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PLAYING GOD: WHO SHOULD REGULATE EMBRYO RESEARCH?*

Baroness Ruth Deech **

It is an honor to be able to celebrate the Belfer family: Ira M. Belfer, member of the Class of 1933, who went on to become a distinguished practitioner of law and a major supporter of Brooklyn Law School; his son Myron, Professor of Psychiatry at Harvard Medical School and Senior Consultant in Child Mental Health for the World Health Organization. The careers and actions of father and son together embody generosity of spirit, a love of legal education, and the desire to put the advances of medicine to use in the interest of children all over the world. These qualities are highly appropriate to the subject that I am to address today.

The title of my lecture was inspired by a comment made to me in 2002 by a Member of Parliament (MP) when I gave evidence to the House of Commons Select Committee on Science and Technology, which was examining embryo research. The MP queried the decision of the Human Fertilisation and Embryology Authority (HFEA), of which I was then the chairman, to permit a couple to benefit from the new technique of embryo selection. Mr. and Mrs. Hashmi have a son called Zain, who suffers from a family-inherited condition of beta-thalassaemia. The Hashmis sought to have preimplantation genetic diagnosis (PGD) carried out on embryos that they would produce in order to be able to select one that would be free of the inherited genetic condition and which would also, if it developed into a baby, provide tissue that was compatible with Zain. Zain needed bone marrow from a compatible donor to save his life. I explained to the Committee of Members of Parliament that the HFEA had felt confident in making this decision within the law and that it was ethically sound. Moreover, I explained, speed was of the essence in such a situation. Little Zain suffered every day from the invasive treatment that he required and his mother was getting no younger. I knew that if a decision on an issue of this magnitude and sensitivity were to be left to legislators, not only would it take a very long time depending on the legislative timetable but it would inevitably attract media and constituent interest. Legislators would vote not only with the broader issue in mind but

* This lecture was delivered at Brooklyn Law School on October 10, 2006, for the Ira M. Belfer Lecture Series. In drafting this lecture, the author has drawn upon previous speeches and publications.

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also with politics at the forefront.¹ When I appraised this dilemma by saying that the HFEA undertook these decisions according to law designed in order to protect legislators from having to make them, the response of the MP was: "Who do you think you are, playing God?" But "playing God" was precisely, in my view, the role assigned to the HFEA by Parliament itself. Moreover, "playing God" may mean either assuming to oneself the power to make decisions that no one on earth should be making; or it may mean doing one's human best to act as a partner with God in improving the lot of mankind and, where necessary, attempting to perfect God's creation.

It was on that occasion that I realized that even though issues of PGD and stem cell research are discussed as if they were ones purely of ethics, law, and science, the realm of assisted reproductive technology is a battleground fought over by legislators jealous of their power, desperate patients, clinicians and companies with considerable earnings, and religious pressure groups. I concluded that the only way to keep the peace is by comprehensive regulation by as neutral and expert a body of people as can be assembled. Any other solutions result in distortions and inconsistencies.

These political and financial aspects of embryo research regulation are masked by various ethical and religious approaches. After introducing the arguments about ethics and embryo research, I will unmask them by explaining the nature of stem cell research and examining the stances of Germany, the United States, Italy, and the United Kingdom and their internal inconsistencies. I will weigh up regulation and autonomy and propose a framework of legislative regulation. I will take as examples the new areas of embryo research where the HFEA took decisions under my

1. The tussle between religious forces and parliamentary ones in this field is made clear by the comment of Pope Benedict at Easter 2006: "There is a move to reinvent mankind, to modify the very grammar of life as willed by God [T]o take God's place, without being God is insane arrogance, a risky and dangerous venture." Pope Benedict XVI, Good Friday Prayer at the Colosseum in Rome (Apr. 14, 2006). The same opinion was voiced in England when the license for PGD offered to the clinic that treated the Hashmi family was challenged as illegal by CORE, a group fundamentally opposed to any form of interference with the embryo at any stage. *R (on the Application of Quintavalle) v. Human Fertilisation & Embryology Auth.*, [2005] UKHL 28, [2005] 2 A.C. 561. CORE stated that the reason they challenged the HFEA in court over the use of PGD for tissue-typing purposes was not to obtain a pronouncement on whether the technique was right or wrong in itself, but to make the point that such a policy decision should be made by a democratically elected government, not by an "unelected" organization, namely the HFEA. The gesture was too late because in 2001–2002 both houses of the British Parliament voted strongly in favor of extending the remit of the HFEA to cover research on embryos for the purposes of treating and learning about serious disease.

chairmanship, techniques which have adapted established In Vitro Fertilization (IVF) procedures to lifesaving and life-altering purposes.

I. EMBRYOS

At the heart of the new ethical debate lie attitudes towards embryos and in particular their use for research. It is very well-known that it is regarded as morally wrong by some because they regard the embryo as human from the moment of fertilization, and therefore one should not take its life or bring it into existence simply in order to be destroyed. This, they say, is as true of the embryo as of children and adults. Indeed, one may take the argument a step further, because if one should not destroy something with the potential to become a human, this could apply equally to eggs, for eggs alone can be converted into embryos through the cloning technique. Up to 70% of natural embryos in the body never succeed in implanting in any case and are lost. The *reductio ad absurdum* of protection of the embryo is that natural intercourse should be avoided because that is bound to lead to the loss of some fertilized embryos.² Alternatively and equally unrealistic, if each embryo is a possible life and should not be wasted, then because all fertile adults are capable of combining to produce embryos at every moment of the day, we should do so incessantly in order to avoid any possibility of wasted potential.

