Modification of the human genome: Human rights challenges raised by scientific and technical developments

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Abstract: The genesis of Human Rights Conventions brings together the messy world of politics and the reflective activities of academia to co-create a new normative order. In their operation they can play a conservative role, using the textual formulations of the past to judge the present and limit imagined futures. They may also operate as living documents, supported by institutional activity and nurturing a methodology for scrutiny and deliberation in the face of new challenges. Such an approach aims to preserve the spirit of the value tradition against those who would dilute it, while avoiding its fossilisation into the letter of past formulations in ways that undermine social justice by blocking the application of science and philosophy for the common good. The question of human genome modification that is now before us invites consideration of how the ban in Article 13 of the Oviedo Convention should be understood, taking into account the preamble and with regard to Articles 15 and 28. It is argued that the genealogy of Article 13 shows that its apparent simplicity obscures the fact that the Convention's creators were acutely aware of the contingencies that made their drafting task difficult. Further, developments in human rights law suggest the need for a clearer exposition of the meaning and basis of the prohibition of germline modifications. To revisit the terms of Article 13 would be true to the values underpinning the Convention, and there should be a broad an informed public debate about the best way to articulate them in the face of current scientific developments.

Introduction

In its recommendation of 12 October 2017, the Parliamentary Assembly of the Council of Europe has asserted that 'Deliberate germline editing in human beings would cross a line viewed as ethically inviolable.'[1] The Recommendation cites in support of this position the text of Article 13 of the Oviedo Convention, whose twentieth anniversary we are privileged to be celebrating at this conference. Article 13 states that

> An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

As was noted by Rogers and de Bousingen in their book *Bioethics in Europe* this opposition to germline interventions 'echoes a wide international consensus'.[2] They summarised the concerns in the following terms

> Somatic cell therapy – say, administering a spray of genetic material into the respiratory system of a patient with an inherited lung disorder – would benefit that patient alone. However, modifications to germ cells would be inherited by the patient's descendants. Doctors would be interfering with future, unconsenting generations.[3]

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[1] Recommendation 2115 (2017) Provisional version 'The use of new genetic technologies in human beings' http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-EN.asp?fileid=24228&lang=en

[2] A. Rogers & D.D. de Bousingen, *Bioethics in Europe* (Council of Europe Press 1995) p 93.

[3] Ibid pp 92-3.

Scientific and technical developments

At the time that the Convention was drafted, the future of gene therapies was uncertain.[4] Twenty years later, somatic modification of the human genome has already occurred, for example to save the lives of children at Great Ormond Street Hospital in London.[5] The gene-edited cells were used to target cancer and were subsequently killed off by the patients' immune systems. Thus, no edited cells were inherited. This clearly acceptable within the scope of the Oviedo Convention.

Imagine, though that a patient seeks a gene therapy that will operate to modify their genome to correct a code malfunction that would otherwise end their life. In this case, the alteration will be transmitted to their children. This is, broadly the case of mitochondrial replacement therapies. This is best understood as a germ-line intervention, as we concluded at the Nuffield Council on Bioethics.[6] Some argue it is not a modification of the human genome because no human genes are changed, just transplanted. Or perhaps the human genome means only the nuclear genome? In the UK Parliament, the responsible health minister, Jane Ellison addressed the issue in the following terms when introducing the legislative provisions that have permitted the licensing of case-by-case use of mitochondrial replacement therapies:

> … the removal of the faulty mitochondria will be passed on to the next generation. That is exactly what we have been describing, but I do not accept my hon. Friend's description of it as genetic modification. It has to be said that there is no universally agreed definition of genetic modification, but for the purposes of these regulations, we have used a working definition and it involves not altering the nuclear DNA.[7]

As well as raising important ethical issues, these scientific developments show how the concept of 'the human genome' is not easy to define. How should we apply the terms of the Oviedo Convention to interventions where the modification is to RNA rather than DNA, as in a study published during this celebratory conference?[8] Given the knowledge that is emerging of epigenetics, there are many things that impact on the expression of genes. Is such external manipulation a 'modification'? Resolution of these ambiguities may be

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[4] For a review of the current scientific position, ethical and regulatory challenges, see G. Cossu, M. Birchall, T. Brown, P. De Coppi, E. Culme-Seymour, S. Gibbon, J. Hitchcock, C. Mason, J. Montgomery, S. Morris, F. Muntoni, D. Napier, N. Owji, A. Prasad, J. Round, P. Saprai, J. Stilgoe, A. Thrasher, J. Wilson *Lancet Commission: Stem cells and regenerative medicine* (Online 4 October 2017) https://doi.org/10.1016/S0140-6736(17)31366-1.

