggs. Although the UK does not propose to legalise commercial 'surrogacy' contracts at present, or to pay outright for eggs, the HFEA consultation was triggered, like India's legislation, by the rise of 'reproductive tourism' and by international markets in women's reproductive labour (4), which has been called "the purchase of fertility from poor women in the developing world". (5)

The fascinating juxtaposition of the three countries' fundamental debates on regulating (or not) reproductive medicine offers a timely opportunity to consider the contrasting underlying philosophical assumptions, which are too often overlooked. In this article I will concentrate primarily on the contrast between the UK and France, leaving the Indian audience to apply their own conclusions to their Assisted Reproductive Technologies Regulation Bill and to the question of whether there is indeed an alternative in Indian biomedical regulation to the increasingly dominant free-market position.

### **The institutional position: the UK and France**

On January 17, 2011 the UK's HFEA announced a consultation on increasing the level of 'expenses' currently payable to egg donors, with the consultation running until April 8. (The consultation results had not been announced at the time this article went to press.) While *payment* for gametes is prohibited under a European Commission directive of 2004, it is left up to each EC country to decide what level of expenses it will permit, and also how to determine what counts as expenses. Article 12 of this EC Tissue Directive stipulates: "Member states shall endeavour to ensure voluntary and unpaid donations of tissues and cells. Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which compensation may be granted."

The HFEA has previously taken the position that expenses do not include wages, but rather only direct costs-unlike Spain, for example, which interprets 'expenses' more leniently and allows up to 900-1200 Euros to be claimed. In contrast, expenses cannot at present exceed £250 in the UK, a sum last increased in 2006 as a result of a previous review, the Eggs, Sperm and Embryos (SEED) consultation. (6) Partly as a result, Spain's burgeoning private IVF clinics have made the country a prime destination for reproductive tourism from other European countries, including the UK. Concerned about the uncertainties these buyers face and perhaps also about the competition threatening private British IVF clinics (although it denies that), the HFEA now proposes, if the consultation permits, to reinterpret the level of allowable expenses. But it faces the obstacle of creating inducements that are impermissible under European law.

The way in which the HFEA consultation document attempted to get round this barrier was to make a distinction

between *creating 'incentives'* to donate and *removing existing 'disincentives'*. If women are eager to donate eggs but are being blocked by failure to pay sufficient expenses, on this reasoning that counts as a disincentive. In the HFEA's view, it could be removed by increasing the level of expenses, without breaching European law.

Apart from the lawyerliness of this reasoning, however, there are major questions about how accurately it reflects women's motivations. In the HFEA's own previous SEED review, women surveyed put lack of financial inducement at the very bottom of the list of reasons why they did not wish to donate eggs. At the top came justifiable concerns about the uncertainty of evidence concerning risks of ovarian hyperstimulation. The survey evidence also showed that only 10% of respondents thought that women should be compensated in the form of expenses, while 35% rejected any compensation, even for expenses-presumably as the beginning of a slippery slope towards a market in eggs.

Although France faces a similar problem of reproductive tourism, together with a shortage - estimated by the French *Agence de la Biomédecine* (Biomedicine Agency) - of about 700 egg donors a year (7), the draft French bill does not propose payment for gametes, not even by the back-door means of increasing expenses. Risks to the donor remained prominent in experts' testimony before the legislature; nor is this mere paternalism. It reflects genuine popular concern.

Before the draft bill was tabled, a series of two-day public consultation meetings was held - symbolically called the Estates-General of Bioethics, like the meetings which were of course the prelude to the French Revolution. Each of the three consultation meetings in different provincial cities authored its own report of its deliberations (whereas the HFEA writes the reports of its consultations, arguably more paternalistically). The Rennes panel, which debated questions about reproductive medicine, condemned any attempt to pay for eggs or sperm, consistently with the long-standing recommendations of the French National Ethics Committee (8)-indicating that distrust of the market is not just the opinion of a metropolitan elite, but also a popular view. The French will also continue to forbid commercial 'surrogacy', although in this case against popular opinion - with 65% of the French populace surveyed favouring de-criminalisation of surrogacy (though not necessarily commercialisation) - and despite a media petition by a number of French academics (9, 10).