The Warnock Committee, whose 1984 Report laid down the foundations of regulation, reached a typically British compromise: in English law the embryo has been given special status but not absolute protection.³ In Britain, the embryo is treated as an entity deserving due attention, which means that is to be used only if there is no alternative, that its use must be ruled by informed consent of the donors, that there are restrictions on exporting embryos or mixing them with non-human material, and that there is considerable recordkeeping to ensure that every single embryo in research is accounted for.

The embryo is defined in section 1 of the Human Fertilisation and Embryology Act 1990 (HFE Act) as a “live human embryo where fertilisation is complete.”⁴ The United Kingdom was the first country in the world to acknowledge as legal and then regulate therapeutic cloning or

2. See John Harris, *Stem Cells, Sex, and Procreation*, 12 CAMBRIDGE Q. OF HEALTH-CARE ETHICS 353 (2003).

3. This compromise has been upheld by the HOUSE OF LORDS SELECT COMMITTEE REPORT ON STEM CELL RESEARCH, REPORT, 2002, H.L. 83-I, § 4.21.

4. Human Fertilisation and Embryology Act, 1990, c. 37, § 1(1)(a), available at http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900037_en_2.htm#mdiv1.

cell nuclear replacement (CNR). This technique of artificially fertilizing an egg which has been enucleated was challenged in the courts.⁵

The House of Lords confirmed that embryos created by CNR did come within the regulatory purview of the HFEA; they reached this conclusion by taking a purposive approach to the interpretation of the word "embryo."⁶ This decision on the one hand upheld the democratic or parliamentary approach to this new field in that it supported the remit of the existing law, but it also enabled the regulators to extend their reach.

The position in Britain now is that a wide range of embryo research may be permitted under license from the HFEA. The extended list of purposes for which research involving embryos may be permitted is: promoting advances in the treatment of infertility; increasing knowledge about the causes of congenital disease and the causes of miscarriage; developing more effective techniques for contraception; developing methods for detecting the presence of gene or chromosome abnormalities before implantation; increasing knowledge about the development of embryos, knowledge about serious disease, or enabling such knowledge to be applied in developing treatment for serious disease.⁷

A word of explanation about the science behind the arguments over the status of embryos. Two non-fertility avenues are being explored. One is PGD and the other is research on adult and embryonic stem cells, derived respectively from adult cells and embryos. The latter can further be divided into research on embryos created by uniting eggs and sperm, and research on embryos created by CNR. The latter technique involves obtaining an egg, which is subsequently enucleated. The removed nucleus is replaced by the nucleus of a cell obtained from an adult, possibly an adult who requires treatment or a volunteer. The new nucleus is fused to the enucleated egg by an electric shock. This apparently causes the egg to believe that it has been fertilized as if by sperm, and it starts to grow. The advantage of CNR is that the resulting embryo will be identical in every respect to the genetic makeup of the adult who donated the nucleus. Were stem cell lines to be derived from this embryo and new organs and tissues created, the adult patient would not reject the new organ, for it would be 100% compatible with his own body. This would end the current position whereby recipients of donated organs have to spend the

5. The grounds were that the statutory definition did not appear to include embryos created by processes that do not involve the union of egg and sperm. CNR does not involve sperm in the creation of the embryo. *R (on the Application of Quintavalle) v Sec'y of State for Health* [2003] UKHL 13, [2003] 2 A.C. 687.

6. *Id.*

7. Human Fertilisation and Embryology (Research Purposes) Regulations 2001, S.I. 2001/188, available at <http://www.opsi.gov.uk/si/si2001/20010188.htm>.

rest of their lives on immuno-suppressive drugs to prevent their bodies rejecting “stranger” organs.

The legislative approval of extended research purposes in England was based on the fact that the HFEA has a good record in ensuring that clinics comply with the law and therefore an extension would not represent a slide down the slippery slope. By way of contrast, much harm has been done to the scientific community by the falsity of the claims of the Korean Professor Hwang, who claimed to have created thirty cloned embryos and eleven stem cell lines. In 2006, it was reported that Professor Hwang used eggs donated by junior team members and faked his research. There are two ethical issues here: the faked research and also the likelihood that pressure was applied to female members of the team to donate the gametes needed for the research.

Bearing in mind the fate that befell Professor Hwang and his team, there is a need to govern and regulate the way in which eggs are obtained. The HFEA is undertaking a public consultation on whether women should be permitted to donate eggs purely for use in medical research. It is already legal in Britain to donate eggs for the purpose of pregnancy on an altruistic basis. Indeed, it is not uncommon for people willingly to give up organs and bone marrow to help others; voluntary kidney donation is quite widespread. This seems to point to the ethical or pragmatic acceptability of the donation of eggs for medical research, even though there is risk to the donor and no direct benefit to herself. The drugs used can be dangerous and the generous payment of expenses to donors, or even the possibility of sale of eggs, as in the United States, for large sums, may tempt the needy.

II. STEM CELLS

Stem cells present the most exciting possibilities for the future, although as yet undeveloped. They are the basic components of the rest of the body and capable of providing new cells. They are found in embryos, in the fetus, the placenta and umbilical cord, and in parts of the body. When the embryo has grown to the eight-cell stage soon after fertilization, each of the eight is totipotent; that is, it could develop into any and every type of cell needed for the body. Some days later when stem cells are present in the inner cell mass they are still pluripotent, that is have the capacity to develop into most types of cell. Because of their ability to reproduce themselves and develop into other types of cells, stem cells offer the prospect of growing new tissue to repair parts of the body damaged by accident or ill health and to treat a wide range of diseases that have developed because the cells have degenerated, e.g., Alzheimer’s, Parkinson’s, and diabetes. If those treatments can be found, there would

be a lifelong cure and new regenerative tissue when needed. Stem cell research has been widely publicized and is seen as a good focus for financial investment and medical research. Adult stem cells, unlike embryonic ones, are allegedly not as useful for growth and research, although opinions differ and knowledge is limited so far. The problem with adult stem cells is that if they are derived from an adult with a disease, the likelihood is that the stem cell may reinforce that disease rather than cure it. Nevertheless, adult stem cells are of significance because work on them does not present the ethical problems associated with work on embryos, whether surplus to requirement after IVF or deliberately created. Most stem cell research is carried out on embryos surplus to requirement, and it must be ethically preferable to use them for beneficial research than to allow them to perish.

