This country is not a religious country in the sense that the US or Poland or Israel may be said to be. Our problems with moral issues or religion tend to be subdued by legislating, giving Parliament the ultimate answer, and leaving morality for the little interstices that may appear in the drafting when an issue presents itself for decision which is not precisely covered by the wording.

That this was to be our approach was evident from the beginning of IVF. As early as 1971, before the technique had even been successfully used, Dr Robert Edwards, the pioneer of IVF, and the clinician who oversaw the birth of Louise Brown, recognised the ethical problems inherent in IVF. Provoked, perhaps, by the refusal of the Medical Research Council to support his work on embryos, Edwards suggested a “simple organisation, easily approached and consulted, to advise and assist biologists and others, to reach their own decisions. Such an organisation must represent widespread but uncommitted interests and be free of partisan politics. It would frame public debate, act as a watchdog, and yet interfere minimally with the independence of science (Edwards & Sharpe, ‘Social Values and Research in Embryology’, Nature 231, 1971, 87-91.) At the same time, another farsighted pioneer, James Watson, was warning about the dangers of human cloning and surrogacy, were they ever to prove possible, and calling for international agreement (‘Potential consequences of experimentation with human eggs’ Comm. on Sci. and Astronaut. Intern. Sci. Policy (1971) 149-161). The fact that Dr Edwards would later describe state interference in reproductive medicine as ‘Nazism and Stalinism’ is one of several illustrations of the fluctuation of support by doctors and scientists for regulation, and a protest against a weakening, as they see it, of the imperative to treat and research. This is the background of my theme, the struggle for domination in the field of embryology and infertility treatment, joined because of its enormous physical and financial potential and fascination.

I would like to look more closely at how this struggle is playing itself out in the newer areas of embryo research, areas where the HFEA or Parliament made decisions, ones that are of global application and interest. These discoveries have moved the science of embryology on beyond the “traditional” area of enabling an infertile couple to have a baby, and they represent, to some, a profound threat to the natural order of things because they use the established infertility techniques for lifesaving and life-altering purposes. There are many such new areas, but for the purposes of illustrating how ethical considerations manifest themselves, I shall focus on stem cell research and so-called “saviour siblings.”

**British Ethics**

Ethics is a word used lightly and claimed by each of the factions to be on their side. Given that my belief is that comprehensive regulation is a good thing, and a solution to most problems, I see “ethical” in this context as a designation for a professionally acceptable practice, reached after deep consideration and liable to mutate within a legal framework. This pragmatic approach dates back to the Warnock Report of 1984 and its maxim, which I quoted in my last lecture, that people want some principles or other to govern the development and use of the new techniques. The Report commented that a society with no rational or religious inhibitions is one in which anything goes and animal instincts prevail, and this is especially true in matters of sexual reproduction, birth and death.

The law that emerged from this Report (the Human Fertilisation & Embryology Act 1990) embodies in the UK a common moral position. Individuals may choose not to take advantage of it, but it sets a framework within which professionals and patients may feel respectable in their pursuits. Indeed, the argument that is often made by commentators is not that there should be more ethics, but that the principled interference with autonomy and the private right to reproduce must be justified, and justify it I will.

**Autonomy**
Associated with this is the argument that respect for autonomy trumps everything else in medical ethics. Some regard it as a universal principle to be recognised in all countries and one that crosses all religions and cultures. Autonomy means that doctors cannot force us to accept treatment that we do not want or to make choices that are good for us, and that there can be no interference, even the slightest, without consent, and it goes without saying that the consent must be informed, otherwise it is not genuine. So the provision of information and the expression of consent have become enormously important in the law and practice of IVF in this country. The purest expression of autonomy is associated with the German philosopher Kant, who is famous for having expressed the view that people should never be treated as mere means to an end, but as an end in themselves. It is ironic that the greatest breach of that dictum was to take place in his own country some 130 years after his death.

But, as we all know, autonomy does not prevail in any walk of life, let alone reproduction, for we live in a community. JS Mill shed clearer light on this dilemma by explaining that while one may have sovereignty over one's own body, conduct that concerns others may be restrained. This is for the avoidance of harm and for the preservation of the same amount of autonomy for others as one has oneself, that is, not using one's own independence to destroy that of others. So it is clear that there may be constraints in reproductive law and medicine, to prevent harm to the baby, to the mother, to other members of society and to public health in general. A patient may not demand that a doctor give her treatment that may harm her. Cloning is banned because of the safety of the baby. Multiple embryo use imperils babies and their mother, and so on.

