

COMMUNICATION FROM THE EUROPEAN COMMISSION

CONSULTATION REGARDING COMMUNITY ACTION ON HEALTH SERVICE

Response on behalf of CARE for Europe

PUBLIC CONSULTATION

Communication from the Commission regarding Community action on health services

Submission from CARE for Europe

Contents

- 0 – Background
- 1 – Ethical Diversity – the Current Situation
- 2 – The Legal Base
- 3 – National Provisions – the European Patchwork
- 4 – Conclusions
- 5 – Supporting Information

0.0 BACKGROUND

- 0.1 CARE (Christian Action, Research and Education) is a registered charity and ethical campaigning association supported by 100,000 individual Christians and churches of all denominations, the greatest concentration of these being in the United Kingdom. CARE is concerned to see Christian ethical principles reflected in national and European law and public policy in issues relating to the family, medical ethics and the value of human life.
- 0.2 CARE for Europe represents the views of our 100,000 supporters on the continent from our office base in the European Quarter of Brussels.
- 0.3 CARE is involved in a range of practical caring initiatives, the organisation of conferences, seminars and the publication of educational and research materials on parenting, marriage and other family issues. CARE also undertakes research and lobbying on associated issues. Our stance on contemporary bioethical issues is summarised in the Declaration on Human Genetics and other New Technologies in Medicine appended to this Statement as Annexe I.
- 0.4 CARE submitted written evidence and was later called to give oral evidence to the European Parliament's Temporary Committee on Human Genetics and New Technologies in Medicine. We also gave evidence at the Public Hearing organised by the European Parliament at the commencement of the legislative process on the Directive on Human Tissues and Cells which has now been adopted as Directive 2004/23/EC. Our evidence statement to that Hearing is appended as Annexe II.
- 0.5 CARE for Europe welcomes the Communication from the Commission and public consultation on Community action on health services. We recognise that it is appropriate to respond to the desire of European citizen's to have easier access to essential healthcare provision whilst they are away from their home country and welcome the clarifications in this regard that have come through the case-law of the European Court of Justice.
- 0.6 However, we feel we must take this opportunity to express our concern in the case of any proposal to limit the current ethical diversity in the provision of health services by attempting a European harmonisation of provisions for access to ethically controversial forms of 'treatment'. This issue appears to be raised in the explanatory text accompanying Question 7, as well as the matter of the appropriate legal base raised in relation to Question 9.

1.0 ETHICAL DIVERSITY – THE CURRENT SITUATION

- 1.1 Because of national cultural and ethical differences there are currently a number of 'treatment' areas over which Member States differ in their willingness to either allow any provision to be made on their territory at all or its availability through the publicly-funded sector. Very often these exclusions

or restrictions have been the subject of intense public debate and large-scale democratic interventions via such means as universal referendums and constitutional amendments. The Commission's paper specifically refers to fertility treatment as an example, but access to abortion services, so-called 'emergency contraception', surrogate motherhood and embryonic stem cells are also among the areas where many Member States currently exercise their right of national conscience to outlaw or restrict the provision of services which are freely available in other Member States

- 1.2 We consider that any proposals to clarify and give legal certainty to patient mobility must respect this ethical diversity and do not oblige Member States to either tolerate on their own territory or fund for their nationals on the territory of another Member State forms of 'treatment' to they are conscientiously opposed.