In Britain, work on stem cells derived from surplus or created embryos is legal and was recommended by the HFEA. It has to be approved by scientific peers and ethics committees and the license from the HFEA takes into account quality approval, justification, legal compliance, consent, and yearly accounting for each one used. This is strict but effective and gives researchers an area of safety and respectability in which to proceed. So far fifteen licenses have been granted.

The research license is granted only if the use of embryos is necessary and the aim is necessary or desirable for the treatment of infertility or serious disease. "Serious" is a fluid concept depending on time and place. As time brings reduced tolerance of ill health and greater expectations of relief, the band of diseases regarded as serious will expand. Under British regulation a sample of every stem cell line derived from a cell taken from an embryo or adult must be deposited in the U.K. Stem Cell Bank, which was set up in 2004 by the Medical Research Council and the Biotechnology and Biological Sciences Research Council. Research is only licensed if it cannot be done from existing stem cell lines in the Bank. The potential benefits are considerable, ranging from organs available for transplantation and ending the current shortage, to tailored drugs, discoveries about the genetic origins of diseases, and cures for infertility. Gametes might be derived from stem cells to provide reproduction for the infertile.

III. NATIONAL ATTITUDES TO STEM CELL RESEARCH

Despite these advantages there has been a diversity of response to this research in Europe and the United States. This is because of cultural, religious, and economic reasons specific to each country. In some, feelings run so high that they cannot reach a compromise position, for example,

using only surplus embryos. Belgium and Holland permit embryo research and have no legislation; Portugal and Germany forbid it.⁸

A. Germany

The contrasting ethical attitudes can be seen most clearly in the case of Germany. Abortion is permitted but embryo research is not,⁹ despite the constitutional guarantee of freedom of research. No egg may be fertilized except for the pregnancy of the donor and, as in Italy, there may be no initial creation of surplus embryos. This has the effect of preventing PGD. Nevertheless, stem cell lines may be imported into Germany provided they were derived before 2002 and subject to restrictions. In that year German law prohibited the derivation of new stem cell lines, even if not defined as embryos. As in the United States, there is a certain amount of ethical hypocrisy in Germany in that there is reliance on stem cell lines created outside the country. The policy is set in the context of human rights and a historical perspective, a determination not to repeat the mistakes of the past, to integrate the disabled, and to protect women and children.

B. Italy

Italy was until recently the most unregulated country in Europe. It was the place to which one went for the treatment of women over sixty, for attempts at cloning, sex and race selection, and embryo splitting. However, in 2004 a comprehensive law was introduced.¹⁰ Gamete donation is banned, as is egg freezing. The number of embryos that may be used per cycle is limited to three, no scientific research on embryos is permitted, and there can be no PGD. Couples seeking IVF must be of two different sexes, married or living together, and no posthumous treatment is allowed. The law amounts to a set of prohibitions rather than the construc-

8. The Council of Europe Convention on Human Rights and Biomedicine, article 18, provides that where the law allows for embryo research it must ensure adequate protection for the embryo and that the deliberate creation of embryos for research is prohibited. Council of Europe, Convention on Human Rights and Biomedicine art. 18, Apr. 4, 1997, 36 I.L.M. 817, Europ. T.S. No 164. Cloning is prohibited and this is reinforced by the Charter of Fundamental Rights of the European Union. Charter of Fundamental Rights of the European Union art. 3, Dec. 7, 2000, 40 I.L.M. 266. There are few ratifications. This is because in England and some other countries acceptance of the research has moved on well beyond the European declarations, affected as they are by religious susceptibilities and history.

9. Herbert Gottweis, *Stem Cell Policies in the United States and in Germany: Between Bioethics and Regulation*, 30 POL'Y STUD. J. 444, 451 (2002) (discussing Germany's 1990 Embryo Protection Act).

10. Law 40/2004, Feb. 14, 2004, Gazz. Uff. No. 45 (Feb. 24, 2004).

tion of a general regulatory framework for the conduct of assisted reproduction. It penetrates a long way into the area of medical discretion, for example banning embryo freezing and limiting the number of embryos that may be transferred in one cycle, thereby reducing the success rate. The law goes even further than the report of the Dulbecco Commission that preceded it, which had recommended that stem cell research should be allowed on surplus embryos. The Italian law has been condemned by some European research organizations in that it greatly reduces the chances of an infertile woman bearing a baby, but it was not voted down by the electorate when they were given the opportunity. The new law is of course wholly consistent with the dominant Catholic religion of the country.

C. The United States

The position in the United States is perhaps the most troubling and inconsistent of all, and its results affect the whole world. The stance is derived from a combination of politics, business, religion, and aversion to federal control. Any general regulation or ethics directive is seen as undermining the doctor-patient relationship and imposing bureaucracy on medicine. Freedom of state action has led to rule by market forces, a general free for all which in turn leads to doctor-patient-baby conflicts of interest, abuses, and dangerous genetic "cures." The regulation that has been attempted by professional bodies in the United States has proved ineffective because no consensus has been reached on the main issues and the guidelines are unenforceable at law. These issues are all bound up with the very sensitive American position on abortion and the tension over childbearing issues between religious forces and the constitutional rights to privacy and liberty.¹¹ Any legislation that interfered with, for example, the "right" to clone could be open to constitutional review by the courts. Much as the United States needs federal regulation of embryo research, it is particularly difficult to achieve because of the Constitution, guarantees of state and personal autonomy, and the political/religious lobby.

