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Judicial control of regulation
Transcript

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JUDICIAL CONTROL OF REGULATION

Professor the Baroness Deech DBE

I hope that I have not given the impression in my lectures so far that all developments in embryology and its applications are controlled by the HFEA alone. I want to make it clear that the law is pre-eminent, that is the law that Parliament has decided on, albeit that it leaves much discretion to the HFEA. The law is more determinative than ethics or science or religion or philosophy. You may wonder, however, at the end of the story that will occupy this lecture, whether the media are not more influential than anything else, especially when coupled with resources.

All public bodies in this country and many private ones (the line is difficult to draw and not relevant for this issue) are subject to judicial review by the courts. That is, there may be an appeal to the courts if it is alleged that a public body has acted outside the powers give to it by the statute from which it derives its powers. That much is relatively straightforward. The oversight by the courts has, however, gone far beyond what it was when the mechanism of judicial review was originally recognised. It incorporates the application of the principles of fairness, known to lawyers as natural justice. Courts insist that every decision of any importance that is taken by a public body or a school, or other body that can affect one's future and career, must comply with these principles. They are: that both sides must be heard (in practice this means that the documentation and the chance to be present and speak must be equally available to both, nothing must be hidden or take place in private, and adequate notice of proceedings must be given); there must be no bias (this does not mean bias as generally understood, but that there should be no appearance, objectively judged, of partiality, for example, a personal stake in the outcome on the part of a judge, or a previous relationship with one of the parties, or a financial interest); and reasons must be given for the decision.

In recent years judicial oversight has been stretched even further on new grounds. One is the incorporation of European Treaty law into British law, so that if actions are taken which, even unwittingly, offend European law, or if a party can take advantage of European provisions, and was not able to when the decision in question was first reached, then European law will be applied by the courts. The second extension is human rights, specifically the European Convention as brought into our law by the Human Rights Act 1998, so that all our law, even pre-existing law, must be interpreted according to the human rights principles set out in the 1998 legislation.

There are several complicating features of this extension. One is that although the judges clearly have enormous power to oversee and void decisions taken by others to whom Parliament has given that decision making power by democratic process, in the end the judges can do no more than nullify the decision - they do not substitute their own decision, but can sweep away the decision taken and request the authority to take it again in the light of the legal principles they have announced. Another is that, unfortunately, most public authorities, for example, schools, do not know about the principles of natural justice and that they are bound to follow them in taking decisions. An example is the case about whether a schoolgirl may wear the Muslim jilbab in place of school uniform (R ex p Begum v Denbigh High School [2006] UKHL 15, HL), a decision taken by the school with the best of intentions but understandably without the headteacher knowing the nuances of natural justice. Although judges protest to the contrary, the principles of natural justice tend to be refined over the years, decision by decision, and are rarely if ever written down for authorities to follow in their own rule books. Thirdly, human rights law does not apply in every situation and its wording is open to a great deal of interpretation; even when it is clear, almost every right that is granted is also subject to limitations and legal interference on the grounds of public health, safety and morals and for the achievement of legitimate government aims. And like human rights law, European law is something of an unknown quantity and lawyers may well argue over whether it should apply in particular circumstances, especially as British lawyers, civil servants and courts seem to take it all more literally than many other European countries do.

I have mentioned cases where decisions taken by the HFEA were challenged by those opposed to the effect of those decisions: for example, the right to select embryos for preimplantation genetic diagnosis was challenged by Comment on Reproductive Ethics, a prolife group, in the case of Quintavalle v HFEA [2005] UKHL 28, and the House of Lords interpreted the statute to permit the selection of healthy embryos that might provide a saviour sibling for a sick child. In another challenge, the clinician Mr. Taranissi sought to use 5 embryos in one treatment for a woman of 47, contrary to the Code of Practice of the

HFEA, but the courts upheld the use of discretion to prohibit this by the HFEA and did not interfere (R ex p Assisted Reproduction and Gynaecology Centre & H v HFEA [2002] EWCA Civ 20). There are other examples where the courts have left these difficult discretionary decisions alone, but not in one celebrated case.

The Blood Case

Diane and Stephen Blood had been married for five years when in 1995 Mr Blood died very suddenly within a couple of days of contracting meningitis. He was aged 30, his wife a little younger. They had had no children but were an ordinary couple receiving no form of fertility treatment. In the last moments of Mr. Blood's life, while he was in a coma and just before the life support machine was switched off, his wife asked the hospital doctors to take his sperm so that she could have the child that, she subsequently alleged, they were planning to have before his death. By chance, the hospital had on its premises a doctor experienced in the technique of removing sperm from mammals, comatose and quadriplegic men, a technique known as electro-ejaculation. An electric probe is inserted into the rectum adjacent to the prostate. The electric current stimulates nearby nerves resulting in ejaculation of sperm into the bladder, from where it can be retrieved and separated out. The doctor performed this on Mr Blood once before death and once immediately after. He did not ask the HFEA for advice, although the Authority was informed shortly after the procedure was completed. If sought earlier, the advice would have been that the removal of gametes from someone who was unconscious or dead would be unlawful, not only because he was unable to consent, but also because he would not be able to sign the necessary storage and use consent forms, let alone receive the required counselling and information, because he had had no opportunity to know what was being done to him.