2.0 THE LEGAL BASE

- 2.1 The Treaty base for Community action in health matters is Article 152 TEC. This states clearly both that '*Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.*' and that any '*harmonisation of the laws and regulations of Member States*' is to be excluded.
- 2.2 In this context CARE considers it unfortunate that the Commission's consultation refers (para 4.1) to the possibility of a binding regulation or directive under Article 95 (Internal Market) which presumes harmonisation. There are three main problems.
- 2.3 First, it contradicts the commitment not to subject health services and medical care to harmonisation.
- 2.4 Second, one of the main means of securing the space for the maintenance of national distinctions if harmonisation was embraced would be derogations. However, although there have been instances where national derogations have been allowed under Article 95 legislation (eg. Article 4.4 of Directive 2001/83/EC (medicinal products for human use) which states that '*This Directive shall not affect the application of national legislation prohibiting or restricting the sale, supply or use of medicinal products as contraceptives or abortifacients. The Member States shall communicate the national legislation concerned to the Commission*) such exceptions have been criticised by the ECJ as undermining the whole purpose of harmonisation in order to complete the single market (1) and it needs to be borne in mind that the normal mechanism for allowing Member State exception to European legal provisions (Article 30) may not be used where harmonisation legislation under Article 95 has been enacted. Derogations made on this basis consequently do not, in our opinion, have sufficient security. If such insecurity was ever to result in health service derogations being overruled by judicial decision it would mean that the single market imperative would have been allowed to effectively "trump" the

commonly understood intent of other treaty commitments allowing national ethical diversity in a way that retrospectively denudes those commitments (2) of any effective value and will erode public confidence in the European policy process.

- 2.5 Third, the consultation gives Watts judgement wider application such that its comments regarding e.g. Article 49EC are extended to Article 125 which Watts does not mention explicitly. This is unnecessary and further compromises the commonly understood meaning of this Article.
- 2.6 Thus CARE for Europe does not believe that the aspects of health services considered by the Community action on health services consultation should be subject to a binding regulation or directive under Article 95.

3.0 NATIONAL PROVISIONS – THE EUROPEAN PATCHWORK

- 3.1 Currently Ireland, Malta, Poland and Portugal have severe restrictions on the provision of abortion services and so-called ‘emergency contraception’ (because of its abortifacient effect). They consider that the basic human right to life begins at conception and therefore an abortion should only be performed where the life of the mother is in danger and it can therefore be considered to be the ‘lesser evil’.
- 3.2 The above countries and some others (notably Italy) also restrict artificial fertility treatment to varying degrees. In addition to these Germany, Austria, Lithuania and Slovakia also have severe restrictions on the destruction of embryos for the harvesting of embryonic stem cells. Although research has not yet (and there is no certainty ever will) proceed to the stage of their use as human treatments this also would be outlawed in the countries concerned. So-called ‘surrogate motherhood’ is also illegal in many Member States.
- 3.3 Also the subject of differential provision as between Member States is the question of euthanasia. In the vast majority of Member States (backed by the clear view of the Council of Europe) the intentional taking of the life of another, regardless of motivation, is a criminal offence. In a tiny minority it has recently become not only legal, but available through publicly-funded health care services as of right. Any attempt to force harmonisation on this issue would be grossly offensive to one side or the other in this sensitive debate.

4.0 CONCLUSIONS

- 4.1 CARE heartily endorses the Commission’s ambition for European citizen’s to have easier access to essential medical treatment when away from their home country. However, it is concerned that this should not compromise the current ability for Member States’ to apply their own national ethical rules, based on democratically expressed national conscience, to prohibit or restrict the provision and/or funding of certain controversial ‘treatments’.

- 4.2 In particular CARE for Europe believes that this is an area in which the use of harmonising legislation in the form of a binding regulation under Article 95 TEC would be totally inappropriate.

5.0 SUPPORTING INFORMATION

(1) ECJ case-law on Article 95 and national exceptions

Case C-376/98 Germany vs Parliament and Council [2000] ECR I-8419

Case C-491/01BAT [2002] ECR I-11453

Case C-217/04 United Kingdom vs Parliament and Council [2006] ECR I-3771

- (2) Cf. Council Written Answer to Parliamentary Questions of 15 March 2001 which stated that *'the Council would remind the honourable Members that national abortion legislation does not fall within the Community's competence.'*

ANNEXE I

DECLARATION ON HUMAN GENETICS AND OTHER NEW TECHNOLOGIES IN MEDICINE

We, the undersigned, acknowledge that scientific and technological progress has the potential to positively transform the health and wealth of our society. This cannot happen if this progress does not protect and promote human dignity; the right to life; the fundamental uniqueness and equality of every human being from the moment of conception to natural death; the special responsibilities of parents and families; and the promotion of individual and common good.