American law prohibits the use of federal funds for the creation of a human embryo for research purposes. This means that private clinics and company laboratories are free to undertake research. In 2001, President Bush announced that federal funding may be used for research on existing stem cell lines, but no others, and set up the Council on Bioethics under the chairmanship of Leon Kass, a conservative thinker. The effect of the law is that no live embryo may be destroyed for research pur-

11. See, e.g., *Planned Parenthood v. Casey*, 505 U.S. 833 (1992).

poses.¹² It is believed that there are seventy-eight existing stem cell lines eligible for federal funding for research, of which twelve have become available to the United States so far and are regarded as unsuitable. Federal funds may be spent on adult non-embryonic stem cells, to which no constraints apply. There is little open and informed debate of the issues in the United States because there is no public accountability for embryonic research and no unified voice speaking for it, only presidential diktat. Private companies are doing considerable unsupervised research, which is profitable and hard to square with concerns over public health. The current position is as unethical as it can be: the public sector is obstructed while private work is unregulated and driven by commercial concerns. There should be no pretence that the Bush pronouncement of 2001 was ethical as claimed: it was one of political expedience prevailing over all the scientific and logical arguments pointing the other way.

There are ways around the ban. A single cell detached from an early embryo can be grown in culture to create stem cell lines, without destroying the embryo. It could theoretically be used to attempt pregnancy, even with one cell removed, as occurs after preimplantation genetic diagnosis, although this would be contrary to English law. Keeping the embryo alive would address the ethical concerns of many, but it is not as efficient as culturing the entire eight-cell embryo. This might be a way to circumvent the federal funding ban. There is pressure from pro-life groups to find alternatives to destroying embryos to grow stem cells. It is a counter-productive search, however, as many embryos are destroyed in pursuit of this one result. Recently, in British laboratories scientists have taken cells from dead embryos and grown them to the stage where stem cells might be extracted. The scientists used embryos that had died naturally during IVF treatment. The embryos in this experiment had stopped developing a few days after fertilization. Nevertheless, the question was immediately raised of how one would know that the embryos were dead, and whether there was something wrong with those embryos that caused the arrest of their development. Other ethicists however regarded this new process as akin to organ donation from dead patients, with no more concerns than surround that process.

The moral arguments have been turned on their heads however by the fact that very recently some states, led by New Jersey and California, have legislated for state funding for stem cell research.¹³ This may lead

12. Balanced Budget Downpayment Act, I, Pub. L. No. 104-99, § 128(2), 110 Stat. 26, 34 (1996).

13. See National Conference of State Legislatures, State Embryonic and Fetal Research Laws, www.ncsl.org/programs/health/genetics/embfet.htm (last visited Feb. 5, 2007), for a useful list.

to a movement of scientists from restrictive states to those that are more liberal. California Proposition 71¹⁴ of 2004 granted \$3 billion funding to stem cell research. The measure included the establishment of the California Institute for Regenerative Medicine to regulate and oversee stem cell research. The Act has a preamble stating that half of California families have a member who has or will suffer from a medical condition that could be treated with stem cell therapies. The Act is designed to plug the gap in federal funding and to shift the emphasis of health care towards prevention rather than expensive cures. It will presumably give a boost to the prestigious Californian universities' research programs. Human reproductive cloning remains forbidden but otherwise all types of research on all types of embryos may be carried out. Accountability is to be achieved by open meetings and annual reports to the public. The Independent Citizens' Oversight Committee of twenty-nine members governs the California Institute for Regenerative Medicine and will include patient, university, and research representatives. The Act directs the Committee to establish standards concerning informed consent, controls on human research, the prohibition of compensation to donors, privacy laws, and time limits for obtaining cells (eight to twelve days after fertilization). There are similar laws in New Jersey¹⁵ and a Stem Cell Institute of New Jersey, with a grant of state funds, albeit very small compared to California.

There will soon be a patchwork of regulation across the United States and a scattering of states where funding for stem cell research will be provided. This will lead to scientific tourism, a reflection of the world situation. This is a further argument in favor of national control and a national regulatory body. This need is not met by the President's Council on Bioethics, because it is allegedly composed of members chosen for their conservative views and appointed by the President, and it has no powers. My experience on the HFEA convinced me that to mix the pragmatic with the philosophical is the best way of going forward. There is nothing so invigorating for a committee containing ethicists as to be confronted with a case needing an immediate practical solution. Questions such as what to do when embryos are mixed up or lost, the use of embryos that are subject to litigation, the payment of donors in a situation of shortage, all force committee members to apply policy and principles and come up with a legal and humane solution.

14. CAL. CONST. art. XXXV, § 1 (approved by the voters of California).

15. N.J. STAT. ANN. § 26:2Z-2 (West 1996 & Supp. 2006).

IV. THE STRUCTURE OF REGULATION

On the basis of examination of the inconsistencies and weaknesses of various national situations, what may be concluded about the ideal regulatory framework? There may be comprehensive regulation or private rights and prohibitions, such as in Italy. There may be regulation or a free market as in the United States. There may be regulation by independent committee or by legislators, which is the question in the United Kingdom. Britain was extremely fortunate in the timing of its legislation, as far back as 1990. It enacted a comprehensive framework before many of today's issues emerged and before positions became entrenched. Hence when new issues arose, such as stem cell research, there was already a framework within which to control them, and the public and Parliament were accustomed to it. Britain was also fortunate in that the statute was well-drafted and was flexible enough to cope well to the present day, although reforms are now being considered.¹⁶

The most interesting analysis of national structures of regulation has been made by D.G. Jones and C.R. Towns.¹⁷ The authors describe four types of regulation of stem cell research.