I will return in a minute to the issue of consent but, in brief, the law on consent to operations is that where someone is unconscious there may only be carried out on him or her that which is necessary in an emergency to make him or her better, or if likely to recover, that which is in her or his best interests. This is not only common law but confirmed in the Council of Europe Convention on Human Rights and Biomedicine, 1997, art. 8. Indeed, any touching that does not have the consent of a patient amounts to assault, and there is many a case on this.

The HFEA subsequently refused permission for the stored sperm to be used, on the ground that there was an infringement of the HFE Act 1990 by the keeping of it, and that use would be a further infringement. Mrs Blood, a public relations professional, sought to have the law overturned after a national media campaign in her favour, spearheaded by stories along the lines of 'Grieving widow seeks husband's baby' and 'I'm so lonely'. She said that although there was no sign of written consent to use or storage she and her late husband had discussed the issue of posthumous birth and that he would have wished this to take place.

Posthumous birth is one thing, the taking of sperm from a dying man is another. The newspaper story to which Mrs. Blood referred when she said that the couple had discussed birth after death actually referred to an insemination of a widow which had taken place using sperm that the man had freely donated while he was alive and had had stored with his consent and knowledge. The Warnock Committee, whose report founded the HFEA, did consider the situation of post-mortem insemination by a husband. They said: 'we have grave misgivings about AIH in one type of situation. A man who has placed semen in a semen bank may die and his widow may then seek to be inseminated. This may give rise to profound psychological problems for the child and the mother.' (para.4.4) Their conclusion was that this should be discouraged. The Act, however, covered this by the strict demands for written consent to every stage of the IVF procedure, and clinics in their standard forms ask patients to say what should happen to their gametes if they die, and of course there can be no use of gametes without the consent of both. So if sperm is taken from a man during his lifetime and he consents to its indefinite use or even specifically use after death, then that can happen, and it does in the case of, say, men facing cancer treatment.

So it is the taking of the sperm that is the issue, a removal without consent. It is basic medical law in the US and in the UK that every human being of adult years has the right to the possession and control of his own person, free from all restraint or interference of others. The ability of the ordinary adult to exercise a free choice in deciding whether to accept or refuse medical treatment and to choose between treatments is not to be dismissed as desirable but inessential. It is a crucial factor in relation to all medical treatment (Lord Donaldson in In re F (Mental Patient: Sterilisation) [1990] 2 AC 1.) The law has developed so as to impose on clinicians an obligation to make appropriate disclosure of relevant information to the individual, in order that the exercise of his autonomy be meaningful; otherwise there is civil assault/battery or trespass to the person. Any touching without consent amounts prima facie to an assault. The central issue is about self-determination, the right of the individual to make a real choice, the fair opportunity to make a decision. The European Convention on Human Rights and Biomedicine says: 'An

intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. . . the person concerned may freely withdraw consent at any time.' (art.5). And it goes on to say that an intervention may only be carried out on a person who does not have the capacity to consent for his or her direct benefit. The taking of sperm from someone who is incapacitated is unlawful, unless it can be argued that it is in their best interests, which in brief means that it will help that person immediately to recover, not a third party.

It was argued in the Blood case that because the couple were married in the Anglican service, he had consented to the birth of children. The words of the service include that marriage is for the procreation of children, and 'with my body I thee worship' (although it is hard to find any express promise to procreate, marriage was taken for centuries to be a legal pact to consent to sex and children.) But in today's world a marriage ceremony does nothing to change the legal situation about consent unless marriage is deemed to give partners some legal control over the body of their partner, a conclusion which seems to be defeated by recent cases in respect of marital rape. It used to be the law that a man could not be treated as a rapist in respect of his wife in criminal law, regardless of consent on the occasion, because she had consented for all time in the marriage ceremony. This was dismissed, with the fervent support of women, by the courts some years ago, and a man can be as liable for the rape of his wife if she does not consent, as of any other woman. The marriage ceremony also contains a pledge that the couple will stay wedded for life: this as we well know is overridden by the law of divorce. So the words of the ceremony, sadly, count for nothing in the face of the law.