The whole area of reproduction is not, and has not been for a very long time, one in which autonomy prevails. On the contrary: the hallmark of a civilised society is that it puts boundaries around issues of rape, incest, the age of marriage and of agreement to sexual intercourse, abortion, forced marriage, prostitution and other sexual practices, not in order to protect autonomy but to protect the health and wellbeing of mothers, babies and all of society.

The HFEA attaches a great deal of importance to the dissemination and quality of information that has to accompany consent, and so does the law. One can see from the website (www.hfea.gov.uk) the numerous publications on reproduction that are available; the statistics relating to the success rate of each clinic (although there are also good arguments against this publication, which may stimulate unhealthy competition and commercialism), and the mandatory offer of counselling.

**Embryos and Morality**

On the other side of the ethical debate is the respect for the embryo which is found to greater or lesser degrees in various cultures and religions. This lies at the heart of the newest ethical debate, which focuses on their use for research, a step further away from "respect" than their use and disposal in infertility treatment. It is very well known that embryo research is regarded as morally wrong by some because the embryo is human from the moment of fertilisation (does this include fertilisation without sperm as in cell nuclear replacement?), and therefore one should not take its life or bring it into existence simply in order to be destroyed. This is said to be as true of the embryo as of children and adults. Indeed, one may take the argument from this perspective a step further: if one should not destroy anything with the potential to become an adult, this could apply equally to eggs on their own, for eggs can be converted into embryos through the cloning technique. Fertilised eggs are lost every month by women naturally without intention and so, arguably, it would be more ethical to refrain from all intercourse save that guaranteed to result in pregnancy, for otherwise fertilised embryos are lost through menstruation. That is the Catholic position, but let us also consider the opposite argument - all time spent in avoiding fertile intercourse is unethical for one is refraining from bringing into being embryos with potential. Most people, however, would not accept that every entity with human potential must be allowed to flourish, either because they accept the difference between gametes and persons, or because the whole of life might be dedicated to the production of potential without the means to fulfil it.

Although embryos die naturally, it does not follow that it is acceptable to destroy them or manufacture them for research, for humans die naturally, yet we all agree that it is wrong to bring life to a premature close by murder or neglect. The Warnock Committee reached a typically British compromise over the status of the embryo by declaring that it should be given by law special status but not one that justifies its being accorded absolute protection. This compromise was agreed with by the House of Lords Select Committee 2002 Report on Stem Cell Research, (chaired by the Gresham Professor Lord Harries) para. 4.21, and by subsequent legislation. What does it mean to say that the embryo is deserving of respect? Under law it means that in general it is to be used only if there is no alternative, and for an approved purpose, that its use must be ruled by the informed consent of the donors, that there are restrictions on the import and export of embryos, and that there is considerable record-keeping to account for the ones used.

**Frozen Embryos**
An illustration of the dilemma, all the more painful for those who believe that human life is in storage, is the question of unclaimed and surplus frozen embryos, left over after IVF. Some years ago it was estimated that there were 400,000 frozen embryos in storage in US clinics, a number that must have grown, and to which should be added considerable storage in Europe and the rest of the world. Couples who have had IVF treatment and whose surplus embryos are stored pay substantial fees every year to clinics to continue storage. Very few, as little as 3%, of the surplus embryos are given for research. Storage presents major problems as parents and would-be parents have either successfully completed their IVF treatment, and do not wish to use their retained eggs, or have failed, and have difficult making decisions that will finalise the storage of the embryos, or they have simply moved home and cannot be traced to give instructions about disposal or retention. Extended storage inevitably creates the risk of accidental melt down and identity mix ups. Both in the USA and in the UK such problems have created headlines and severe legal problems. (The electricity failure leading to loss of fertilised embryos; the loss of identity labels and the inability to DNA test embryos without thawing them.)

A time limit had to be placed on the retention of frozen embryos. Nevertheless when in 1996 the first time limit set by the 1990 Act was reached for disposal of embryos no longer required, under the 1990 Act, the resulting destruction of many thousands created adverse headlines for the IVF community. The situation was made worse by the tendency of newspapers to illustrate the story with pictures of fetuses rather than embryos, and by offers from wellmeaning volunteers, such as nuns, to “adopt” the frozen embryos. This is not possible because they may only be given away with the consent of the parents; and usually an infertile couple need either donor eggs or donor sperm, not usually embryos. The law, which allows storage for 10 years now, gave priority to the autonomy of the adults concerned over the moral interests, if any, of the embryos and other infertile couples.