The first is the prohibition of all human embryo research: Ireland, Austria, Norway, and Poland. The second is permission to use stem cell lines already in existence before a certain date: the United States and Germany. The third is to use stem cells only from embryos surplus to IVF requirements: Canada, Greece, Finland, Hungary, Netherlands, Taiwan, and Australia. The fourth is to allow also the creation of embryos specifically for research: the United Kingdom, Belgium, Israel, Singapore, Japan, South Korea, and Sweden.¹⁸

The authors then point out the inconsistencies.¹⁹ In some countries where all embryo research is forbidden because the embryo is sacrosanct, IVF is allowed. IVF cannot normally be carried out without engendering a certain number of embryos that are surplus to requirements and are eventually destroyed. This is more unethical than using them for research purposes. Germany and Italy are at least internally consistent in that they do not allow any embryos to be created that will not immediately be used for pregnancy, avoiding the creation of extra ones. This is at a cost of some detriment to the woman's health. Instead of banking extra embryos,

16. SCIENCE AND TECHNOLOGY COMMITTEE, HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW, 2004–5, H.C. 7-1, at 175–89.

17. D.G. Jones & C.R. Towns, *Navigating the Quagmire: The Regulation of Human Embryonic Stem Cell Research*, 21 HUMAN REPRODUCTION 1113 (2006).

18. *Id.* at 1113–14.

19. *Id.* at 1114–16.

she will have to undergo ovarian stimulation by drugs repeatedly. Multiple births are more likely to occur because all the embryos will be transferred in one attempt rather than using only one or two and keeping the remainder. Multiple births are dangerous to the health of mother and baby and costly to society. States that ban all embryo research are also quite likely to take advantage of stem cell research in other countries. In Germany the import of stem cell lines from other countries where they have been derived from surplus embryos is allowed under strict conditions.²⁰

If permission is given to use stem cells created before a certain date (the second category) they may be inappropriate for research and will eventually be too old. Those countries that prohibit the creation of new stem cell lines on the basis of the sanctity of the embryo are also likely to allow the destruction and creation of embryos for the purposes of IVF. The use of surplus embryos (the third category) does at least make a utilitarian use of embryos that are in existence and would otherwise perish. However, the creation of embryos for research that are specific to the patient is blocked. This position accepts that surplus embryos will be created and destroyed during IVF and therefore accepts that embryos are disposable, despite imposing restrictions on research. The fourth category, the most liberal one, is based on not accepting that every single embryo has human potential. It maximizes research opportunity and secures a diversity of embryos for research, including ones that will be compatible for the purposes of transplantation.

Another way of categorizing the different national attitudes to embryo research is to look at the contenders, the winners and losers. When no research is allowed at all or only on old stem cell lines, this is an advantage for the religious/political factions. If prohibition can be evaded by import or export of gametes then commerce benefits but not patients and domestic researchers. If research is allowed only on surplus embryos, this inhibits scientists. If the most liberal attitude is taken, all interested parties benefit except that legislators are denied the control that they seek.

The ethical positions are further muddled by the existence of "reproductive tourism." If patients, researchers, and gametes may move from country to country in search of the desired facilities that may be legally available to them, as is permitted to Europeans by the Treaty of Rome,

20. Stammzellgesetz [StZG] [Stem Cell Act], June 28, 2002, BGBl. I at 2277, § 4; see also Rosario M. Isasi & Bartha M. Knoppers, *Beyond the Permissibility of Embryonic and Stem Cell Research: Substantive Requirements and Procedural Safeguards*, 21 HUMAN REPRODUCTION 2474 (2006).

there is little point in restriction in a few countries, other than to send a signal. The ethics of the entire continent of Europe have to sink to the lowest point because the scientist who is unable to carry out embryo research in Italy may move to England; the would-be patient who prefers to have an anonymous sperm donor may leave England or Sweden and go to Belgium; and so on. This situation highlights the need for a liberal regime in the knowledge that those who have principled objections need not take advantage of what is going on, but that it is safer and cheaper to have treatment in the home country.

I conclude from this brief overview of the national positions that there is no substantive ethical or qualitative difference between research directed to stem cell derivation and the use of embryos for IVF and general research. If one activity deserves attention and regulation, so do the others. Stem cell research alone cannot be usefully singled out for regulation, and indeed the regulation of stem cell research on its own is not efficient.

V. THE HUMAN FERTILIZATION AND EMBRYOLOGY AUTHORITY OF THE UNITED KINGDOM

It is often asked by what moral right do the members of the HFEA pronounce on these issues. It is because it embodies the democratic compromise between strongly held views in society, reached by the HFE Act 1990. The Authority works within the Act to reconcile opposing views and point to a way forward, with public accountability. The HFEA licenses and monitors clinics that carry out IVF treatments, donor insemination, and embryo research; it strives to ensure that treatment and research are undertaken with respect for human life and responsibility towards the parties, recognizing the vulnerability of patients and the expensive nature of the treatments. One in six couples seek infertility treatment and there may be many more who are infertile but do not seek medical advice. Care should be taken not to exploit them.