What makes the law of consent most clear is to imagine how the Blood case would have looked had the facts been the other way round. Suppose that Mrs. Blood had been the one to have fallen prey to meningitis, and that on her death bed her husband had requested that her eggs be removed, fertilised by him and stored as embryos until a surrogate mother had been found to carry them to pregnancy and birth? In many ways, this is an even more relevant question, because there is a commercial market for eggs, which are in short supply, and to be able to remove them from the dying might supply a need for which many would pay handsomely were it lawful. Mr Blood might well have argued that the couple wanted children even after death. He could in the alternative have asked that in order to fulfil this wish, which he would say was in her best interests, Mrs. Blood should be kept on a life support machine for at least nine months while her fertilised eggs were reimplanted in her womb, for a child may grow in the womb of a comatose woman, and there have been some cases in the US where this has occurred (Susan Torres in 2005 and anecdotally 12 women worldwide have produced babies in these circumstances.) Moreover it might be argued that Mrs. Blood could be kept on a life support machine for as many years as it took to produce the number of babies that the couple had wanted. I imagine that this scenario would be greeted by horror generally, for the public is much more aware of the inviolability of women's bodies without their consent, following a long feminist campaign, than it is of men's equivalent rights.

The need for written consent to the removal of gametes remains in the law and its necessity and morality were reconfirmed in a report on the consent elements of the Blood case by Professor Sheila McLean in 1998. The only situation where written consent might be dispensed with is where a person is incompetent and undergoing treatment after which he is expected to recover, but which will render him sterile. Removal of gametes would be authorised at common law by use of the 'best interests' test and any subsequent use of the gametes would have to be authorised by the person concerned when he had recovered.

Best interests

Who knows best what the best interests of a comatose person may be? The basic law is that it must be for him, so there should be no question of anything being done that would benefit, not him, but another person, even if she is his widow-to-be.

You may well wonder why this matters when the person is dead. His best interests are hardly a live issue: why should not his nearest and dearest decide what to do with his remains? There is no analogy, in my view, with organ disposal, although even there the positive giving of consent is still vital. Reproductive tissue is different: it represents the beginning of another life, more relatives for those left behind who had not expected this and after the deceased's affairs had been settled. Then there is the obvious factor of children to be born without a father, possibly many years after his death, born to order for one adult, not two, a controversy rather like that raging around the birth of saviour siblings. It must not be for a wife or other relative to decide what is in the best interests of a dying individual, short of assisting in his recovery, because this is an infringement of reproductive autonomy, namely, that we should all have a say, by action or intention in creating the next generation. It is no more seemly for the widow to say that removal of his gametes is what the dead husband would have wanted, than it is for men to say, as they

have done over the generations, that they know what is best for women in sexual or domestic matters. Even doctors are not allowed to insist on a procedure that is objectively in the best interests of a patient who objects to it or an unborn child, no matter how irrational the refusal of the patient may be (St George's Healthcare NHS Trust v S [1998] 3WLR 936).

One would have thought that the outcome of a challenge in the courts to the clear breach of the law and ethics in the retrieval and use of Mr. Blood's sperm would have been absolutely straightforward. And so it was at first instance (R v HFEA ex p Blood [1996] 3 WLR 1176) and indeed the consent issue remained firm even on appeal. The new factor was the application of European Treaty law within English law. On appeal, Mrs. Blood successfully asserted that the HFEA had not taken sufficient note of European law when dismissing her request to have her husband's sperm exported to a country, Belgium, which did not have the same strict regulation as we do. Under s.24(4) of the 1990 Act, the HFEA has discretion to allow the import and export of gametes into and out of the country, subject to conditions, and has the power to waive the requirements of ss.12-14 (concerning sale, records, welfare and consent) on those occasions. The HFEA refused Mrs. Blood's request to have the sperm exported to Belgium, largely on the ground that the request was being made in order to avoid the British law about consent and the taking of the sperm, and that it had always been the HFEA's policy not to allow export simply to overcome British regulations. If that were not its policy, then serious unethical breaches of the Act could be overcome by the all too simple expedient of exporting the gametes or embryos to another country free of restrictions.

European treaty law grants freedom of movement to seek medical services, and freedom of movement of goods and services. The HFEA was conscious of this in its deliberations, but it did not consider that these provisions of European law could possibly cancel out the benefits of and need for strict maintenance of the British regulatory scheme, with its benefits of health and identification. Individual European nations have the right to diverge from European provisions where there are strong national reasons relating to cultural and social matters best dealt with by the home country, which seem to it to outweigh the benefit of the European laws. Nevertheless, the Court of Appeal found that the HFEA had not sufficiently weighed the European principle of freedom to seek medical services, and decreed that the Authority should take its decision afresh in the light of the judgment. It also held that if Mrs Blood were permitted to take the sperm abroad, the fact that it was unlawfully obtained would not be an impediment. When the Natallie Evans case was heard, in which a man was allowed to withdraw his consent to the continued storage of the embryos created by him and his former partner, I wondered why her counsel did not argue that she should be allowed to take the embryos to Belgium.

