

Department of Health review of the Human Fertilisation and Embryology Act

A submission from the Genetic Interest Group, November 2005

Introduction and Summary

The Genetic Interest Group (GIG) is a national alliance representing individuals and families affected by or at risk of genetic disorders. We have 130 groups and many individuals in membership. For parents at risk of having a child with a genetic disorder genetic testing either of embryos prior to implantation or during pregnancy is a very important option. GIG and its members also broadly support research using embryos, whether to improve assisted reproductive techniques, improve understanding of genetic disorders or gain understanding that may lead to cell-based therapies. Accordingly, we have taken a keen interest in the issues over the course of the past 15 years. Indeed, the passage of the Human Fertilisation and Embryology Bill through its final Parliamentary stages was a factor leading to the formation of our group. In this response we focus on two things. Firstly, broad issues of regulation, and secondly, particular issues posed in the consultation that relate to the experiences and interests of our members.

Who should decide?

The most basic question is: who will decide what is and isn't allowed, at the broadest level, and how? The answer to the first question is obvious, especially in the light of this review: Government will propose and Parliament will decide, through a vote. But how should Government and Parliamentarians decide? In our view, so long as no clear harm to others can be demonstrated, families should have the freedom to make individual choices and researchers should have the freedom to undertake scientific inquiry, even if some people disapprove of the choices and activities.

Precautionary principle

While we agree with the underlying sentiment expressed by the House of Commons Science and Technology Committee in its recent report, Human Reproductive Technologies and the Law ('alleged harms to society or to patients need to be demonstrated before forward progress is unduly impeded'), it seems clear to us that the Government's interpretation of the principle is more in keeping with its usual use: if something new is proposed that *might* carry risk, or simply the possibility of harm, caution is advisable. However, this only confirms us in our scepticism regarding the use of the principle in this area. Government should be required to provide evidence of harm before restricting uses of reproductive technologies. Furthermore, if real evidence can be produced this should be considered in the balance rather than constituting grounds for prohibition. Small, statistical risks are commonly accepted in many areas of life, including reproduction. In the concrete individual case the positives, which could



include the simple fact of life existing where it would not have before, saving the life of a sick sibling and the pleasure of having and rearing children of one's own, may well overwhelm the negatives.

The character and purpose of regulation

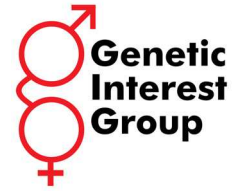
Fifteen years on from the passage of the HFE Act, against a background of broad public support for many aspects of assisted reproduction and embryo research, we favour a different regulatory regime. The primary purpose of regulations should be to uphold high clinical standards and ensure patient safety. The new regime should avoid formally criminalising unspecified activities. In other words it should not specify the kinds of research or treatment that are permitted. Instead, the assumption should be that research and treatments are legal unless they are expressly forbidden (modelled on the current prohibition on implanting an embryo in a woman created by means other than fertilisation). This would provide a more suitable and flexible system, one that could more adequately cover new scientific and clinical practices by allowing them to develop and be assessed. The new regime should also have the facility to exempt some practices from the requirement of being conducted under a license from the regulatory body. Periodic review, informed by experience and evidence, could determine the categories of treatment and research that did and did not require a license.

Welfare of the child

In preparation for its consultation on this issue (*Tomorrow's Children*, 2005), the HFEA surveyed public opinion. It found that patients do not like the vetting process that is implicit if not explicit in welfare of the child assessments. They find it intrusive, and they believe it to be discriminatory—fertile couples do not of course face such hurdles when they begin the process of trying to have a child. The Genetic Interest Group shares this perspective. It is our view that the women and couples that we represent, but also couples who simply want IVF rather than PGD, should be able to access the services they need without being subjected to a prior process of appraisal.