[5] M. Le Page, 'Gene editing has saved the lives of two children with leukaemia' New Scientist 15 January 2017, https://www.newscientist.com/article/2119252-gene-editing-has-saved-the-lives-of-two-children-with-leukaemia/. Q. Qasim et al, 'Molecular remission of infant B-ALL after infusion of universal TALEN gene-edited CAR T cells' Sci. Transl. Med. 9, eaaj2013 (2017), http://stm.sciencemag.org/content/9/374/eaaj2013.full.

[6] Nuffield Council on Bioethics, *Novel techniques for the prevention of mitochondrial DNA disorders* (2012) paras 3.24-3.31.

[7] House of Commons debate 3 February 2015, https://hansard.parliament.uk/Commons/2015-02-03/debates/15020348000001/HumanFertilisationAndEmbryology

[8] D. B. T. Cox, J. S. Gootenberg, O. O. Abudayyeh, B. Franklin, M. J. Kellner, J. Joung, F. Zhang 'RNA editing with CRISPR-Cas13' *Science* Published Online 25 Oct 2017, DOI: 10.1126/science.aaq0180.

required if legal action is brought around the use of Article 13 to deny patients access to therapies. While the Oviedo Convention does not provide for rights of individual petition, it is already being used in European human rights jurisprudence.[9] A consideration of the human rights challenges raised by scientific and technical developments related to the modification of the human genome therefore needs to consider the precise meaning and impact of the prohibition of germ-line interventions.

The need for an 'affirmative genealogy

In this paper, I want to outline an 'affirmative genealogy' of Article 13, building on the model that Hans Joas has developed in his book on human rights, *The Sacredness of the Person*.[10] An affirmative genealogy aims to provide an account of the genesis of ideals that reminds us of its historical contingency, but does so without 'negating our commitment' to the values that it enshrines, and in a way that 'opens our minds to the way in which historically embodied meaning calls upon us.'[11] It is not therefore about denying or resisting the process of 'value generalization'[12] that led to the drafting of the Oviedo Convention, but 'affirming the way in which historically formed ideals call upon us… with a sense of subjective self-evidence and with affective intensity.'[13] We need to understand the genealogy of the Convention precisely because it matter to us that we remain true to its spirit.

This is fully in accordance with the European tradition of understanding human rights conventions as 'living documents'. It will help us avoid the agonies that Ronald Dworkin has documented in relation to the USA in his book *Life's Dominion*; showing how the sterility of originalist fundamentalism around the meaning of constitutional documents has horribly distorted the bioethical debates on abortion. [14] In the European tradition, the interpretation of human rights conventions is sensitive to the evolution of norms, the degree of consensus across states (recognising that a margin of appreciation that is appropriate where such a consensus does not exist), and also to the development of scientific knowledge. The Recommendation of 12 October recognised this, in that it recommends a process of debate and notes that there is an explicit mechanism for amendment of the Convention (should such debate conclude that it is appropriate). Of course, this is implicitly to accept that the line related to genome-editing that can be inherited may not in fact be 'inviolable' at all.

I shall show in the next section how the particular genealogy of Article 13 demonstrates reasons to be concerned about inappropriate absolutism and unintended side effects. Before turning to that, however, it is important to make some general points about the genealogies of human rights norms. The first is that all conventions have specific histories in

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[9] European Court of Human Rights, Research Report, *Bioethics and the case-law of the Court* (2016) available at http://www.echr.coe.int/Documents/Research_report_bioethics_ENG.pdf .

[10] H. Joas, *The Sacredness of the Person: A new genealogy of human rights* (2013 Georgetown UP) chapter 4.

[11] Joas p 127.

[12] Joas Chapter 6.

[13] Joas p 127.

[14] R. Dworkin, *Life's Dominion* (Random House 1993).

which we see coming together strands of expert reflection, political deliberation, and (at least in in recent years) debates amongst interested publics (which may engage quite distinct constituencies, hence the plural noun).