A significant feature in the Court's deliberations was that the factual situation was and would always remain unique. In response to the HFEA's fears that the grant of judicial review would mean that every widow in similar circumstances would seek to circumvent the law, the court suggested that no doctor would ever be likely to remove gametes in such circumstances again, as all of them would know that the laws of consent in the Act could not be fulfilled, and that storage and use would be illegal. So the HFEA met again to consider its decision in the light of the judges' comments; it was not persuaded that the situation was any the less unethical and illegal, but money and pressure forced it to change the decision; the cost of fighting the case to the House of Lords meant that it was outside its reach.

In fact in the wake of the publicity surrounding the Blood case, many telephone calls were received by the HFEA staff at all times of day and night, seeking advice or permission to remove sperm from comatose and dying men, usually after traffic accidents. The most striking one was from would-be grandparents, who said at first that they had found a letter in their dead son's possession authorising the removal of his sperm to impregnate his girlfriend. The girlfriend let it be known that she was not willing to undergo this, whereupon the parents of the deceased said that they had found another letter expressing the son's wish that his sperm could be taken to impregnate any willing woman. The case was taken no further once the genuineness of the letters was challenged.

It seemed to the HFEA that the court had not dealt with the basic issue of consent on the facts of the case, namely, whether it should be legal for gametes to be removed from the many thousands of young people who die unexpectedly every year from accident or illness, leaving behind a bereft widow or widower, fiancé or fiancée, parents, grandparents or partner. The practical difficulties of having to decide, in the few hours available for the procedure to be carried out effectively, whether the person requesting the removal is entitled to do so, and what category of person that should extend to, and whether the same considerations should apply to the removal of eggs from a dying woman as sperm from the dying man are major questions, and Parliament has not opted to legislate for this. As is well known, Mrs. Blood went on to have two sons with the assistance of the clinic in Belgium known for its expertise in intracytoplasmic sperm injection.

The effect of European law on ours is startling. Article 59 provides for the abolition of limits on freedom to provide services within the Community, with an exception for the preservation of the religious, moral and ethical values of the national state within its

own territory. This can drive a horse and coaches through all British professional services and regulation of IVF. At the same time, had the HFEA been given the chance, it could have argued that the values at stake in the Blood case would permit it to deviate from Art. 59, that there were, in the words of the law, proportionate British interests that merited protection: protection of the body, autonomy, the protection of human dignity and freedom of choice, respect for reproductive tissues and the body and for the family of two living parents. The inability to do so represents a levelling down of standards.

It came about in large part because of the media campaign, which misrepresented the vital part of the story, the way in which the sperm was taken. The press ignored the opening paragraph of the explanation as given by the HFEA, and persisted in representing the case as one where Mr. Blood had voluntarily given his sperm, but had failed to sign a piece of paper when death overtook him, a very different scenario from the actual one. A sample of the press cuttings is attached to this lecture. Lacking any account of how the sperm was taken, it made a great story, and the pictures were persuasive. The appearance and press impression made by the parties involved can be absolutely crucial in media attention, favourable or otherwise, to a case, and politicians and judges are not immune from the sentiments engendered. Moreover, contributions sought by the media met Mrs. Blood's legal expenses, which were also awarded to her by the court, while the HFEA ran out of funds to fight and was refused extra assistance by the Department of Health, which might have underwritten a final appeal to the Lords.

There is a footnote case. In June 2007 a husband died unexpectedly in hospital after an appendectomy. He and his wife had a 10month old daughter. The widow persuaded the hospital to remove his sperm and then sought a declaration that it was lawful to store the sperm with a view to taking it abroad for her insemination. The first judge legalised the storage of the sperm pending a decision about its use. The second judge however, quite rightly refused to make the declarations sought by the widow, that the storage and use of the sperm after her husband's death was lawful. The HFEA's discretion to allow storage and export remained.

A final footnote on the effect of European law. There was and still is a shortage of sperm donors in Glasgow. It may be because of the lifestyle there, or the removal of anonymity from donors in the future. In the late 1990s the whole of Glasgow was served by only sperm donor. The clinic there asked for permission to import sperm in bulk from Denmark, which had surplus available for export. The HFEA resisted this at first, because there could be no reassurance about health standards of the import; there would be difficulties in the future in identifying the donors if the law changed; there was unclarity about legal parentage abroad, and Danish donors were allowed to father 25 children each (it is limited to 10 here), so Scottish donor conceived children might find out one day that they had at least 25 half-siblings in Europe. Nevertheless, legal advice was that if Denmark wanted to export the sperm, permission had to be granted because of the European principle of freedom of movement of goods and that European countries had to accept each other's hygiene standards as good enough. A thousand years ago, blond Viking invaders raped and pillaged their way through Scotland. History has repeated itself in a more European and voluntary way.