PGD and other treatments

Regarding selection to avoid genetic disorders, GIG consulted its members in 1996 and again in 2000 and 2004, each time getting the same response that individuals and families, after consultation with their clinical team in some instances, are the best judges of what is appropriate for them. Accordingly, we believe that the ultimate decision should rest with the parents of the child to be. It is clear that they should be well informed and that is the role of the genetic services and other professionals. However, in principle GIG is opposed to rules and regulations restricting or preventing the intentions of the parents to be. Indeed, as a matter of principle it is hard to see why, if a test is reliable, there



should be any restriction on the genetic conditions that could be selected against. Additionally, GIG supports in principle the idea of creating embryos to treat disease and, if it could be performed safely, genetic modification of embryos for reproductive purposes.

Research and the definition of the embryo

In chapter nine of the consultation document, a number of possible extensions to research are considered. GIG's view is that these should all be allowed. Fundamentally, so long as the resulting embryos are not implanted into a woman, genetic modification, replacement of a cell of an embryo, the creation of hybrids and other possibilities should be allowed so as to advance fundamental knowledge of embryo development and develop understanding of disease among other important reasons. Where we take issue with the reasoning of the consultation is the assumption that a list of such reasons, such research purposes (the approach taken in the current, 1990 Act), is necessary. Perhaps we could be reassured that the current list of purposes is exhaustive, or that if it is not more can be added prior to a change in the law after a collective racking of brains. However, bearing in mind that the definition of the embryo will remain imprecise, and that we cannot foresee all future possibilities, there is always the danger of creating barriers, perhaps where this was never the actual intent. A better approach would be to make the default position one of allowing research without specifying exactly the purposes for which it is allowed.

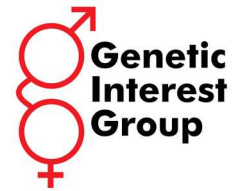
A draft Bill

It is stated in the consultation document that Government intends to produce a draft Bill for consultation. We welcome this. If Government wishes us to comment further on any of the issues contained in this response prior to or after the publication of such a draft, we would be more than happy to do so.

Who should decide?

Traditionally, anti-abortion groups and politically sympathetic allies have led the opposition to IVF, genetic testing of embryos (selection) and embryo research. In many ways this is still the case, as evidenced by the recent Parliamentary debates on the extension to the research purposes in the HFE Act and the legal challenges both to that change and the licensing of tissue typing in conjunction with a genetic test to avoid a genetic disorder.

In an important sense, those fundamentally opposed to these practices have lost the argument. 'Conventional' applications of Pre-implantation Genetic Diagnosis (PGD) are now widely accepted, even if some or even many people have some unease about some applications. Indeed, surveys indicate majority support for more novel applications of the technology as well, such as tissue typing of



embryos prior to implantation for the benefit of another (ill) child (the creation of a 'saviour sibling'). Embryo research is also broadly supported.

However, to set alongside the picture of continuity and steady if slow expansion of research and treatment options, we need to consider some changes and new concerns. In the context of embryo research and clinical applications, the argument put is that there is a risk of undermining the value given to the human embryo or, perhaps more pertinently, a threat of 'commodification'. Internationally, influential writers such as Francis Fukuyama¹ and Jurgen Habermas² have taken up this theme. In the UK, feminist academic Hilary Rose and (opportunistically?) some of the anti-abortion campaigners are obvious proponents.

The most basic question is: who will decide what is and isn't allowed, at the broadest level, and how? The answer to the first question is obvious, especially in the light of this review: Government will propose and Parliament will decide, through a vote. But how should Government and Parliamentarians decide? In its recent consultation on sex selection, the HFEA took a poll of public opinion and conducted focus group discussions. This can be seen as an extension of the well-established practise of consulting the public, which the HFEA has done several times in the past 15 years. More rigorous polling might be seen as preferable to simply asking for responses to a consultation document, which is open to the charge that the 'usual suspects' (such as ourselves) will contribute the majority of responses.

This consultation can be seen as a development and a refinement of previous calls for opinion: as well as asking the questions, the consultation document maps out apparently exhaustive possible answers, in effect asking respondents to vote for the arguments they agree with. Combined with public opinion surveys it is doubtless expected that a fairly clear view of public beliefs and opinions will be gathered in time for any Parliamentary debate that might take place on amendments or alternatives to the 1990 Act. It would then be up to Government and Parliament to decide how to regulate in the light of the sentiments and opinions expressed, taking account of course of many other factors.