While the HFEA consultation document downgraded ethical concerns as an obstacle needing to be 'balanced' against the need to increase donation, a group of French parliamentary deputies has stated that "Law, morality and progress are compatible." (11) These deputies were signatories to a petition demanding the Assembly's right to make key decisions in reproductive medicine, rather than devolving its powers to the national Biomedicine Agency. By contrast, the HFEA-even though it has demonstrated an increasingly pro-market slant in previous consultations as well as this one (4: 79 ff.) - is set to be abolished before the end of the current Parliament in

the current government 'bonfire' of regulatory agencies. Even though it also has a centre-right government, France appears willing to accept or even increase the role of state regulatory agencies, although not without debate.

Do the French purchase their generally stricter and more principled approach to regulating reproductive medicine at the cost of highly centralised control and government sclerosis? This is a common accusation: the sociologist Paul Rabinow, for example, concluded from his comparative study of US and French human genome research that France is poorly equipped to deal with the global biotechnology industry. He alleges that France is too accustomed to relying on the state to regulate, while the state is too inconsistent in its stance and too ponderous to deal with the quick cut-and-thrust of modern commercialised biotechnology (12).

True, there are some heavy-handed aspects to French regulation of reproductive technologies, most notably the long-standing restriction of IVF to heterosexual couples who are either married or in a long-term relationship. This issue was been freely debated during the bill's passage, and it appeared at one point that lesbian couples would be able to gain access to assisted reproductive techniques. That this measure eventually failed was indeed a disappointment to many. The level of debate was high and extensive, however, which would not be the case if the accusations of autocratic government were true. In general, the old stereotype of the French political system as statist and static looks increasingly threadbare to many observers (13) (14).

Indeed, some might feel that the UK that now possesses the unattractive combination of a highly centralised government, bent on implementing an unprecedented level of public services cuts not included in the party manifestos during the elections, with a lax regulatory regime for commercial interests and easier access for firms to government procurement. The *Guardian* reported on May 31, 2011, that the government was awarding £56 million a day to private companies in outsourced contracts, and that 3,000 new contracts had been issued since the start of the calendar year.

### Philosophical assumptions and presumptions

Although the HFEA consultative report seemed to view ethical concerns as a nuisance to be 'balanced' against the need for increasing egg donations, of course it was implicitly taking an ethical position: a utilitarian one. The implicit presumption was that welfare would be maximised by increasing the level of egg donations, benefiting recipient couples directly by obviating the need to travel abroad and doing no harm to donor women, since their 'expenses' would be met. But the notion that ethical concerns can be 'balanced' against welfare also assumes that they are secondary to the production of favourable consequences, a position that would be challenged by philosophers from Plato to Kant (15). Although only three per cent of women surveyed for the previous SEED review considered low compensation to be the main barrier to egg donation, the HFEA position also made the materialistic

assumption that people are most reliably motivated by financial considerations.

There are other highly debatable moral positions at stake here as well:

- that the needs of egg purchasers are the primary consideration, rather than the possible vulnerability of egg providers;
- that individuals have rightful ownership of their body parts, allowing them to do whatever they like with their tissues;
- and that by giving their consent to donation in return for an increased level of expenses, egg providers have made an autonomous choice, which puts paid to any charges that they might be being exploited.

All these positions have been challenged in the bioethics literature, by feminist critics and many others (16-19), but they do continue to dominate ethical debate in the UK. Subsuming them all is a set of simplistic assumptions that biomedical science is best left to biomedical scientists, that those who propose regulation are anti-technological Luddites, and that the state's minimal role should be to provide the conditions in which commercialised biotechnology markets can flourish (20).