Respect for embryos seems to me to go in inverse proportion to attitudes towards the taking of adult life. In countries where capital punishment is still common and where in past times execution was widespread for criminal, moral and religious failings, great respect was due to the life possibilities of embryos and not so much to fully grown adults. Permissive Western societies where embryos may be relatively easily created and disposed of, at the same time express great concern for the welfare of the adult human body, both in terms of abolishing capital punishment, health care and human rights.

The Law and Ethics

Not only is the British attitude to moral questions pragmatic and parliamentary, the issues that arise are almost always covered fairly comprehensively by legislation, of which there is more and more. Not just the founding act, the Human Fertilisation & Embryology Act 1990 and its 2008 successor (currently delayed because of controversy over the abortion provisions which are unfortunately and I think inappropriately also contained within it), but also the Human Tissue Act 2004, the Human Reproductive Cloning Act 2001 and the Research Purposes Regulations of the same year extending the purposes for which embryo research may be carried out. The Human Rights Act 1998, based on the European Convention, has thrown into the fine balance of English common law an extra weight of individualism, which is occasionally used to attempt to divert the 1990 Act away from the public good to the private. There is also international law: the European Convention on Human Rights and Biomedicine 1997; the Unesco Universal Declaration on the Human Genome and Human Rights 1997 amongst others. The UK government has been careful not to sign away its rights to research and is not a full party to the international conventions for this reason. This illustrates the difficulty of getting one international convention to cover all nations.

Decisions made by the HFEA are open to judicial review by the courts, and have been reviewed on some occasions, although only two challenges were partly successful Blood on export of the deceased’s sperm and Taranissi on the technical issue of a warrant to search. That means that in every decision it takes the HFEA must follow all its procedures in detail and must have regard to human rights, to the principles of natural justice, such as avoiding bias and hearing both sides; and it must also be mindful of the provisions of the European Union treaties, which allow freedom of movement to seek medical services and freedom of movement of goods and services. To rely on European law is ultimately to be able to circumvent just about all the carefully crafted provisions of British law, as we shall see.

So the number one consideration in what might otherwise be an ethical dilemma is the law - whether it was the question of the use of frozen eggs, or the number of embryos to be used in any one treatment, or the screening of embryos for disease, or therapeutic cloning for research. The resources to fight a decision in court against a well funded or legally aided litigant is another consideration, as are likely media treatment and political attitudes. It is amazing what an effect well chosen human stories and pictures of attractive women wanting to be parents have on public attitudes to otherwise well understood ethical prohibitions!
HFEA and Ethics

But when all that was taken account of, the HFEA developed five ethical principles from the law and from the developments that took place under its supervision:

1. The assurance of human dignity, worth and autonomy. Hence nobody may be treated as a convenience or a bank of spare parts. Consent and counselling are vital.

2. The welfare of the potential child. Consideration of its need for a father was in the original legislation, a compromise between those who would have confined IVF to married or heterosexual couples, and those who would permit it for any person. Welfare underlies the ban on embryo splitting and cloning babies, because of the family difficulties it would cause. There are careful legal provisions to establish the parentage of IVF children: whether or not they should be able to discover their paternity is a live question.

3. Safety first. The birth of healthy children must be the aim, not risk or experiment. Hence, consideration of the high risks attaching to multiple births, (low birth weight, cerebral palsy, early deaths and stress on the carers) led to the requirement that only two embryos, and now one, should be replaced in any one treatment cycle. This is sometimes resented by clinicians, who strive to achieve the highest possible success rate in “take home babies”, but is a rule designed to support public health and welfare.

4. Respect for the embryo and human life at all stages, expressed in care over creation, use and disposal. This principle has received a great deal of attention recently because the Bill of 2008 legalises for research purposes mixed animal/human embryos, or hybrid embryos. The main type of mixed embryo is one where human DNA is inserted into an empty animal egg (this is genetically 99% human); other combinations are animal DNA in a human egg; and a mixture of the sperm of a human with the egg of an animal or vice versa. In fact, for years male infertility has been tested, without controversy, by inserting sperm into a hamster egg. If it responds, this is a positive sign of the male’s fertility. Many of my women friends have wondered which animal is most like a man, and of all the answers that one might give, hamster was not often a candidate!

