



HORIZON 2020 5 REASONS WHY RESEARCH WHICH DEPENDS ON THE DESTRUCTION OF HUMAN EMBRYOS SHOULD NOT BE FUNDED

PUBLIC CONSULTATION

Communication from the Commission regarding Horizon 2020 Programme

Submission from CARE for Europe

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0.0 BACKGROUND

0.1 CARE (Christian Action Research & Education) is a registered charity and ethical campaigning association supported by some 60,000 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 as Annexe I.

0.2 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.

0.3 We support the ambition of the European Union to become 'the most advanced knowledge-based economy in the world' and recognise that market share in the face of globalised economic competition can only be maintained if European research spending rises so as to become closer to the proportion of GDP devoted by other major economic powers such as the USA and Japan.

0.4 However, the European Union, as the Treaty of Lisbon makes clear, is a Union of values. Decisions on research funding should not be made in an ethical vacuum but should respect Europe's fundamental values as spelt out in documents like the Charter of Fundamental Rights.

0.5 CARE therefore welcomes the inclusion in the Commission's proposed Research Framework Programme document for Horizon 2020¹ at Article 16 of a section entitled 'ethical principles' which includes a list of unethical activities which should not be financed. However, it is our contention in the light of the reasons given later in this submission that this list is incomplete and there should be a further addition to the list of research not to be funded of research which depends on the destruction of human embryos.

1.0 NON-COMPLEMENTARITY WITH NATIONAL RESEARCH EFFORTS

1.1 The Treaties stipulate at Article 180 TFEU that in order to achieve the objective of strengthening research activity Community activities shall be carried out by the EU '*complementing the activities carried out in the Member States*'. However, the various national jurisdictions of the EU have a range of legal provisions in relation to research activity: which depends on the destruction of human embryos.

1.2 Countries such as Austria, Lithuania, Slovakia and Poland prohibit all forms of human embryonic stem cell research in specific legislation. In addition countries such as Malta and Ireland do not have specific legislation but have a national constitutional position which protects early human life.

1.3 There are then countries which will permit research on pre-existing embryonic stem cell lines (ie. those which had already been 'harvested' – whether in the host country or elsewhere – before the legislation came into force). Germany and Italy have such a position

¹ COM (2011) 809

1.4 Then there are the Member States which allow the destruction of so-called ‘supernumerary’ embryos left over after IVF (medically assisted reproduction), these include the Czech Republic, Finland, France, Greece, Latvia, Portugal, Spain, Greece, Denmark and the Netherlands), but do not permit the creation of embryos specifically for research purposes, whether by so-called ‘therapeutic cloning’ or otherwise, either by specific law or because they have ratified the Oviedo Convention¹ which prohibits the deliberate creation of human embryos for research purposes..

1.5 At the final extreme are just three Member States (only the United Kingdom, Belgium and Sweden) which permit all types of destructive embryo research including so-called ‘therapeutic cloning’.

1.6 In these circumstances the requirement in the Treaties referred to above that Community activities shall be carried out by the EU ‘*complementing the activities carried out in the Member States*’ is surely not being met. How can one complement a non-existent (because illegal) activity? European funding should surely be reserved for activities where there is a clear European ethical consensus and at the very least the activity concerned is not illegal in more than one Member States.

2.0 INEQUITY IN RELATION TO MEMBER STATE DIVERSITY

2.1 As outlined in the section above, there is currently a patchwork quilt of legislative approaches in relation to research which depends on the destruction of human embryos. Some Member States ban it outright – whether by constitutional provision confirmed by popular referendum or by statute law; others allow it under limited specified circumstances and in a very small minority of Member States it is permitted seemingly without limits.

2.2 To allow a continuation of the current situation in which EU research funding is selectively available for human embryo research just in certain countries only (as it is illegal elsewhere) is surely an affront to the basic principles of solidarity. As mentioned above, the Treaties stipulate that in order to achieve the objective of strengthening research activity Community activities shall be carried out by the EU ‘*complementing the activities carried out in the Member States*’. To complement the activities only of certain selected Member States despite the fact that all Member States had contributed to the funds used is surely a case of inequitable treatment and a breach of the principle of solidarity. Moreover to apply European funding from the common purse to which all have contributed to activities considered not just illegal by certain Member States, but a criminal offence rendering citizens liable to prosecution wherever in the world the offence is committed, is to demean the ethical position of those Member States who do not permit such research.