The HFEA regulates the storage of gametes, registers information about donors, treatments, and children, safeguarding the biggest database of its kind in the world. It issues a Code of Practice to clinics; gives advice and information to patients, donors, clinics, and the government; and keeps new developments under review. It has staff and premises in London, and twenty members selected openly on merit after advertisement. It issues an annual report, holds open meetings, and keeps in touch with all elements of the relevant professions. Its overall aim is to ensure that public understanding and reassurance move at the same pace as the new developments that it licenses. In the sixteen years of its existence, the HFEA has overseen major steps forward in infertility treatment, ex-

tending from "simple" IVF into matters of convenience, lifesaving, and life alteration.²¹ The HFEA has faced several legal challenges, all but one of which have failed.²² The HFEA is not universally popular with scientists, who resent the extra paperwork surrounding permission to pursue relevant research. It has however been successful in blocking the slippery slope. As far as is known, no one has tried to keep an embryo in vitro for more than fourteen days from fertilization, or has cloned, because policing of the laboratories is part of the system.

Legal regulation in Britain has probably served to protect clinicians and scientists not only from legal action for malpractice (where they have followed the HFEA Code of Practice) but also to give them a shield against accusations of ethical malpractice, for they are acting within the parameters agreed by Parliament and the HFEA. These safeguards clearly do not apply where there has been a total breakdown in the clinic controls and the deliberate flouting of the criminal law, which has happened once or twice.

Regulation has disadvantages too, as I shall show, but in general the history of regulation shows that work on embryos might never have been permitted in Britain at all had it not been for the existence of, at first, voluntary professional self-regulation and, subsequently, statutory controls. It has progressed with reliability and in tandem with public and peer acceptability. Judged by those criteria, regulation in principle has been a successful move. In addressing issues relating to public fear of new technologies, family issues, safety, and extent, regulation has been more of a success than a failure. The HFEA has tried to achieve a judicial use of its powers, combined with a consultative and consensual ap-

21. *E.g.*, HFEA, First PGD Guidelines, 1999, CE13/08/1999; Press Release, HFEA, HFEA to Permit Use of Frozen Eggs in Fertility Treatment (Jan. 25, 2000); 1994 HFEA ANN. REP. 18 (noting that the first ICSI licenses were granted in 1993).

22. *Evans v. Amicus Healthcare* [2004] EWCA Civ 727, [2005] Fam. 1 (upholding a man's right to withhold consent to IVF treatment); *R (on the Application of Assisted Reproduction & Gynaecology Centre) v. Human Fertilisation & Embryology Auth.*, [2002] EWCA Civ 20 (upholding the policy of limiting the numbers of embryos that may be transferred); *R v. Human Fertilisation & Embryology Auth. ex parte Blood* [1999] Fam. 151 (permitting the use of sperm taken without his consent from a dying/dead man); *see also* *R (on the Application of Quintavalle) v. Human Fertilisation & Embryology Auth.*, [2005] UKHL 28, [2005] 2 A.C. 561; *R (on the Application of Quintavalle) v. Sec'y of State for Health* [2003] UKHL 13, [2003] 2 A.C. 687. Recent decisions concerning fertility treatment under the HFE Act have been affected by the introduction into British law of the European Human Rights Convention by the Human Rights Act, 1998, c. 42, available at <http://www.opsi.gov.uk/acts/acts1998/80042--d.htm>. This gives greater weight to individual wishes. Nevertheless human rights law does not support an absolute right to have children or to be supplied with medical assistance to do so.

proach to regulation, and it aims to secure confidence and respect from Parliament, the public, patient groups, and the professions. Parliament, having set the framework, can rely on the Authority for the day-to-day management of the many legal and ethical issues that have emerged from the field.

VI. REGULATION FOR ALL?

Is regulation a good thing for the whole world? It has certainly achieved a great deal in Britain without too much dissent. There are some deeper issues that need consideration however. How does regulation square with human rights and autonomy? What issues should be settled in the legislation and what left to the discretion of the regulating committee or the patients? There are no general criteria for resolving this but different answers are given in different systems. They are linked to the competition for power to which I alluded, between market forces, religious forces, politicians, drug companies, doctors, and patients. It is rare for these competing forces to be recognized and addressed. They tend to be disguised by ethical and legal discussions.

There are many ways to justify legislative regulation. One could start with the simple issue of safety. No new treatment which affects the bringing into being of a new life should be allowed to proceed unless there is as much evidence as can reasonably be obtained that there will be no harm to mother or baby. Human reproductive technology has tended to proceed under a precautionary principle, balancing the benefits to be obtained against the possible harm. Thus the introduction of intracytoplasmic sperm injection (ICSI) and frozen egg technology was delayed in Britain while assurances about their safety were sought. Safety bears on issues such as the insemination of women over sixty, cloning, posthumous births, and donor gametes. I regard it as legitimate to curb reproductive autonomy when its exercise unreasonably impacts on the independence of others or threatens harm. Multiple births with their attendant private and public costs, sex selection with its effects on existing children, and PGD all have a long-lasting impact on society and may place a burden on others. It follows that society may have a legitimate reason to control through the democratic process the choices that may be made by individuals with their doctors.²³ It is right to grasp the nettle and

23. Rosamund Scott, *Choosing Between Possible Lives: Legal and Ethical Issues in Preimplantation Genetic Diagnosis*, 26 OXFORD J. OF LEGAL STUDIES 153, 175 (2006); see also RONALD DWORKIN, *FREEDOM'S LAW: THE MORAL READING OF THE AMERICAN CONSTITUTION* 104 (1996); ONORA O'NEILL, *AUTONOMY AND TRUST IN BIOETHICS* 58 (2002); JOHN A. ROBERTSON, *CHILDREN OF CHOICE* ch. 2 (1994); John Harris, *Rights and Reproductive Choice*, in *THE FUTURE OF HUMAN REPRODUCTION* 5, 34 (John Harris &

accept that reproductive autonomy can co-exist with regulation rather than leaving many profound issues to be decided, slowly, by individual court cases.