Why would one want to mix the two species, giving rise to the most deeply felt protests on the part not only of religious groups but many others in 2008? It is primarily because of the shortage of female eggs for research. Our knowledge of the origins of Alzheimer’s, Parkinson’s and motor neuron disease lie in the study of how these diseases originate. The DNA of people who have them will be used to create affected embryos of mixed animal-human origin, and then to grow the stem cells to discover how the disease might be eradicated or better understood. The research is backed by Nobel Prize winners, the government’s chief scientific officer, the Wellcome Trust, the MRC and others; it was also found that in explaining the technique to initially sceptical public focus groups, as they came to understand what was to be done, they became more accepting. The technique was approved by both Houses with large majorities. It must be recalled that the popular image of a half human half animal was not at all what was in issue - it is for research in the laboratory, and not for anything concerned with actual reproduction.

5. The lifesaving potential of embryos is a new principle that has emerged with the development of stem cell research and its possibilities. Most of those involved, and now Parliament, have accepted the utility of stem cell research which necessitates the creation and destruction of an embryo in order to obtain the early cells that may replace and renew failing adult tissue.

Stem Cell Research

I address in brief the moral history of stem cell research, for it is a topic to which a whole lecture ought to be devoted. As soon as the birth of Dolly the Sheep was announced in 1997, the HFEA undertook a public consultation together with the Human Genetics Advisory Commission on the issues raised by cloning. The resulting report, Cloning issues in reproduction, science and medicine (1998), showed that there was widespread concern about human reproductive cloning, including safety and other ethical issues arising from the reproduction of an adult whose genetic makeup was engineered to be identical to one adult, not two parents. The Report supported a total ban on reproductive cloning for any purpose, and indeed there is no form of infertility for which it is the only cure. However, many saw benefits in cloning cells for research, but certainly not for introduction into the womb, and which could result in relief for serious medical conditions. The Report recommended the legislative banning of reproductive cloning, but that the government should also consider extending the law to permit embryo research for methods of therapy for diseased or damaged tissues and organs. The public attitude in Britain to cloning indicated that concerns were less about entitlement to a unique genetic identity, but more about collateral issues like safety and consent. The consultation also highlighted the need for greater public understanding of human genetics, and the failings of our science education -
especially in my generation! The cloning issue was reported on also by the Royal Society, the Wellcome Trust, the Nuffield Council, the Medical Research Council, the British Medical Association, a House of Lords Committee and the Chief Medical Officer, and just about anybody with weight in the field of medicine. They all concurred that the benefits of embryo research outweighed the concerns about the use of embryos, and so the ground was laid for a parliamentary debate.

It was one of the most thorough and moving of its kind, and Parliament was lobbied both by patients in wheelchairs begging for the go-ahead for cures, and pro-life groups speaking for the inviolability of the embryo. In 2000 the whole country and its legislators were engaged in a deep debate whether it was moral or practicable to extend the purposes for which embryo research may be permitted. Although it had already been carrying on for some time, many members of the public seemed unaware of this (this happened again in the discussions about embryos and animal-human embryos in the new legislation of 2007-8). Susceptibilities were heightened by the publicity given to the Human Genome Project and any venture designated as "gen" (food, engineering etc.) Much media time was spent on explaining the creation of embryos by cell nuclear replacement and the distinction between that and reproductive cloning.

In the end, after a passionate debate in both Houses, a large majority in each House approved new regulations which came into force in 2001, permitting research for a) increasing knowledge about the development of embryos; b) increasing knowledge about serious disease and c) enabling any such knowledge to be applied in developing treatments for serious disease. Oversight is by the HFEA and other bodies. The importance of this is, in brief, that single cells removed from early embryos may be persuaded to grow into replacement brain, eye, heart etc. tissue matching the person whose cells have been cloned. This is because the early cells are "totipotent" - they have not yet become specialised parts of the body but are capable of growing into any type of human tissue. As the embryo grows, its cells are designated for the parts of the body that we know, for example, the first sign of the backbone is at 14 days. Then it may be too late to achieve the desired tissues and cures.

The stem cell story is a good example of ethics and pragmatism, scientific expertise combined with public consultation, lobbying and parliamentary debates. One can ask for no more in the governing of scientific work. American researchers sometimes look at us with envy, for President Bush has condemned the work and federal funding is withheld. The situation is likely to change if there is a Democratic President in 2009.