Mary Ann Glendon's account of the genesis of the Universal Declaration of Human Rights draws out the twin strands of its origins.[15] The primary strand concerns the deeply political processes of drafting and negotiation of the texts, through many months of discussion and through many layers of the United Nations machinery. Alongside this, she stresses a second strand of philosophical reflection, co-ordinated by UNESCO through its Committee on the Theoretical Bases of Human Rights.[16] This involved serious philosophical reflection by the members of the Committee, but also canvassed the views of leading scholars and political leaders through a questionnaire.[17] While the text of the Declaration is the most obvious legacy, Glendon suggests that its achievement lay less in the precise terms of its wording than in the ability of 'a group of men and women who learned to cooperate effectively despite political differences, cultural barriers, and personal rivalries…. To bring forth from the ashes of unspeakable wrongs a new era in the history of rights.'[18] It was not that the text was perfect, as was widely acknowledged in the General Assembly debate on its adoption,[19] but that it was 'an important milestone on a long and difficult journey… to deeper understanding in the future.'[20]

We do not possess such a detailed and richly personal account of the genesis of the Oviedo Convention, but we can see that it shares some of these features. The French title of the book commissioned by the Council of Europe from Arthur Rogers and Denis Durand de Bousingen better captures the flavour of the project that came to fruition in Oviedo on April 4th 1997 than the English version. In English it sounds as though there is some alien enterprise of bioethics that arrived on the continent as part of its travels. *Bioethics in Europe* could be part of a series, in which the heroic protagonist 'Bioethics' travels the world in search of adventures. There would be other volumes covering Bioethics in the USA, Asia, Australia and wherever else she went. In French, however, the volume is entitled *Une Bioethique pour L'Europe* – making the work a chronicle of the search for a ('une') distinctively European expression of bioethical principles that would embody its moral values and serve its peoples ('pour' – 'for' Europe, not merely 'of' or 'in').

The book shows how various European states developed national committees to engage with bioethical issues, beginning with France in 1983. The European Commission established its first advisory group in 1991. At the Council of Europe, both the Parliamentary Assembly (PACE) and Council of Ministers have long been active in bioethics and in 1992 the Ad hoc Committee of Experts on Bioethics became the Council of Europe Steering Committee on Bioethics (CDBI) and was charged with developing the Convention on Human Rights and

[15] Mary Ann Glendon, *A World Made New: Eleanor Roosevelt and the Universal Declaration of Human Rights* (Random House, New York, 2001).
[16] Ibid ch 5.
[17] Jacques Maritain, *Human Rights: Comments and Interpretations* (London, Wingate, 1949).
[18] Glendon, p xxi.
[19] Ibid pp 163-171.
[20] Ibid p 231.

Biomedicine.[21] Thus, the drafting of the convention was partly a matter for the experts. Nevertheless, the PACE maintained a degree of democratic scrutiny and issued an opinion on the Draft Convention that recommended a significantly different wording for what became Article 13 (which was at that stage Article 16 of the Draft Convention, see further below).[22] Finally, the Convention took legal effect as a formal treaty between the member states. Thus, its authority is not merely legal. It has democratic and expert roots and draws its legitimacy from those foundations.

This is an example of what Joas describes as a process of 'value generalisation'.[23] Through social and political interactions a 'single legitimizing value pattern'[24] can be crystallised in which specific and separate 'value traditions may develop a more general, and mostly more abstract understanding of their content, without being entirely uprooted from the specific traditions and experiences that are the source of affective binding force for the actors involved.'[25] The problem facing us in interpreting Article 13 is precisely concerned with understanding the foundations of the 'affective binding force' of the values that lay behind its production.

One of the pathologies of bioethics, particularly apparent in its US manifestations, is its displacement of 'thick' discussion of deep values with 'thin' explorations of 'public reason'.[26] This draws on the insights of John Rawls into how principles of justice (as fairness) can delineate the common principles of public ethics, which he argues can be justified without reference to the 'thick' theories of morality that are adopted from within value traditions but require some degree of commitment to those traditions. 'Public reason' in this sense latches onto the formulations (whether in documents such as Oviedo or in quasi-canonical writings, such as the Beauchamp and Childress formulations of the 'four principles' of autonomy, non-maleficence, beneficence and justice). This invites technocrats, skilled in extracting the meanings of value statements to drive public bioethics.