Regulation is also called for to control the market forces in this field, in the way that any big business is legitimately a target of regulatory control. Some of Britain's most well-known clinicians are reputed to be amongst the wealthiest men in the country. Because IVF and embryo research are big business, it is not wise to leave regulation to the professional bodies in the field because they will have conflicts of interest. Where there is a nationalized health system, decisions have to be made about resource allocation because resources spent on IVF and embryology will have an impact on other areas of medicine and their effectiveness has to be assessed. Britain accepts that it is dangerous to leave personal choice in IVF and the new genetics to market forces. In the United States it is accepted that IVF is a billion-dollar business, and even gametes and surrogacy are for sale.²⁴ There is an urgent need to control sale of gametes and embryos, like the sale of other organs, bearing in mind the dignity and vulnerability of individuals and the health and welfare of the potential baby.

Identity and recordkeeping are especially important in regulation, in case IVF children as adults are entitled to seek information about the identity of the donors. A register of data is also important as an epidemiological tool, searching for factors affecting the success of IVF, and presenting data on multiple births, birth defects, and success rates. Confidentiality of data should not be so strict that follow-up studies are ruled out. Of course a regulatory authority needs sufficient resources, without which the purpose is defeated and dangerous mistakes may be made. It

Søren Holm eds., 1998). The state interest was spelled out in the case of *Dickson v. United Kingdom*, App. No. 44362/04, Eur. Ct. H.R. (2006). In this case a prisoner was refused the right to artificial insemination of his wife while he was in prison. The argument that society allows children to be born to single persons in poor circumstances was not regarded as sufficient to entitle the prisoner to achieve something similar. This was because the state was being asked to become an "active accomplice and participant" in the conception. *Id.* (Bonello, J., concurring). "I believe a responsible state to be right to require of itself standards higher than those beyond its control in the free procreation market." *Id.* In Israel, Larissa Trimbobler sought artificial insemination by her husband Yigal Amir, who is in prison for life; the couple were granted conjugal visits.

24. The characteristics of potential gamete donors are available on the Internet, although whether their descriptions match the reality is another issue. It has even been pointed out that in an unregulated market, an embryo could be split, and once one of the twins has been born and the other embryo frozen, the frozen one could be offered for sale knowing what its twin looked like. GEORGE J. ANNAS, *SOME CHOICE: LAW, MEDICINE, AND THE MARKET* 11 (1998).

needs to be answerable to the legislature and to give a full account of its workings in a way that the public can access and understand. Its members need to be appointed in a way that gives people without a professional interest a chance to be represented. My own experience was that a majority of lay members over professionals on the authority was a good thing. Expert evidence can always be acquired from outside the membership. In particular, it needs to take evidence on the developments that lie ahead so that it is not caught unawares when a sudden application for new treatment is made or a new technique is problematic. It will be expensive and litigation can never be entirely avoided because there will be statutory interpretation issues arising from new developments and the regulator is bound to upset both clinicians and patients at some stage by its decisions.

The country that is in most urgent need of regulation is the United States,²⁵ because it is the most advanced scientific nation with an impact on all world science. Such federal law as there is appears to be concerned more with funding than with substance. There is no supervision of activities in IVF and embryo research; disasters are bound to happen. The private companies that do research may do well, but this activity is not necessarily undertaken with concern for public health and for the inequities between the medically insured and the uninsured Americans. There is a lack of clarity about standards and achievements because the private work is undertaken in conditions of commercial confidentiality and competitiveness. It must surely be possible for the United States to establish a public oversight body and comprehensive legislation. The Council on Bioethics is no substitute; in fact it may provide false assurance because its powers are non-existent.

But what is the reality of experiencing and administering regulation? Are there disadvantages?

Regulation has to be financed, and it is the patients who bear the expense, which is passed on to them by the clinics. Relatively little free IVF treatment is undertaken by the U.K. National Health Service (NHS) and, even in those cases, the NHS has to absorb the extra cost represented by regulation, and therefore ultimately it reduces the resources available elsewhere in the hospital system. Regulation also engenders avoidance, not in the sense of law breaking, but in the practice of reproductive tourism, going abroad to obtain a treatment banned at home. It stimulates constant discussion, criticism, and demands for reform. There

25. See George J. Annas, *The Shadowlands: The Regulation of Human Reproduction in the United States*, in CROSS CURRENTS 143 (Sanford N. Katz, John Eekelaar & Mavis Maclean eds., 2000).

are effective lobby groups and political opponents of any decision made by the regulators.

In approaching a new decision in the regulation of embryology, the following are the factors that in practice determine the outcome in a regulated environment.

First, the legal framework. Every regulatory decision has to be taken in the knowledge that it is likely to be challenged in the courts, either by a disappointed individual or by a pressure group, and that it is important to the regulator to succeed in the litigation. There is in Britain no overarching written constitution that might ensure success on the basis of a higher principle of freedom. However, our detailed regulatory legislation is boxed in or, some would say, made porous, by recent human rights and European Treaty provisions. The application of the Human Rights Act 1998 to legislation enacted before that date has tilted interpretation towards individual rights and liberty in applying legislation that was already carefully drafted to balance public health demands and individual desires. The European Treaty principles of freedom of movement of goods and services, and the right to seek medical treatment abroad, may in the last analysis undo all the careful regulatory constraints applied in the home country.

Second, money, to fight and to enforce. The regulatory authority needs to be sufficiently well-financed. Litigation cannot be brought to enforce the measures of a regulatory authority unless the authority has the funds available to fight a case all the way to the House of Lords (our Supreme Court). It is often the case that a popular litigant will be better funded by a newspaper to which he or she has sold his or her story, than the government authority in opposition. The HFEA was occasionally chastised for mistakes that were in truth unavoidable as long as the technology is in the hand of humans. A well-known example was the birth of black twins to a white couple, where the wrong sperm had accidentally been used in the clinic treatment. The consequent reprimands and demands for ever tighter regulation and inspection were made even while the Authority was being denied the resources that would make seven-day-a-week supervision possible.