Despite the common contemporary perception of ethical pluralism that refuses to accept the existence of commonly shared European ethical principles, we hold that the tragic events of September 11, has demonstrated that there is universal agreement on the evil nature of some human acts (terrorism). Furthermore, that it is universally valid and 'reasonable' to pursue the moral 'good' of global peace. Thus, regardless of cultural or religious context, it is possible to construct a system of ethical principles that we can all share. Indeed, we affirm the fact that respect for human dignity is at the heart of every International and European legal Instrument upholding fundamental rights and is the foundation of every European constitution.

Respect for Human Dignity in the field of Biomedical research requires universal acceptance of the principle that Science must serve Humanity rather than Humanity serving Science. There is a particular need to protect vulnerable, handicapped, or unborn members of the Human Family. Human life, in whatever form, whatever its appearance or capacity, has inherent and indisputable dignity. Basic biological principles irrefutably show that from the moment of conception or creation the embryo inside or outside the womb is a unique human being with a unique genetic code. Even the creation of twins during the first days of life does not deny the individual character of these new human beings. The period of gestation of the Embryo requires no fundamental alterations or changes to the genetic pattern established at fertilisation. This fact alone seriously undermines the assertion that the embryo is merely a "potential human being" or the attempted distinction between "human beings" and "human persons".

On research on human embryos and stem cells

The creation of human embryos for research purposes, the production of hybrids or chimeras and any commercial exploitation of human embryos must be forbidden.

To allow research that involves the destruction of human embryos, and therefore research on human embryonic stem cells, would undermine the foundations of democratic societies, not least because it represents a form of instrumentalisation of some human beings for the sake of other human beings. This kind of research is therefore against human dignity and fundamental human rights and must be outlawed by civilised societies. Experimentation on the human embryo must only be permitted in individual cases where the aim is to protect the life and health of a specific embryo. Biomedical solutions in the field of human stem cell research must only be permitted with techniques using adult stem cells and the re-programming adult cells, more efficient than techniques using embryonic stem cells.

On human genetic testing and interventions

Any intentional pursuit of research activity intended to modify the genetic heritage of human beings which could make such changes hereditary must be forbidden.

Pre- and post-natal genetic testing should only be permitted if it is demonstrated there is a reasonable proportionality between the risks involved for the embryo by the sampling technique and any the potential therapeutic benefits. Professional genetic counselling must always be provided. Patients and their families are entitled to professional, humane, and life-protecting guidance that supports them in their decision-making. Eugenic pressure on parents not to accept a child with a handicap should be outlawed.

On human cloning

When human dignity is at stake in a civilised society, the ends can never justify the means.

Human cloning, regardless of its purpose and method, is ethically unacceptable and should be legally prohibited. Every clone created necessarily involves a violation of fundamental human rights and the human dignity that society must protect. We wholeheartedly commend the existing European and International agreements banning human cloning that have recognised the dangers of eugenics that we now face and urge European citizens of good will to stand together with us for the sake of future generations.

PROPOSED EU HUMAN TISSUES DIRECTIVE PUBLIC HEARING 29/01/03

Evidence Statement on behalf of CARE for Europe by David Fieldsend, Office Manager, Brussels

BACKGROUND

Ladies and Gentlemen: Good afternoon. I represent CARE (Christian Action Research & Education) a registered charity and ethical campaigning association supported by 100,000 individual Christians and churches of all denominations, the greatest concentration of these being in the United Kingdom. Our stance on contemporary bioethical issues is summarised in the Declaration on Human Genetics and other New Technologies in Medicine appended to this Statement.