Not so in France, where parliamentary debate and the long consultation preceding it have turned on the values of non-commercialisation, dignity, bodily inviolability, justice and protection of the vulnerable. Where there is dispute, it tends to be over the question of who counts as vulnerable, with Roman Catholic commentators and those Assembly members sympathetic to them pressing strongly for the protection of the embryo as the most vulnerable party. But even between the 'Catho' commentators and the political Left, there is a surprising level of agreement on a communitarian approach to bioethics, emphasis on social solidarity and dislike of individualistic 'Anglo-Saxon attitudes.' This underlying French concept of governance is more influenced by Louis XIV and Jean-Jacques Rousseau than by Adam Smith and John Stuart Mill.

As I wrote earlier:

In France the effect of democracy, in its direct Rousseauesque variant, was to transfer the personality of the monarch wholesale to the entire people. It is the sovereign people which exercises power and enjoys rights in this formulation of democracy; individuals are also accorded rights by virtue of their membership in the collectivity, but not as individuals per se. The collectivity, or body public, is primary. Liberal democracy, by contrast, conceives of the individual in the state of nature as the basic building block, and of the state as secondary, formed through the social contract and limited by the rights of individuals. (16:150)

A striking example of this anti-individualistic approach in practice can be found in the official French view of gamete donation as a gift from a fertile couple to an infertile one—not, as in the United States, as a consumer good for which markets are stratified according to the buyer's preferences in

physical appearance, intelligence, and even such 'must-haves' as musical ability (21). The legislative passage of the French bill did take account of the legitimate charge that this official view discriminates against gay couples, but there was a stalemate between the Senate's preference for allowing lesbian couples to have access to IVF and the Assembly's rejection of this proposal on the grounds that infertility treatment should be for a 'medical' rather than a 'social' condition. (Either way gay men would have continued to be denied access to IVF, since they would require a 'surrogate' mother, which will remain illegal.)

In France there seems to be rare agreement among academics and politicians that the market approach to gametes is to be distrusted, along with other Anglo-American philosophical paraphernalia. According to Sylviane Agacinski, professor at the École des Hautes Études en Sciences Sociales (22), the individualistic view predominant in Anglo-Saxon culture ignores human dignity and societal justice. Individual informed consent is necessary but not sufficient, she argues. It is not the last word in any regulatory debate-as, for example, in the claim commonly heard in the Anglophone world that there is no affront to women's dignity in allowing them to sell their eggs, provided they have given an informed consent (23).

In the Anglo-Saxon countries, as Lisa Ikemoto has argued (24), the language of choice, autonomy and equality-originally liberating for women in the US abortion decision *Roe v Wade* (25)- has now become a justification for untrammelled free-market individualism. That linkage serves the interests of the US and global markets in 'baby-making,' including not only the monies paid to egg sellers but also the massive revenues to drug companies for fertility drugs and the profits of private IVF clinics (4:2). The language of choice and consent, then, is insufficient, and even misleading. Instead, the communitarian view argues, we must also consider the possibility that disadvantaged economic or social circumstances lie behind women's ostensible consent.

In France, Philippe Gosselin, a parliamentary deputy and secretary of the committee revising the bioethics laws, has insisted that the new legislation must continue to reject what he sees as the dominant utilitarian voice in the UK and elsewhere in Europe. "Neither objectification nor commodification," he insists. "A human being cannot be reduced to the level of a thing and should not become an object of commerce." (26)

Although Gosselin might not identify it as such, this is a Kantian position. While autonomy is of course central to Kant, those US and UK scholars who view choice as a knock-down argument ignore the way in which Kant himself *denied* that we are free to sell our own tissue or to buy the tissue of others. To treat parts of the body as fungible objects is to treat the provider not as an autonomous member of the kingdom of ends, but merely as a means, which is forbidden by one version of the Categorical Imperative. Even if the seller of tissue voluntarily consents to treat her own body in this fashion, it is still wrong for any would-be buyer to treat her in this fashion, because it is inherently degrading (27).

Many UK and US authors have of course provided substantial critiques of the dominance of autonomy in Anglo-American bioethics: most recently Amitai Etzioni's complaint that overemphasis on individual choice marginalises the broader interests of society (28)-and, one could add, does the socially dispossessed few favours. But what sets France apart is that those critical of commercialisation and markets are not voices crying in the wilderness; rather, they constitute the political mainstream. Their views often make public policy.