Third, the power of the media in a small country where everyone reads the same newspapers and in general watches the same TV news. Newspaper and television coverage is often wholly inaccurate, but if there is a good human story, the more attractive of the two litigants will carry greater weight. When a young woman is featured in the media, making an appeal for a baby (by some risky method), it is clear that the public will side with her and that deeper issues in the decision will not be considered.

Fourth, politics. There is no doubt that government departments and ministers are apt to take a certain view in relation to questions that are widely debated, whether it is genetically modified food, fluoridation, or reproductive technology. While the pressures they exert may be indirect, they are nonetheless forceful.

Finally, and only if there is any room at all left for debate and choice, ethics. The HFEA developed five ethical principles derived from the legislation and from our deliberations on real cases day-by-day. The ethical considerations were bolstered by widespread public consultation. First was the assurance of human dignity, worth, and autonomy. In line with international conventions, nobody should be used as a convenience or as a bank of spare parts: consent and counseling are vital. No comatose or dying person should ever have gametes removed from them without their prior consent or even knowledge. Second, the welfare of the potential child. Consideration of its need for a father is enshrined in the legislation, although this requirement is now open to debate. Hence, the concern about cloning and the difficult family relationships that might ensue. Third, safety was given the greatest weight. Newly discovered treatments, such as preimplantation genetic diagnosis and egg freezing, were sometimes delayed for safety checks and trials of viability. Despite public pressure and compassion for those seeking treatment, the safety of the child and mother must be considered. Fourth, respect for the status of the embryo. Legislation lays down the parameters of permitted research and prohibits the mixing of humans and animals, cloning, and research on embryos over fourteen days old. These principles informed decisions about, for example, the posthumous removal of sperm and the ban on sex selection for social reasons.

A fifth principle has now emerged, which is that the saving of life is a good use to which new advances in embryology may be put. An example is the decision to allow preimplantation genetic diagnosis and HLA-typing to attempt to create a sibling whose umbilical cord blood might save an older child. Another example is the legalization of stem cell research.

Despite these complications, there is no doubt in my mind that comprehensive regulation is urgently needed in every state of the United States. The visiting English regulator, listening to the debate in the United States about federal funding of stem cell research, finds herself on another planet.

It seems obvious from history that one cannot commence the process of regulation with stem cell regulation, as if building an inverted pyramid. One has to build up to it from a broad and tested base. One cannot regulate stem cell work more or less in a vacuum without a foundation of

data, sanctions, inspection, monitoring, and uniformity. This is all the more so since there is to my mind no genuine difference between stem cell research and other types of embryo research, with shared safety and ethical issues. There is no genuine moral distinction between the use of embryos for procreation, research, and stem cell growth.

In the United States there appear to be too many cross-sector rules that are unenforceable and overlap: the NIH on research, the FTC on advertising, the FDA on drugs, the ASRM on laboratory accreditation, and state licensing. Even within one state there is a proliferation of guidelines with no enforcement. The California Institute of Regenerative Medicine (CIRM) has guidelines for the use of its funds in research, but there is a second set of guidelines for non-CIRM research.

Overall in the United States there seems to be no uniformity, or only fragmented rules, and reliance on professional self-regulation which is inherently weak. There appears to be no monitoring of the health of mothers and babies in IVF; no regulation of the extent of preimplantation genetic diagnosis; no oversight of the creation and disposal of embryos, or of the move from technology to safe medical treatment; no regulation of commerce in gametes; and no safe register of the names of donors and the outcome of the treatments.

Casting a British eye over U.S. practice, there is a need for uniform substantive legislative prohibitions in relation to cloning, controls on experiments in the womb and genetic manipulation; there is a need for surveillance of laboratories and clinics, and enforcement of the fourteen-day rule for keeping embryos in the laboratory. There should be regulation of the buying and selling of gametes, and consideration should be given to legislation banning the patenting of embryological research.

There is a need for U.S.-wide legislatively guaranteed procedures and openness. There should be studies of the health of IVF children and there should be publicity for the adverse consequences, if any, of certain treatments. Acknowledging the dangers of competition between clinics, there should be standards to ensure the integrity of statistics and to enable comparison between clinics. There should be good patient information, a limit on the number of embryos to be used in any one treatment, uniform safety standards, and penalties for their breach. The United States needs laws about the destination of embryos after the expiration of the permitted storage period and in situations where previously given consents are unilaterally withdrawn, typically upon divorce. Patients' and donors' rights, information, and consent in relation to distant research will become increasingly important and must be addressed. There needs to be supervision by an independent, central, and transparent body of people empowered to grant licenses, monitor and permit research, and

impose sanctions backed by criminal penalties. Britain is not alone in having confidence in this method. It has been adopted in Canada, Australia, France, and Japan to some degree.

Whatever the political disadvantages of, and the political jealousies engendered by British-style regulation of embryo research and use, these are minimum standards that are necessary.

In conclusion, I argue that the benefits of regulation are overwhelming. Scientists are sometimes mistrusted; there is unacknowledged competition between the politicians who would like to control every move in this interesting and momentous area, and the clinicians who have, as one would expect, personalities to match the tremendous strides forward into the unknown they have made. (I heard one of them say: "I have made a thousand women pregnant.") There is also the rich commercial market to be considered and the desires of patients who may be under pressure and uninformed. Only comprehensive regulation can hold the ring and bring order and consensus to this topic.