**Saviour Siblings**

Another case which was initially left to the HFEA to assess was the so-called saviour sibling: where a sick child needs stem cells from cord blood or bone marrow from a matching donor, and no donor can be found unless the parents give birth to another child with matching tissue. The Hashmi family have a child Zain, who suffers from the unpleasant and life threatening disease of beta thalassaemia, which requires daily invasive treatment. The Hashmis knew that they needed a donor of stem cells whose tissue would match Zain. They conceived another child naturally in the hope that the new baby's umbilical cord blood would help to cure Zain, but the new baby's blood was not a match for him. Unwilling to continue to conceive children who might not only suffer the same disease, beta thalassaemia, but whose blood also would not match the needs of Zain, they applied to the HFEA for a licence for a novel procedure. An alternative, equally undesirable, was to become pregnant naturally and have an abortion if prenatal screening were to indicate that the fetus was not a match as required. They wished first of all for PGD: this is a procedure which is allowed by the HFEA only in serious cases of life threatening inherited disease. It enables parents to select an embryo, created by IVF, which is shown by biopsy after a few days of development to be free of the feared disease. But they also wished to narrow the selection of an embryo to choose one that, if Mrs. Hashmi were to become pregnant, would result in a baby whose blood would be compatible with that of Zain. It should be noted that there was only a 1 in 16 chance of finding such an embryo and that a pregnancy consequent on this procedure would have a very slim chance indeed of succeeding. Statistically, the odds were against the Hashmis; nevertheless a decision in principle had to be made.

The HFEA considered the request carefully over a number of months. It considered the welfare of the child that might be born, as well as Zain's, under s.13(5) of the 1990 Act as amplified in the HFEA Code of Practice. The baby's welfare might in fact be enhanced by its success in helping its older brother. It reminded itself that people should be free to act as they wish unless there was a need to interfere in the interests of public health or morals. Some said that the parents were calling for an action that could lead to eugenics. To counterbalance this the HFEA looked at parental motivation. Was the new baby going to be a means to a further end or an end in itself? Clearly the parents loved their existing children and there was no reason to think they would not love another child, regardless of its usefulness in curing the older child, for parents tend to love their children equally, and the love available in this case was immense, given the procedures which the Hashmis were prepared to undertake for the sake of Zain.
To inquire into motivation for having children is a very modern issue. From the beginning of mankind until the end of the 20th century, a child would arrive or not arrive, and there was no shame in admitting that it was wanted to work for the family, to inherit the name, the estates or the Crown, to cement a relationship, even to provide an excuse for a mother not to go back to work. It would be raised as the parents wished and the issue of why or whether they should do this simply could not be raised. Even in these days of choice, it is not incompatible with the welfare of the child that the parents’ desire for the child for its own sake is not their primary or sole motivation. There are many common reasons why children are brought into the world naturally which would not satisfy the welfare of the child assessment under the law of IVF!

The HFEA was careful to consider the "thin end of the wedge argument" in relation to eugenics, this being a procedure which might be abused for the selection of traits such as intelligence, blue eyes and so on. It thought that it could choose a morally significant factor to demarcate those uses of the saviour sibling procedure that were acceptable and those that were not, namely for serious conditions for siblings.

In the end the HFEA agreed that the selection could be compatible with the welfare of the unborn child. Any family proposing to go to such lengths is likely to possess extraordinary strength by virtue of having reached this decision, even though the family context is likely to be highly stressful. The HFEA felt that tissue donation was not in itself a problematic reason for having children, and was certainly no worse than other common reasons. Once the child was born, it would have the same rights as any other child, and there could be no further question of use of anything other than the umbilical cord blood (often thrown away at birth) with the proper legal procedures appertaining to this. The birth was not eugenics, because the explicit purpose of the treatment was to cure a particular condition, not to eradicate the condition from the gene pool entirely.

Sadly the Hashmis have not so far succeeded in a pregnancy with a suitable embryo. And their licence was challenged, unsuccessfully, in court by a pro-life group. The House of Lords agreed with the HFEA in its judgment that under the Act of 1990, suitable treatment included the selection of the embryo that was for the proper purpose pursued by the Hashmis *(Quitavalle v HFEA [2005] UKHL 28)*.

So ethics was backed up by law, by the Authority, and eventually by public consultation on saviour siblings. They are now expressly legalised under the Bill of 2008, (Sched. 2, para. 3, for “serious” conditions) and Parliament has the last word.