For example, France was the only country to ban the exhibition by Gunther von Hagens of plastinated bodies, on the grounds that it was a commercialised violation of individual dignity and that the donors' supposed consent was spurious, in light of indications that the bodies were those of executed Chinese criminals. From its beginnings the French national consultative ethics committee, the oldest in Europe, has consistently reiterated a stance against commodification of the body (8).

In the name of its cherished principles of altruistic and anonymous donation, France has also rejected proposals from private cord blood banks to set up operations there-a potentially lucrative market, given the high French birth rate. The value of social provision over private was restated in this context by Senator Marie-Thérèse Hermange: "Cord blood should be available to all, in a framework of public solidarity, at no cost, not privatised." (29) The country now has 10 public cord blood banks, with more being set up, but has rejected overtures from combined private-public banks as a Trojan horse enabling the private sector to infiltrate the public. As the medical evidence base suggests that publicly banked allogeneic blood is clinically more efficacious than privately banked autologous blood (30), this position makes both medical and ethical sense.

## Conclusion

France is not a Shangri-La isolated from global markets and their accompanying neo-liberal economic orthodoxy. There are powerful voices arguing for the nation to move with the times, to become more internationally competitive in scientific research and biotechnological investment by embracing those distrusted Anglo-Saxon attitudes. Professor René Frydman, who helped to create the first IVF baby in France and who favours paid egg provision, has complained, for example, that his country "always prioritises risks before progress" and argues that "there can be no progress without commercialisation." (30, 31)

Nor is France a paradise; indeed, there are fears that it may become something more like a Paradise Lost. In the words of Emmanuel Hirsch, professor of medical ethics at the University of Paris-XI, "How long can our bioethical standards continue to resist the rise of other logics-particularly financial ones-which are worming their way into the governance of medical research and determining its objectives, its norms and its values, to the detriment of the common good?" (32) Given global trends in India, China and other developing countries-not just the dominant US and UK market-friendly systems of regulation-this is a serious and troubling question.

Hirsch's doubts were borne out during the Senate debate, in which some commentators detected an increasing influence of

commercialised biotechnology. As the senator Bruno Retailleau put it, "The Senate prides itself on protecting individual liberties, but at the risk of neglecting the public welfare," which he attributed to the way in which "the influence of the scientific lobby on the Senators grows and grows." The former director of the national research network INSERM, Professor Alain Privat, remarked that "This lobbying is incomprehensible from a medical or scientific viewpoint, unless you attribute it to the need for certain organisations to justify to their generous funders the highly important investments they've made in stem cell research, despite the fact that this research hasn't yet resulted in any effective therapies anywhere in the world." (33)

Some might contest my depiction, which I share with most French commentators, of the way in which market norms dominate Anglo-American regulation of reproductive medicine. The HFEA enjoys a global reputation for well-considered governance, particularly among US scholars who are troubled by their lack of any equivalent national regulatory agency. In the HFEA's most recent consultations, however, the balance seems to be increasingly tilting away from regulation towards permissiveness, as in the view of ethical considerations as something to be offset. It might be said that the ongoing and rather undeserved conviction that the UK's regime outshines that of other countries, France presumably included, resembles nothing so much as Thackeray's certitudes about the moral and physical superiority of the Englishman over the Frenchman:

I say to you [the English reader] that you are better than a Frenchman. I would lay even money that you who are reading this are more than five feet seven in height, and weight eleven stone; while a Frenchman is five feet four and does not weigh nine. The Frenchman has after his soup a dish of vegetables, where you have one of meat. You are a different and superior animal—a French-beating animal (the history of hundreds of years has shown you to be so); you must have, to keep up that superior weight and sinew... simpler, stronger, more succulent food. (34)

As I remarked in an earlier newspaper article (35), "Of course, we now know that a diet of bully beef is likely to result in hardening of the arteries, whereas the vegetable-centered Mediterranean diet is much better for human health. Enough said?"

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#### Note

All translations from the French are the author's own.