We support the ambition of the European Union to introduce regulation in this sensitive area and are appreciative of the many benefits that flow from the availability Of donated human tissues and cells. We are satisfied that the proposed quality controls to protect the health and safety of the recipients of donated material are likely to be both ethical and effective. However, we have a number of concerns in relation to the proposed regime governing the interests of donors.

ETHICAL ISSUES

These issues are dealt with in Chapter III entitled 'Donor Selection and Evaluation' which will therefore be the focus of attention in this Statement.

To put the underlying ethical dilemma related to this process at its starkest we are dealing here with the 'cannibalisation' of one human individual to provide 'spare parts' which will improve the life chances, or even be essential to the survival of another human individual or individuals.

The EGE report felt that the only ethical justification there could be for this process was that of a '*voluntary act of solidarity*' (para 7 of Explanatory Memorandum). We agree with that concept and consider that it is only fulfilled when the following **six** criteria are respected with regard to the position of the donor:-

- 1. The donation is basically an act of altruism and not primarily motivated by financial gain. AND The 'voluntary' nature of the donation is not undermined by the offer of a disproportionate financial inducement such that those in financially vulnerable circumstances will feel strong economic pressure to donate.**

This also affects the position of the recipient. Where 'donation' is elicited by excess economic pressure there will be a temptation for 'donors' not to make a full and frank disclosure of their medical history in order to gain the financial inducement. Adverse public health consequences inevitably follow.

- 2. This 'altruism' on the part of the donor is not compromised by the possibility of donated material later becoming a basis for commercial gain by others.(1)**

Unfortunately the high sounding language of Recitals 12 and 13 is not borne out in the proposed legislation at Articles 12 and 13. The mere 'take fully into account the principles of' in relation to the Convention on Human Rights and Biomedicine is too weak (2) and the 'shall encourage' wording in Article 12 is not an effective requirement at all (3). Only a binding legislative requirement can prevent high standards in this area being undermined by the 'lowest common denominator' Member State provision becoming effectively adopted through litigation at the European Court of Justice where single market considerations will take priority over unenforceable statements of principle.

- 3. The donor's altruism is informed by full disclosure to them of the risks and benefits of the necessary procedures for procuring the material to be donated and transferring it to the recipient/s.**

The information requirements at Annex III are the bare minimum and do not really form a satisfactory basis for Europe-wide safeguards. Something like the code for 'Advance Directives' contained in the recently considered United Kingdom Mental Incapacity Bill would be more effective.

- 4. The 'voluntary' nature of the donation is not undermined by the potential donor being in an emotionally, psychologically or otherwise**

vulnerable state. eg. elderly, handicapped, couples seeking fertility treatment etc.

An age bar of 60 years should be considered to prevent pressure on elderly individuals to consent to an Advance Directive or tissue donation.

- 5. The ‘voluntary’ nature of donation is not undermined by authorising the use of material from pre-birth human individuals who are not capable of granting consent in any meaningful sense.**

Article 3/c states that the term ‘donor’ for the purposes of this Directive includes ‘non-natus’ sources of human cells or tissue. Such sources could not possibly comply with the principle of voluntary solidarity.

- 6. The ‘altruistic’ nature of the donation is safeguarded by the identity of both donor and recipient being mutually anonymous – with the exception of gamete donation for the reasons outlined below.**

We believe that it is right that an exception to the general rule of donor anonymity should be made in the case of the donation of gametes (sperm and ova) for artificial reproduction. In a number of Member States adopted children now have the right to discover the identity of their biological parents once they reach maturity. It is considered to be such an indispensable part of the knowledge of ‘who they are’ that it should not be denied to them. Studies have backed up the need for this by documenting adverse psychological consequences from the denial of this right. We do not consider that there is any sound argument for not extending this right to children conceived by artificial reproduction methods. Concerns that have been expressed about the possible adverse effect on the level of donations of the removal of donor anonymity have not been born out in practice in those jurisdictions where the right of artificially conceived children to know the identity of their biological parents has been granted. (4)

Where the donor is deceased or incapacitated we would expect these same criteria to be safeguarded in relation to responsible next of kin on the basis of their intimate knowledge of the donor’s intentions and outlook before they became incapacitated. However, we do not accept that there can be responsible next of kin in relation to embryos/foetuses who have not had the chance to communicate their wishes/intentions. We would also support an extension of these donor protection requirements to tissues taken for research purposes.