However, this approach has its critics. In a trenchant critique of the HFEA publication following consultation on sex selection, John Harris³ isolated the slip from gathering public opinion to basing regulation upon it: does Government (or the HFEA in the context of Harris' argument) actually *agree* with the sentiments

¹ F. Fukuyama, *Our Posthuman Future* (Profile Books 2002).

² J. Habermas, *The Future of Human Nature* (Polity Press 2003).

³ *J Med Ethics* 2005; **31**

expressed? And how does it propose to decide what *weight* to give them in any case? Politicians might not find this argument as troubling as the Deputy Chair of the HFEA (a fellow philosopher) did, and might respond that it is sensible politics to work with or at least not run too far ahead of public opinion. But Harris has another point that we also very much endorse: if a form of treatment for a couple is restricted, or a form of research prevented, freedoms and activities are being curtailed, both of which are very important to individuals and society. Indeed, so long as no clear harm to others can be demonstrated, the freedom to make individual choices and the freedom to undertake scientific inquiry, even if some people disapprove of the choices and activities, has long been accepted within Government and society.

In our view it is not enough to say that some people fear that certain kinds of activity threaten human dignity, or the psychological wellbeing of children. Government should state clearly which if any arguments it agrees with if it proposes to restrict these activities, and it should provide evidence.

Precautionary principle

A related set of issues arise in relation to possible risks and harms, and the application of the (in)famous precautionary principle. While both agree that the principle is relevant, the House of Commons Science and Technology Committee and the Department of Health disagree on how it should be applied to this field in their report and consultation document respectively. The former argue that: 'we do not see why the area of human reproductive technologies should do anything other than proceed under a precautionary principle currently prevalent in scientific, research and clinical practise. This means... that alleged harms to society or to patients need to be demonstrated before forward progress is unduly impeded.' (Recommendation 3, Human Reproductive Technologies and the Law, 2005).

The Government 'agrees that reproductive and research freedoms must be balanced against the interests of society, and that the area of human reproductive technologies should proceed under a precautionary approach. The Government disagrees, however, with the Committee's interpretation of the precautionary principle. The potential harms that should be taken into account may not necessarily be susceptible to demonstration and evidence in advance. For example, in our view the application of a precautionary approach requires that consideration of harms to society or to patients must include the consideration of potential harms to future offspring.' (Paragraphs 5 & 6, Government Response).

While we agree with the underlying sentiment expressed by the Committee ('alleged harms to society or to patients need to be demonstrated before forward

progress is unduly impeded’) it seems clear to us that the Government’s interpretation of the principle is more in keeping with its usual use: if something new is proposed that *might* carry risk, or simply the possibility of harm, caution is advisable. However, this only confirms us in our scepticism regarding the use of the principle in this area.

Prior to this consultation, in public debate possible and theoretical harms to children born following novel applications of reproductive technologies—whether physical or psychological—and the possibility of offending public sensibilities have been highlighted by a number of UK commentators, but most significantly by the HFEA Chair Suzi Leather. Leather discussed the Authority’s concerns in speeches and press interviews relating to both tissue typing and sex election for social reasons. For example, of the former she said: ‘we don’t know what the social and emotional consequences of being a so-called “saviour sibling” will be. It seems to me that in this area of considerable uncertainty, where there is a possibility of theoretical risk, that we should adopt a precautionary approach.’

Initially the Authority distinguished between cases in which tissue typing was additional to a test to determine whether the embryo was free of a serious genetic disorder, and those in which it was the sole reason for analysis. It permitted the former but not the latter. Since then the Authority has approved the latter as well, i.e. tissue typing for the benefit of a sibling without an accompanying test to determine whether the fetus is affected by a genetic condition. In general it seems that it is being more selective in its use (or perhaps public endorsement) of the principle. But what Leather’s comments do illustrate is that the principle can be used as something of a last refuge when other arguments fail—for while the ostensible reason for revisiting the issue was an analysis of the literature on the risks associated with cell biopsy in particular, it was clear to most observers that there was no evidence of harm prior to the literature review. Government is justifying the use of the principle in this way when it argues that ‘the potential harms that should be taken into account may not necessarily be susceptible to demonstration and evidence in advance’.