In the context of germ cell science, John H Evans discusses this type of 'thin' argument in terms of the working out of the supposed shared principle of non-maleficence in terms of risks of harm or loss of control and their management. This became dominant through the early framing effects of enthusiastic scientist-entrepreneurs and especially the institutions in which they work. He suggests that both professional bioethics and this framing effect serves to privilege the avoidance of suffering and the value of knowledge discovery.[27] Further, it crowds out 'thick' debates about value. He argues that such arguments tend to be dismissed (citing 'religious' or 'intrinsic objections' such as violations of nature, commoditisation of life, 'playing God') as 'vague, simplistic or ill-conceived' as he quotes from an MIT Press

[21] Recommendation 1160 (1991).
[22] Opinion No 184 (1995).
[23] Joas chapter 6.
[24] T. Parsons, *Social Systems and the Evolution of Action Theory* (1977) p 308, quoted by Joas at p 179.
[25] Joas pp 180-1.
[26] J. H. Evans *The History and Future of Bioethics: A sociological view (*Oxford, OUP 2012).
[27] J. H. Evans '"Teaching Humanness" Claims in Synthetic Biology and Public Policy Bioethics' In: *Synthetic Biology and Morality: Artificial Life and the Bounds of Nature*, G.E. Kaebnick & T.H. Murray (eds) (Cambridge Mass, MIT Press 2013), 177-204, see especially 179-80.

book.[28] Alan Petersen has made similar points about the way in which the globalisation of bioethics has 'establish[ed] ways of marginalizing competitors such as the Catholic Church'.[29] An affirmative genealogy seeks to recover rather than to exclude the affective power of the values that are generalized into human rights documents and 'thin' theories offer too anaemic reasons to commit to their implementation.

We might think about the tasks of bioethics governance, of which the Oviedo Convention is part, in terms of three challenges: pluralism, relativism, and nihilism.[30] These distinctions can clearly be related to the models of co-existence, cosmopolitanism and constitutionalism that Sheila Jasanoff introduced in her presentation, although their function and the perspective from which they are drawn is slightly different. My purpose in drawing attention to them is to delineate the nature of the legitimation challenges that we need to address when constructing our 'affirmative genealogy'.

The context is clearly determined by the existence of moral pluralism. We are faced by respected, well-articulated, and enduring value traditions that find themselves grappling with difficult boundary issues. In the account that Joas provides of the emergence of human rights, the process of value generalisation secures the crystallization of fundamental values in a way that enables societies to hold together conflicting views in order to adapt to social change without compromising their foundational moral solidarity.

However, the fact of moral pluralism is not a reason for regarding all the asserted positions as equal. We need to guard against the challenge of relativism, which would deny us the basis for critique of different value traditions and suggest that there are no limits than can be justifiably set. Perhaps on the basis that they are objectively required of us, or at least command such widespread consensus that they can be treated as objective. Article 13 of the Oviedo Convention engages this issue. Does it serve to establish the boundary of acceptable moral pluralism? If so, to abandon it would be a betrayal of the values that were generalized and would constitute a collapse into a relativism that cannot hold developing science properly to account. Or is it better understood as a jurisdictional device that was used in 1997 to establish a boundary that could not be crossed without careful deliberation about its merits when the scientific prospects could be more clearly considered? I consider that it is better understood in the latter terms, as I have also suggested in relation to the UK's limitation of human embryo research to the emergence of the primitive streak.[31]

The reason for this relates to the third challenge that must be met, that of nihilism. The problem here is that if the establishment of bioethical principles is nothing more than mere

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[28] M. A. Bedau and Triant 'Social and ethical implications of creating artificial cells' in *The Ethics of Protocells: Moral and Social Implications of Creating Life in the Laboratory* M.A. Bedau and E.C. Parke (eds) Cambridge Mass, MIT Press 2009:31-48 at 35.

[29] A. Petersen, *The Politics of Bioethics* (Routledge 2011) 81.

[30] The first two of these were discussed briefly in J. Montgomery, 'Bioethics and a Governance Practice' Health *Care Anal* (2016) 24:3-23. https://doi.org/10.1007/s10728-015-0310-2

[31] See J. Montgomery, 'Introduction' to *Human Embryo Culture" Discussions concerning the statutory time limit for maintaining human embryos in culture in the light of some recent scientific developments* (Nuffield Council on Bioethics, August 2017, http://nuffieldbioethics.org/wp-content/uploads/Human-Embryo-Culture-web-FINAL.pdf) especially 4-7.