2.3 The only way to allow Member States to maintain their cultural and ethical diversity on this subject is to exclude research activities which depend on the destruction of human embryos from the scope of common EU funding under the Horizon 2020 Research Framework Programme proposals and leave the funding of such activities to the national budgets of Member States where such activities are permitted.

2.4 The European Parliament's adopted 2005 resolution² clearly points to this as a way forward which will not hamper those countries wishing to press ahead with ethically controversial research – who will surely not be hampered by loss of the small amount of European funding concerned (€22M so far in the Seventh Framework Programme, of which €15.5M has been devoted not to research with the prospect of human therapeutic application, but to researching alternative product testing methods to reduce the use of animals in experiments) - whilst respecting the cultural norms of those Member States who find this practice abhorrent by '*applying the subsidiarity principle so that Member States in which this kind of research is legal fund it from their national budgets*'³.

3.0 ETHICAL PERSPECTIVES

3.1 The EU Charter of Fundamental Rights states at Article 1 that '*human dignity is inviolable. It must be respected and protected.*' And at Article 2 that '*Everyone has the right to life.*'

3.2 Unfortunately there has been no European consensus as to how to apply these resounding phrases when it comes to what may or may not be permissible so far as early human life is concerned. Although biologically it is incontrovertible that a unique new human life (with its own separate DNA signature) begins at conception with the fusion of sperm and ovum (whether by natural or medically assisted reproduction), some jurisdictions argue for the full protection and rights accorded to an individual human being to be postponed to some later stage in the development of the embryo.

3.3 However, whatever else the early human embryo may be considered to be, it is certainly something of the *genus humanae* and so should surely be accorded some degree of respect and differentiation of treatment in comparison with, say, inanimate objects or animal subjects for experimentation.

3.4 The Council of Europe Convention on Human Rights and Biomedicine⁴ states at Article 2 that '*The interests and welfare of the human being shall prevail over the sole interest of society or science*' and at Article 18 that '*1. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo. 2. The creation of human embryos for research purposes is prohibited.*'

3.5 Although there may be various interpretations of what ‘adequate protection’ amounts to, it is surely stretching language to an unacceptable degree to assert that killing is included in ‘adequate protection’ – and yet that is what is involved in the obtaining of stem cell lines in order to undertake embryonic stem cell research. Technology does not presently permit the obtaining (harvesting) of embryonic stem cells without the destruction of the embryo from which these cells are extracted.

3.6 Also, in the recent ruling of the European Court of Justice on the patentability of the results of embryonic stem cell research⁵, of which more in the next section, the Court’s reasoning for upholding the ban on patentability introduced by the directive on the patenting of biotechnological inventions⁶ is firmly rooted in the concept of human dignity, particularly as applied in the Charter of Fundamental Rights to the non-commercialisation of the human body or parts thereof, ‘*the preamble to the Directive states that although it seeks to promote investment in the field of biotechnology, use of biological material originating from humans must be consistent with regard for fundamental rights and, in particular, the dignity of the person. Recital 16 in the preamble of the Directive, in particular, emphasises that ‘patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person’.Additional security is offered by Article 6 of the Directive, which lists as contrary to ordre publique or morality, and therefore excluded from patentability, processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes. Recital 38 in the preamble to the Directive states that the list is not exhaustive and that all processes the use of which offends against human dignity are also excluded from patentability (see Netherlands v Parliament and Council, paragraph 71 and 76)..... The context and aim of the Directive thus show that the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected.*’ (from articles 32 to 34)

4.0 NON-PATENTABILITY OF THE RESULTS OF RESEARCH

4.1 The recent ruling of the European Court of Justice referred to above, has highlighted the provisions contained in the 1998 Directive on the patenting of biotechnological inventions⁷ which clearly rule out the awarding of patents anywhere in the EU to processes which depend on the destruction of human embryos, including through the use of embryonic stem cells. ‘*Article 6(2)(c) of Directive 98/44 excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos..... Any human ovum after fertilisation constitutes a ‘human embryo’.*⁸

4.2 The current Seventh Framework Programme (and previous Framework Programmes) stresses the importance of safeguarding intellectual property rights⁹ and expects that researches should seek patents for their results. It is therefore illogical to include in the scope of the new Horizon 2020 Programme research activity the results of which have been so clearly ruled not to be patentable.