In our view, as with the use of ‘dignity’ and ‘commodification’ arguments, Government should be required to provide evidence of harm before restricting uses of reproductive technologies. Furthermore, if real evidence can be produced this should be considered in the balance rather than constituting grounds for prohibition. Small, statistical risks are commonly accepted in many areas of life, including reproduction. In the concrete individual case the positives, which could include the simple fact of life existing where it would not have before, saving the life of a sick sibling and the pleasure of having and rearing children of one’s own, may well overwhelm the negatives.

The character and purpose of regulation

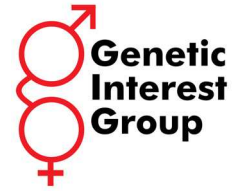
The HFE Act 1990 was crafted in such a way as to allow most of the things scientists and patients wanted at the time, and to provide a framework to consider, and in principle permit, foreseeable extensions of existing research and clinical applications. The 2001 extension of research purposes, which made possible research into embryonic stem cell derivation and therapies, is a good example of the forward-looking character of the original Act. However, it would be a mistake to see the facilitative character of the Act as equating with an anything goes attitude as some of its critics contend. In fact the Act created criminal sanctions and a licensing regime to cover both research and treatment. It did this by establishing the *illegality* of research and treatment carried out without a license, and by establishing the categories under which the Human Fertilisation and Embryology Authority could license activity.

Fifteen years on, against a background of broad public support for many aspects of assisted reproduction and embryo research, we favour a different regulatory regime. The primary purpose of regulations should be to uphold high clinical standards and ensure patient safety. The new regime should avoid formally criminalising unspecified activities. In other words it should not specify the kinds of research or treatment that are permitted. Instead, the assumption should be that research and treatments are legal unless they are expressly forbidden (modelled on the current prohibition on implanting an embryo in a woman created by means other than fertilisation). This would provide a more suitable and flexible system, one that could more adequately cover new scientific and clinical practices by allowing them to develop and be assessed. The new regime should also have the facility to exempt some practices from the requirement of being conducted under a license from the regulatory body. Periodic review, informed by experience and evidence, could determine the categories of treatment and research that did and did not require a license.

The consultation document rightly asks questions about the efficiency of the regulatory regime. There are concerns that the HFEA currently takes too long to come to decisions and simultaneously takes too detailed an interest in individual procedures, technical aspects of procedures, or lab management that can and should be matters for other bodies or of professional competence.

Welfare of the child

In preparation for its consultation on this issue (*Tomorrow's Children*, 2005), the HFEA surveyed public opinion. It found that patients do not like the vetting process that is implicit if not explicit in welfare of the child assessments. They find it intrusive, and they believe it to be discriminatory—fertile couples do not of course face such hurdles when they begin the process of trying to have a child. The Genetic Interest Group shares this perspective. It is our view that the women



and couples that we represent, but also couples who simply want IVF rather than PGD, should be able to access the services they need without being subjected to a prior process of appraisal.

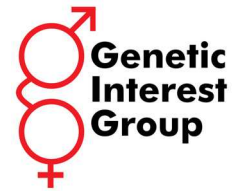
The issue is posed with particular clarity if we focus on those women and couples who may want to use PGD. Assuming they are fertile, they could conceive naturally, have an antenatal test and termination of an affected pregnancy without any external interference prior to conception. But if the same couple wanted to begin a pregnancy in the confident knowledge that the fetus was free of a particular genetic condition, they would be subject to such an external inquiry.

Of course, women and couples want to know about any risks involved. They also understand that if particular processes are thought to carry significant risks to the mother or future child society will take some interest. However, it is our understanding that neither routine IVF nor the processes involved in PGD carry such risks in general. Furthermore, we are not convinced that couples should be refused treatment even if such extra risks were inherent given their particular circumstances. Accordingly, we would wish to see section 13(5) removed from the HFE Act.