'fiat', an exercise of will that creates values out of nothing, then there is little to oblige those who were not part of their creation to regard them as binding. Ronald Dworkin argues that the fact that *Roe v Wade* changed abortion law through such an exercise of will, by a majority vote from an unelected Supreme Court, is one of the reasons why its legitimacy has never been universally accepted in the USA.[32] Sheila Jasanoff noted judicial anxiety about this from the US Supreme Court in the case of *Diamond v. Chakrabarty* (1980), quoting Burger CJ: "... *legislative or judicial fiat* as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides"[33] To counteract the challenge of nihilism, we need to be able to articulate the connection between the wording of the Convention and the values to that demand our commitment. It is not sufficient to point only to the fact that they were agreed.

A genealogical approach guards against the problem of nihilism by excavating the historical processes by which formulations were reached, so as to expose their contingency and alert us to the risk of giving undue authority to socio-politically constructed compromises. The 'affirmative' approach focuses the genealogical analysis on its roots in values. It demands that we take seriously the need for commitment to those values, so that pluralism is respected rather than marginalised. The attention to the process of generalisation, through which such affective commitments become shared helps us with the problem of relativism, because it recognises that there must be mutual recognition of common ground and a communal judgement that the values are sound.

A genealogy of Art 13

The genealogy of Article 13 undermines the claim that there is anything 'inviolable' about this particular line. The absolutist interpretation of the ethical position adopted in the Convention does not sit well with the discussion from which the text emerged. It obscures an expectation that it would quickly be reconsidered, which was manifest throughout the deliberations. Further, considerable effort was put into trying to find a way to craft exceptions in order to avoid excluding therapeutic uses that were regarded as acceptable and even desirable. The final version was a result of the political processes rather than the expert deliberation. It was characterised more by a desire to achieve simplicity and to express the Convention's provisions as deep principles than by carefully reasoned argument on the supposed inviolability of the line. In short, the drafters of Article 13 had persistent concerns over the risks of absolutism, unintended consequences, and the challenges of suitable terminology. We can reasonably infer that they would be surprised at the suggestion that there was a simple and inviolable moral rule against all germ-line interventions.

The worry about absolutism

Consideration of how to avoid an absolute prohibition of germ-line interventions is apparent from the travaux preparatoires. In its meeting of December 1992, the Working Party

[32] R. Dworkin, *Life's Dominion* (Random House 1993).
[33] *Diamond v. Chakrabarty* (1980) 447 U.S. 303, at 318, emphasis added.

considered two alternative proposals. One supported an absolute prohibition on 'interference with the germ cell line'. The other would have recognized some 'exceptional cases (where there is no conceivable alternative) in order to correct recognised abnormalities provided that it is carried out for the purpose of ending of alleviating severe human suffering and that strict standards of reliability and safety are observed.' If this alternative had been adopted, reliability and safety concerns were to have led to a requirement of prior approval from 'an independent body, preferably a national ethics committee'. It was proposed that developments 'should be closely monitored by the CDBI and the relevant national bodies' and the possibility of revising the article was to have been specifically mentioned in the Explanatory Report. Although the alternative version was not accepted, it was unanimously agreed at that meeting to state that there should be a review of the provision within a specified time (giving as an example five years after the entry into force of the Convention).[34]

The Steering Committee recognized the importance of periodic review generally, and in particular of Article 13. However, it resisted the suggestion of one delegation that 'given the current state of scientific knowledge' should be inserted because it would create too much uncertainty and it would be unclear who would make the judgment that science has 'made sufficient progress to render the provision no longer applicable.'[35] Both these concerns address problems of regulation, the need for clarity and accountability, rather than reflect a substantive certainty on the moral question.

These concerns persisted right up to the final stages of the Convention's birth. In Paragraph 112 of the draft explanatory report from the Steering Committee, referring to what was then Article 16, it was noted that the advisability of exceptions had been examined in the light of recent or expected scientific developments:

> 'However, it was felt that, at the present stage of scientific knowledge, it was impossible to know all the effects that these interventions might have on following generations. Owing to this uncertainty, it was decided to adopt the rule as it appears….'[36]

It was not the unacceptability of impact on future generations that was the issue, but its unpredictability (and therefore the impossibility of assessing the risks and potential benefits). The final version of the explanatory report does not contain this material. It thus obscures the genealogy of the germ-line prohibition, which was intrinsically connected to uncertainty and the limitations of contemporary scientific knowledge rather than to a moral principle about intergenerational effects.