CONCLUSIONS

The Directive in its present form is not even handed as between the interests of donors and the interests of recipients of human tissues. Binding legislation is proposed to protect the interests of recipients by way of quality control of the testing, processing and storage of donated materials. However, the promotion of ethical standards for the donation process to implement the high sounding principles contained in the Recitals – specifically that donation should be purely voluntary, based on well informed consent and linked to the reassurance for the donor that donated materials will not subsequently be used as a vehicle for commercial gain – is left entirely to the

discretion of Member States' who are merely 'encouraged' to bear these principles in mind when forming their own legislation.

We strongly advocate a correction of this imbalance by making the interests of both parties the subject of binding community legislation. Not forgetting that these interests are, in any case, related as quality control will be compromised if and inappropriate level of financial inducements is offered to secure 'donations'.

SUPPORTING INFORMATION

References

- (1) See 'Moore v Regents of the University of California (in *Legislating for the New Predictive Genetics*, Galton and O'Donovan, Human Reproduction and Genetic Ethics, vol.6, no.2, 2000) where it was ruled that '*failure to inform a patient that a cell line from his spleen had been developed into a pharmaceutical product and patented, was a breach of fiduciary duty affecting the patient's consent, or alternatively that there had been no consent.*'
- (2) The phrase '*taking into account the principles of*' is a meaningless expression in legal terms. In **Ishak v Thowfeek** ([1968] 1 WLR 1718, PC) before the United Kingdom Privy Council it was held that one could take a principle into account and then promptly ignore it – but it had still been technically taken into account for legal purposes.
- (3) If the Directive fails to introduce binding Community legislation on this matter it is likely, on the basis of precedent, to be ultimately decided by the European Court of Justice in the context of intra-Community trade. (see Advocate General Van Gerven in Case C-159/90 SPUC v Grogan [1991] ECR 53 at paragraph 31.)

The EGE report refers to '*the need to regulate the conditions under which human tissues circulate within the European market*'. There is a single market. That market will not indefinitely tolerate the distortion generated by differential national procurement regimes. This particularly becomes the case if there is (as seems likely without community regulation) a widening divergence of treatment of 'commercial' considerations. Will donors in Member States sticking to a strict interpretation of voluntarism (or the Member State authorities acting on their behalf) be able to be confident that their donation will not become a means of commercial gain further down the line in a different Member State with a more liberal interpretation? Wouldn't any export prohibition on this basis be seen as a barrier to trade? When importation of material from third countries is concerned there is supposed to be monitoring in place to ensure that procurement methods in that third country are up to European standards – but whose European standards? Likely those of the lowest common denominator, ie, the Member State with the most liberal interpretation of these provisions.

(4) In Sweden the numbers of gamete donors dropped back following the introduction of legislation removing donor anonymity BUT they then began to pick up again and that trend has gradually reversed. *'Evidence from Sweden and New Zealand indicates that not only can reports of a decline be exaggerated, but it is also possible for service providers to maintain viable DI services using only identifiable donors'* (*Sharing Genetic Origins Information in Third Party Assisted Conception: A Case for Victorian Family Values?* Blyth, Children and Society, vol. 14, no. 1, 2000). Similar legislation has also been passed in Austria and Victoria (Australia). In the latter case the legislation also allows the donor to obtain non-identifying information about the offspring.



© CARE (Christian Action Research and Education) for Europe AISBL 2002
57 rue Archimède, B-1000 Brussels, Belgium.
Tel: +32 2 732 1147. Fax: +32 2 732 1228. E-mail: info@careforeurope.org

This paper represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.