While there is debate about how the principle should be applied, the idea that the Welfare of the Child (to be born) should be considered prior to the use of assisted reproductive technologies (ARTs) is often presented as common sense. At the last evidence session of the House of Commons Science and Technology Committee inquiry into Human Reproductive Technologies and the Law, Suzi Leather, HFEA Chair, stated: 'My personal position is that children flourish best within a stable relationship between two people. That is my personal view. The Authority's view is that the welfare of the child is an important principle, and that the welfare of the child of course should be taken into account by clinicians when deciding whom to treat. However, the welfare of the child is much more important than simply a child's need for a father, or an age cut-off. I think that it has to be looked at in the round.'⁴

The assumption seems to be that the involvement of the medical profession somehow gives society (the state) a right to take an interest in the prospective parents and their motivations. This was put bluntly by Professor Eric Blyth at an earlier evidence session: 'I think the bottom line is that the state is actually involved in helping people with the creation of a child. That would be our major view, that because of that, because of the State's responsibility for children it is

⁴ <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/c7-iii/c702.htm>



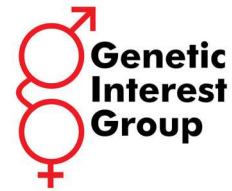
helping to bring into being, it has that responsibility.’⁵ In the current consultation, Government gives voice to this point of view: ‘Those who argue for society having the power in principle to intervene in the reproductive choices of people requiring assisted conception, but not in the reproductive choices of people able to conceive naturally, may do so on the basis that this represents a justifiable difference in treatment rather than discrimination. In other words, that there is a difference between preventing someone from exercising their capacity to reproduce, and enabling someone to reproduce who could not otherwise do so.’ (3.17).

Evan Harris MP and others pursued a critical line of questioning on this issue throughout the Committee’s inquiry, and elicited a number of interesting comments from witnesses.

Melanie Johnson MP, Parliamentary Under-Secretary of State for Public Health, stated: ‘I think there are differences [between natural and assisted conception] because we are putting people through a process and other people are involved in that, but as you have ably illustrated, even for those born as a result of natural conceptions, sometimes the welfare of the child is considered to be best dealt with away from its natural parents and therefore society does not ever stand back entirely from the welfare of the child - as indeed it should not. There are different triggers, as it were, for fertility treatment and different triggers for those who are naturally conceived, but there is probably quite a lot in common. I do not think any of us think there should be more intrusion around natural conception. It has been a fundamental belief in our society for many centuries that that process should not be interfered with by the state, and indeed in societies where that has happened clearly there is a very different cultural assumption and often a lot of resistance to that interference. I do not think any of us would suggest that. In the case of IVF or similar procedures what is happening is there is the intervention, there is the question of creating the child, there is the question of the welfare of the patient, and there is the question of the technology and use to which it is put, so there are a lot of ethical and moral questions which arise which do not arise in the context of natural conceptions... the 1990 Act says that clinics must take account of the welfare of the child before treatment, and the guidance which is given in the HFEA’s code of practice for clinics sets out the expected proper conduct and it includes a range of factors - medical and social, the risk of harm from inheritable disease, multiple births, commitment to raise children, the age and health of the parents.’⁶

⁵ <http://www.publications.parliament.uk/pa/cm200304/cmselect/cmsctech/c599-ix/c59902.htm>

⁶ <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/c7-iii/c702.htm>

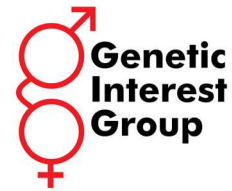


Responding to a question posed by Dr Iddon during the inquiry ('The majority of the population, at some time in their lives, have had almost complete reproductive freedom. Why then do we impose a "welfare of the child" provision on the infertile?') Vivian Nathanson for the BMA made a similar argument, with a nod in the direction of the 'adoption analogy', but was careful to emphasise that treatment should only be refused in extreme circumstances: 'There are a variety of answers to that, including the fact that we always have, in the sense that if you want to adopt or foster we actually assess your suitability to be parents but we do not assess people who produce children naturally, as it were, without any help. I suppose the answer is that, in the same way, when we are looking at assisted reproductive technology, there is the question of the harm to any child that might be created using that technology. However I would emphasise that we do not believe in blanket exclusions and we do not believe in idealised family concepts; we believe that every individual should be looked at separately and every individual case or every individual person involved, and that the exclusions should be truly exceptional, where there is very good evidence that there would be a serious risk to the welfare of any child created to that individual. So it would be truly exceptional. It is different in that society does have a role, as society is encouraging and supporting in some way the use of this technology and, therefore, the creation of a child in a way which is different to natural reproduction.'⁷