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[34] CORED 14-16/12/92 (summarised in CDBI/INF (2000) 1 Provisional at pp 63-4)
[35] CDBI 6-9/07/93 (p 64)
[36] A. Rogers & D.D. de Bousingen, *Bioethics in Europe* (Council of Europe Press 1995) reproduces the draft explanatory report on pp 261-90, the quotation is found at p 285.

The worry about unintended consequences

Also in the genesis of Article 13 we can see nervousness about the potential inflexibility of a hard rule against modification and the possibility that its rigidity might outlaw important therapeutic options. The original rejection of 'any therapy on the human germinal line' in 1989 was replaced by an attempt to distinguish licit therapies which impacted on genes from those who raised fundamental concerns.[37] At the Steering Committee on Bioethics meeting in July 1993, concerns were raised by several delegations that the drafting might exclude some cancer treatments that had a side effect of interfering with the germ cell line. Their proposal to deal with this by addressing the intentions of the 'interferors' rather than the objective fact of interference was taken forward by the Working Party in January 1994. Their acceptance of the focus on the 'purpose' of the intervention was partly supported by the argument that 'for the time being' there would be oversight from ethics committees because the techniques were 'still at an experimental stage' and that the Article would also fall to be reviewed after a certain period of time.[38] Thus, the issues were assumed to be appropriate for governance rather than prohibition.

There was a persistent tension between a subjective approach based on intentions and the search for objective tests, based on categorising the activities involved or the proper scope of applications of techniques. Thus, the Parliamentary Assembly's Recommendation 934 (1982) on genetic engineering proposed a European agreement on what constituted 'legitimate application to human beings (including future generations)' based on 'a list of serious diseases which may properly, with the consent of the person concerned, be treated by gene therapy'.[39] Such a position assumes the acceptability of some applications that impact on offspring, but searches for clear and objective lines that can be established by regulators to constrain the enthusiasm of researchers. There is a balance to be maintained and the Recommendation notes that due recognition of rights at stake must 'not impede development of the therapeutic applications of genetic engineering (gene therapy), which holds great promise.'[40] When the Assembly came to issue its opinion on the draft bioethics convention in 1995, it proposed an amendment that focussed on the actual impact of the techniques, so that the good intentions would be insufficient and permissible only 'without any intervention in the germ-line'.[41] The search for a clear and objective distinction thus continued.

Concerns were also raised in the Parliamentary debates about the possibility that drafting would exclude well-established therapies. In 1995, the Danish delegation raised concerns that proposals to amend (what was then) Article 16, coming from the Committee on Science and Technology, would prohibit chemotherapy treatment for cancer.[42] The Rappporteur of the Committee on Legal Affairs and Human Rights proposed an amendment to Art 13 (as it

[37] See Recommendation 1100 (1989) on the use of human embryos and foetuses in scientific research, Appendix para 18, reproduced in A. Rogers & D.D. de Bousingen, *Bioethics in Europe* 311-19, the specific reference is at 318.
[38] CORED 24-27/01/94 (p 65)
[39] Para 7(a) & (c).
[40] Para 4(iii).
[41] Opinion 184 (1995) para 8(x).
[42] Mrs Arnold, 2 February 1995, reproduced in CBI-INF(2000) p 8.

had become by September 1996) that sought to permit radiotherapy for curative purposes, despite effects on defendants, by adopting the language of intention. It would have amended the text so that 'intervention in the human germ cell line shall be neither an aim nor an accepted secondary effect'. However, this was rejected on the advice of the steering committee because it failed to reflect the values on which the Convention was based.

> If we say that life-saving interventions that have the additional accepted medical side effect of impairing the ability to father or mother healthy children must not be carried out, we are doing something that the committee believes is unethical. It is also against the Hippocratic oath: we cannot forbid a doctor to heal a patient if he is aware of the method of achieving that end…. the wording is not useful. It is too restrictive and the amendment should be rejected.[43]

It is therefore clear, that concerns about excluding therapeutic interventions merely because they had an effect on the germline were apparent throughout the genesis of Article 13. Revisiting its impact in order to assess whether its consequences have unintentionally compromised patient care would be consistent with the values that lay behind the drafting.