5.0 (LACK OF) NEED FOR SUCH RESEARCH

5.1 We would affirm from the analysis above that any research which necessitates the destruction of human embryos, for whatever purpose those embryos were originally created, is incompatible with the Treaty provisions on complementarity; inequitable in the distribution of community funds as between Member States; unethical according to international norms; and any results obtained from it unpatentable, . However, we are aware that a strong, sometimes emotive, case is made in some quarters that in spite of this there is an overriding human need for this kind of research to be permitted because it holds out the hope of cures for various debilitating human diseases and it would be inhumane to deny the sufferers of these diseases the hope of a cure.

5.2 Sadly, this ‘hope’ is largely an illusion. As the recent editorial in the *New Scientist* makes clear¹⁰, the breakthroughs and the research activities providing the most promising hope of near term therapeutic use are coming from stem cells extracted from post-born humans or foetal material which is discarded as not needed by the developing embryo/foetus (eg. umbilical cord and placenta). The NIH (US National Institutes of Health website¹¹ records 3,744 clinical trials using such cells (figures for adult stem cells and umbilical cord combined). These therapies are increasingly well established and pose no ethical problems. Sadly this has the consequence that there is little media interest in them. This contrasts with the extensive press coverage¹² for the one and only European trial involving the use of embryonic stem cells after a decade of hype. This has only recently commenced and there are as yet no results for this trial and no published scientific papers in peer-reviewed journals, nor are any expected before 2013 at the earliest.

5.3 All the above points to the need to give the highest priority to somatic (adult) stem cell research if cures for diseases within the foreseeable future are what is desired.

6.0 CONCLUSIONS & RECOMMENDATIONS

6.1 CARE heartily endorses the ambition for Europe to become ‘the most advanced knowledge-based economy in the world’. We agree with the European Commission that a substantial level of funding for research activities is an essential component of the strategy necessary to achieve this goal.

6.2 However, we strongly assert that decisions on research funding cannot be taken in an ethical vacuum. In particular, as with all EU activities, they need to

respect the framework of common European values as set out in documents like the EU Charter of Fundamental Rights and the Council of Europe's various Conventions of which the Convention on Human Rights and Biomedicine is the most pertinent in this case.

6.3 The ethical controversy surrounding the procurement and use of embryonic stem cells is well known with many Member States prohibiting the procurement and/or experimental use of such cells in their national legislation subject to criminal penalty. In these circumstances we would argue that (i) the principle of complementarity of community funding and national research effort enshrined in the Treaties is breached if research which depends on the destruction of human embryos is funded under a Framework Programme; (ii) similarly there is a breach of the principle of solidarity and equitable treatment as between Member States if community funding to which all have contributed is made available for activities from which some are barred from benefitting; (iii) the funding of such research breaches fundamental international bioethical norms; (iv) such research is unpatentable in Europe as confirmed by the recent ECJ ruling and therefore cannot conform to the provision in all previous Framework Programmes that the results of funded research should be the subject of an early patent application by the researcher; and (v) that such research is unnecessary because work using somatic stem cells taken from human beings after birth or from the umbilical cord and placenta are proving much more promising in offering the realistic prospect of effective therapies for the treatment of human diseases and disorders in the near term.

6.4 CARE therefore respectfully recommends that the list of research activities excluded from funding on ethical grounds at Article 5(3) in the draft Horizon 2020 proposal should be extended to include all research activity which depends on destruction of human embryos. This will principally, but not exclusively, rule out the use of human embryonic stem cells.

¹ Convention on Human Rights and Biomedicine, Council of Europe, European Treaty Series No. 164

² P6_TA-PROV(2005)0074 of 10th March 2005

³ P6_TA-PROV(2005)0074 of 10th March 2005

⁴ Convention on Human Rights and Biomedicine, Council of Europe, European Treaty Series No. 164

⁵ Judgment on ECJ Case No. C-34/10, Oliver Bruestle v. Greenpeace e.V of 18th October 2011

⁶ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

⁷ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

⁸ Judgment on ECJ Case No. C-34/10, Oliver Bruestle v. Greenpeace e.V of 18th October 2011, Article 53 (3) and (1)

⁹ Decision No 1982/2006 of 18th December 2006, OJ L 412/1-41, Annex I pp.8-9

¹⁰ <http://www.newscientist.com/article/mg21228343.200>

¹¹ <http://clinicaltrials.gov/ct2/search>

¹² <http://www.bbc.co.uk/news/health-15017664>

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 wholehearted 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.