These quotes highlight that the principle is intended to cover more than simply the physical risks that may or may not be associated with IVF and other ARTs. In principle at least it involves a social assessment. Suzi Leather wants to move away from the focus on the need for a father. The Under-Secretary of State is keener to retain this clause. Vivian Nathanson is opposed to blanket exclusions and beliefs about idealized family concepts. But all three want to look into the circumstances of the lives of those presenting for treatment. All take the view that medical help (or 'intervention') provides the rationale for taking such an interest.

The Genetic Interest Group disagrees with the arguments advanced by these witnesses. In the case of adoption it makes sense to find a suitable family in which to place an existing child who is separated from her natural parents for whatever reason. This reasoning does not hold prior to conception—whether or not the woman or couple needs access to ARTs. That professional help is needed to attempt to conceive does not change the nature of the initial decision or the outcome in general. The need for professional help does of course mean that the process of conception is likely to be more difficult than if it were not needed. Women and couples undergo an often lengthy, trying and expensive

⁷ <http://www.publications.parliament.uk/pa/cm200304/cmselect/cmsctech/c599-viii/c59902.htm>



process. The evidence suggests that on average such people are as or more strongly committed to bringing children into being and caring for them compared with those who do not experience fertility problems. So why put extra hurdles in the way?

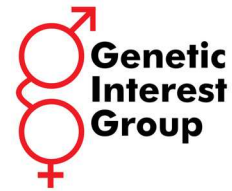
It is worth highlighting a general contradiction here. If it were surgery to correct a problem following which the couple was able to conceive naturally, the surgeon would not have to consider the welfare of any possible future children. It is hard to avoid the conclusion that section 13(5) lacks coherence in addition to being intrusive and discriminatory based on the arguments advanced in its favour.

There are other arguments for distinguishing assisted conception from natural conception that avoid the charge of incoherence. One is that Government would like to assess everyone or sub-groups of the whole population but that this would be too intrusive in the case of the fertile so the opportunity is taken with a more select group. Some suspect that this sentiment does lurk in the background, but dare not be admitted. A second argument is that ARTs allow things to occur that could not occur naturally, and that it is therefore legitimate to regulate and restrict their application. Post-menopausal pregnancy is an obvious example. A weaker example is provided by so-called 'saviour siblings' (weaker because fertile couples can try for such a possibility naturally).

Since the first possible argument is not admitted or put forward we do not respond to it here. In regard to the un-natural argument, GIG has taken a broadly liberal and supportive attitude to applications in this class. Nevertheless, we do not doubt that if a discussion was held there would be examples where some or all would be sympathetic to medical professionals who were unenthusiastic about treating an individual woman or couple. But does such unease concerning some individual cases justify a general regulatory clause?

In practice, some professionals use the principle as an excuse not to treat particular classes of patients. This is perhaps less of a problem than it was fifteen years ago. Other professionals are uncomfortable with the welfare principle. They are aware that many of their patients do not like it, and they are reluctant to inquire too keenly. This is widely acknowledged. In the penultimate evidence session to the House of Commons Science and Technology Committee inquiry, Professor Allan Templeton, President of the RCOG Scientific Advisory Committee argued that the Welfare of the Child provision could be removed from the Act, and the principle subsumed within good medical practice:

'It is good medical practice. I am talking here about a patient who needs IVF or donor insemination, or whatever, within the law - therefore it is the welfare of the child - but I may well be seeing another patient who is requesting some other



form of fertility treatment, and it is good medical practice to ensure that the treatment we are offering is appropriate to those patients' conditions. I do not actually see that there is a need for specific welfare of the child issues within any act; it is good medical practice. The welfare of the child recommendations came about because of concerns, at that time, of single women having children through assisted reproduction...