Conceptual instabilities

A third reason for being cautious about interpreting the text narrowly and inflexibly becomes apparent when the terminological challenges that the drafters struggled with are considered. There are significant shifts in the language used through the drafting process that shed some light on what was understood to be at stake in the deliberations. These movements should not be given anachronistic significance, as if they somehow knew how scientific understanding would develop in the future. We should also recognise that the language of human rights conventions does not always use precise legal terms of art so much as metaphors, although given the legal status of the Oviedo Convention a proper understanding of the terms used is important.

The drafting process settled on the term 'human genome', a term that we have already seen is now recognised to be ambiguous. However, these ambiguities were not at the forefront of the drafters' minds and the term was not used initially. There has also been an interesting transition of metaphors that illustrates some important underlying questions. The initial draft of Article 13 referred to outlawed aims as relating to 'interference with the germ cell line'. The agreed version refers to the 'genome' but not germ cells and adopts 'intervention' in its title and 'modification' in its text. We are now discussing the 'editing' of the human genome. As Sheila Jasanoff's presentation showed, there is also the metaphor of 'engineering' that has been used in this area and was the term used by the Parliamentary Assembly in Recommendation 934 in 1982. These metaphors have subtly different meanings. Interference is a form of obstruction, it prevents a pre-existing purpose being fulfilled.[44] In interventions and modifications the actor supplies the purpose (although perhaps with less control than in engineering). An editor does something in between, they

[43] Mr Plattner, 26 September 1996, reproduced in CBI-INF(2000) p 38.
[44] On this, see the approach taken by Pope Benedict XVI in *Dignitas Personae*, discussed below.

improve or perfect the material on which they are working in order to enhance its meaning. These linguistic turns indicate different underlying attitudes to what is at stake.

In a parallel shift, the atomistic and mechanical component germ cell line has become the integrated entity of 'the human genome' with an ontological ring to it.[45] The 'human genome' is an obscure concept.[46] It is unclear whether it suggests that the drafters had in mind a sort of species genome, which was thought to be shared by all humans, Alternatively, it might refer to a category of human genomes; recognising that we all have a unique genome but asserting that it belongs in the category of human genomes that can be distinguished from those of other species. Thus, should we understand the drafting to direct the prohibition to the modification of a human person's genome? Or to the introduction into humans of non-human DNA?

In the 1982 position of the Parliamentary Assembly, the issue at stake was understood to concern 'Right to inherit a genetic inheritance that has not been artificially interfered with' (although this was not absolute and exceptions were recognised 'for example in the field of therapeutic applications').[47] The Assembly thought this right was implicit in Articles 2 (right to life) and 3 (right to human dignity (sic)) of the European Convention on Human Rights.[48] This seems to adopt an individualistic approach, protecting specific human beings from indignity. Yet, Committee discussions also examined the idea that 'human genes are the common heritage of mankind' but rejected that wording, although they 'accepted the inherent principle to the extent of its implication that in genetic manipulations performed on human beings it is imperative to preserve the human species and refrain from combinations with other species.'[49]

The tensions between these interpretations are likely to become significant if individual patients come to perceive the provisions of the Convention as denying them access to therapies that they would like to use. This may require us to consider whether the way in which the limitations on germ-line interventions were phrased in 1997 is consistent with the individual rights to benefit from scientific advance and to respect for personal privacy and autonomy. We need, therefore to consider how to interpret the Convention in the light of developments in European human rights law. As we have seen, the Parliamentary Assembly believed that the Oviedo Convention drew from the fundamental values enshrined in the European Convention on Human Rights and envisaged that the two documents should be read together.

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[45] CDBI-INFO(2000)1 Provisional pp 63-68 records the committee debates. ADDENDUM I CDBI/INF (2000)1 has the various draft texts. ADDENDUM II CDBI/INF (2000) 1 contains extracts from the parliamentary assembly debates. All are available from https://www.coe.int/en/web/bioethics/oviedo-convention.

[46] See Nuffield Council on Bioethics, *Genome Editing: an ethical review* (NCoB 2016) paras 1.4-1.8.

[47] R934(82) *Genetic Engineering* Art 7(b).

[48] R934(82) at Art 4(i). It should be noted that the summary of Article 3 as a right to human dignity is problematic, as that article is concerned with protection from 'inhuman and degrading treatment'

[49] CORED 14-16/12/92. See CDBI-INFO(2000)1 Provisional p 7.