... It is good medical practice. I do not think you need guidance. Why would you need guidance to try and make a decision? It is the same issue as whether you treat an HIV-positive patient or you have two patients who happen to be heroin addicts and whether you should treat those within your clinic. That is the discussion you have. You cannot generalise; it is good medical practice to take a decision about the appropriateness of treatment in any given circumstance.⁸

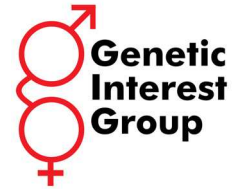
The virtue in Professor Templeton's suggestion is that it takes it away from there being something special about IVF. However, patients might find themselves feeling subject to similar intrusive questioning under such good medical practice. It is one thing to raise extreme examples for discussion, it is another to use them to justify a blanket professional practice. While the medical profession legitimately exercises a degree of autonomy and conscience in this area, it must also remember that it has a monopoly of expertise that patients have a reasonable expectation of access to. Of course we do not wish to imply that Professor Templeton himself was arguing for a restrictive practice. Indeed, in response to questioning from Evan Harris he stated that he would be happy with a legislative steer that said treat everyone but keep a note and inform social services if there is risk of abuse after the birth, as in the case of the naturally reproducing woman / couple. We would agree with this approach.

PGD and other treatments

The Government asks a range of questions (5.19-5.23) about the possible purposes to which Pre-implantation Genetic Diagnosis (PGD) could be put, and how these should be regulated. This is against a background of legal judgements and much media discussion of the 'saviour siblings' issue as well as extensions of existing procedures to cover new conditions (such as late onset conditions for which the gene is not fully penetrant and / or some form of treatment is available).

Tissue typing to maximise the chance that a child will be a match for a sibling is undoubtedly outwith the applications of the technology considered when the existing Act was discussed in Parliament. However, along with a majority of the population GIG has no trouble in endorsing it as a humane solution in very

⁸ <http://www.publications.parliament.uk/pa/cm200405/cmsselect/cmsctech/c7-ii/c702.htm>



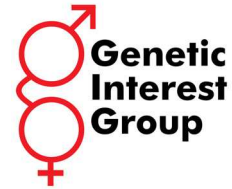
difficult circumstances. What little evidence there is in the public domain to date suggests that the procedure is both efficacious and without harm to the younger sibling. If there is any lingering doubt as to the legality of the procedure, when the Act is re-considered it would be good to clarify that it is both legal and a suitable treatment option in certain circumstances.

It is less clear to us that extension of existing practises to encompass late onset conditions for which the gene is not fully penetrant and / or some form of treatment is available is as novel or problematic as recent press discussion might suggest. Indeed, it is now more than a decade since a license was first granted for such a procedure, and a wider media debate about related possibilities accompanied this. GIG consulted its members in 1996 and again in 2000 and 2004, each time getting the same response that individuals and families, after consultation with their clinical team in some instances, are the best judges of what is appropriate for them. Accordingly, we believe that the ultimate decision should rest with the parents of the child to be. It is clear that they should be well informed and that is the role of the genetic services and other professionals. However, in principle GIG is opposed to rules and regulations restricting or preventing the intentions of the parents to be.

Indeed, as a matter of principle it is hard to see why, if a test is reliable, there should be any restriction on the genetic conditions that could be selected against. To take but one example that has been debated recently, we can well understand that a woman might want to have a child free from a serious adult onset condition or the substantial risk of one. After all, many if not all people would view removing the certainty or significant risk of developing a disorder in later life for an individual already born as an unequivocal good. If PGD is not in itself wrong, it is hard to see why its use to achieve the same ends should not be greeted with the same positive endorsement.

In practice, taking account of all that is involved, there are many disincentives to using PGD. Most if not nearly all women would not seek out PGD services in the absence of a known family history or unless they were receiving IVF already and it was thought that chromosomal analysis could improve the success rate. However, looking to the future, if a woman was already undergoing IVF and was to make a request for a broader genetic screen, we can see no objection in principle. Indeed, it may become possible in time to effectively screen pre-implantation embryos for a range of conditions, much as presently the technology has been developed to screen such embryos to improve the chances of a successful pregnancy. As the HFEA recently acknowledged,⁹ there is no evidence of harm to the future child as a result of biopsy, and much evidence of

⁹ <http://www.hfea.gov.uk/AboutHFEA/HFEAPolicy/Preimplantationtissuetyping>



safety. Additionally, there is no 'slippery slope' because the only outcome is a child free of a particular condition. Of course, there is a question of whether there should be public funding in all circumstances, but that is a separate issue.

Three other specific issues are raised that we wish to comment on: creation of embryos for the *treatment* of serious disease (9.47), genetic modification of embryos for reproductive purposes (5.38) and embryo splitting.

By the first suggestion we understand, for example, 'therapeutic cloning', the use of cell nuclear replacement into an egg or single cell embryo to develop an embryonic stem cell line to treat the donor of the cell nucleus. Another possibility might be tissue typing of embryos to determine the most appropriate one to use for developing a cell line for an ill relative rather than as a precursor to implantation. Currently these procedures are forbidden. It seems natural to us that they should be permitted. At the very least the idea of patient-specific treatments was considered to be a possibility when therapeutic cloning *research* was legalized in 2001. It may be, as was discussed then, that research leads to ways of developing tissue-matched embryonic stem cell lines without using embryos, which might be preferable for a range of reasons. However, all options should be kept open through an appropriate and logical extension of the law.

Nearly all if not all people reject, for the moment or indefinitely, genetic modification of the nuclear DNA of an embryo prior to implantation. The consensus is that it is currently unsafe, and what is more many uses to which it might be put can be achieved by the far safer (and more reliable) method of embryo selection. However, it is possible to envisage a number of possible applications at some future date if it could be done safely. Government asks whether any new legislation should contain a power for Parliament to relax this ban through regulations rather than a further round of primary legislation. We believe it should.

While government is open to the possibility of allowing the use of embryos for treatment and the future therapeutic application of germline modification, it seems that it is firmly opposed to embryo splitting for treatment. Indeed, in its response to the House of Commons Science and Technology Committee it says that it can see no reason to do it. This puzzles us, for it is not hard to construct a realistic scenario where it might be very useful for a real individual. Consider, for example, a woman who is unable or unlikely to produce any more viable embryos. Perhaps this is because of age or illness, or both. If embryo splitting were shown to be safe, one or more of the viable embryos could be split to provide a greater chance of achieving a successful pregnancy simply by increasing the number of embryo available to be implanted. A number of objections might be raised to this (such as concern about the deliberate creation

of identical twins, perhaps separated in time), but this is a different matter than saying that the procedure has no foreseeable applications or benefits.

Research and the definition of the embryo

'The Government considers that the best approach is to define the forms of embryo which may be placed in a woman and in what circumstances, and to regulate other forms of embryo insofar as these are created and used for research.' (2.22).

GIG agrees with this approach. Vagueness would remain as to what was and was not a human embryo, but this would be dealt with, it appears, by taking a broad meaning, the assumption being that anything that appeared to be an embryo is an embryo for the purposes of law and regulation governing research.

In chapter nine, a number of possible extensions to research are considered. GIG's view is that these should all be allowed. Fundamentally, so long as the resulting embryos are not implanted into a woman, genetic modification, replacement of a cell of an embryo, the creation of hybrids and other possibilities should be allowed so as to advance fundamental knowledge of embryo development and develop understanding of disease among other important reasons.

Where we take issue with the reasoning of the consultation is the assumption that a list of such reasons, such research purposes (the approach taken in the current, 1990 Act), is necessary. Perhaps we could be reassured that the current list of purposes is exhaustive, or that if it is not more can be added prior to a change in the law after a collective racking of brains. However, bearing in mind that the definition of the embryo will remain imprecise, and that we cannot foresee all future possibilities, there is always the danger of creating barriers, perhaps where this was never the actual intent. As we outlined above (in the section 'The character and purpose of regulation'), a better approach would be to make the default position one of allowing research without specifying exactly the purposes for which it is allowed.

A draft Bill

It is stated in the consultation document that Government intends to produce a draft Bill for consultation. We welcome this. If Government wishes us to comment further on any of the issues contained in this response prior to or after the publication of such a draft, we would be more than happy to do so.