Human Rights challenges to denial of access to germ-line therapies

We can now envisage that a human rights challenge might be brought to clarify the possible tension between the articles of the Convention and also with wider human rights law. This is not the place to make that argument fully, but I shall outline its shape to show why I think it is a serious matter. My main purpose in doing so is to use it as a springboard for assessing how we might re-examine the terms of the Oviedo Convention in the light of such human rights concerns, and in the light of the resolution of the European Parliament.

There is no right of individual petition under the Oviedo Convention, but there is value in considering how Article 13 might be considered in cases where an individual claims that they have been wrongly been denied access gene therapies in breach of their human rights. This possibility is not fanciful. We know that the Convention has been cited in cases before the European Court of Human Rights.[50] Working within the Oviedo Convention, a petitioner might claim that their Article 3 rights of equitable access to health care are breached in a way that discriminates against them because their genetic heritage is different to those who can be treated through somatic therapies (thus breaching Article 11 – Non-Discrimination). They would note also that the Universal Declaration on the Human Genome and Human Rights (1997) explicitly states in its Article 12 that the 'benefits from advances in biology, genetics and medicine, concerning the human genome shall be made available to all' that 'the applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals'. This is echoed in the Preamble to the Oviedo Convention.

Coming before the European Court of Human Rights, and therefore drawing on the European Convention on Human Rights, the claimant would argue that their rights to respect for private and family life under Article 8 entitle them to access gene therapies that modify the germline because it is arbitrary and discriminatory to deny them when other gene therapies are permitted. The Court has held that access to assisted reproductive technologies engages Article 8 rights to private life, [51] and that states must be consistent in their restrictions.[52] The UK experience of litigation against the fertility clinics and against the regulator, the Human Fertilisation and Embryology Authority, also suggests that human rights arguments can be raised against restrictions on access to services. In *Evans v Amicus Healthcare Ltd* the English Court of Appeal accepted that 'the refusal of treatment is an interference with, and therefore a failure to respect, Ms Evans' private life', and that 'by regulating the circumstances in which Ms Evans can have an embryo transferred to her, the state has interfered with Ms Evans' private life for the purposes of Article 8'. [53] There must

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[50] *Bioethics and the case-law of the Court* (2016) available at http://www.echr.coe.int/Documents/Research_report_bioethics_ENG.pdf .

[51] *SH v Austria* (Application no. 57813/00, Judgment 3 November 2011.

[52] *Costa and Pavan v. Italy* (Application no. 54270/10, Judgment 28 August 2012.

[53] [2004] EWCA Civ 727 [60] and [108]. NB the European Court of Human Rights agreed that Article 8 was engaged, although the UK's regulations fell within the margin of appreciation, see *Evans v. the United Kingdom* [GC], Application no. 6339/05, Judgment of 10 April.
2007. See also *Warren v Care Fertility (Northampton) Ltd &* Anor [2014] EWHC 60Para 119-20 'Mrs Warren relies on Article 8 in that she has the right to decide to become a parent by her deceased husband, which would accord with his wishes, and the written consent he gave…. I accept the proposition that she has this

be legitimate reasons for such interference, and the interference must be proportionate. Blanket bans are inherently problematic, although not always impermissible, because they cannot easily balance competing considerations.[54]

Faced with the counter-argument that there is a European wide consensus against germ-line modification, the applicant might assert that freedom of scientific research (Oviedo, Article 15) is being improperly constrained because, although that freedom is explicitly subordinated to other principles, there has been no public debate or consultation as required by Article 28. The failure to introduce appropriate review or amendment could be argued to make the continuation of the ban arbitrary, as scientific advances have been ignored. The failure to explore the prohibition of potentially life-saving treatment means that the ban disproportionately interferes not only with their Article 8 rights but also their right to life (Art 2 ECHR) and further that this is discriminatory under Article 14 because the ban is based on their genetic status.

I am not claiming that these arguments would succeed, merely that there are human rights arguments that suggest that we need to consider very carefully the proper status of the ban on germ-line modification. What is at stake here can be characterised, in part, as the suppression of individual human interests to the demands of society, using a line drawn in the sand that is of dubious ethical validity and even could be characterised as arbitrary. When Ms De Sutter spoke as rapporteur of the report to the Parliamentary Assembly, she asked of the scientific enthusiasm for human genome editing:

> Is this to the greater benefit of society, of humankind, of all patients? Is there justice involved? Or are we going into a world where genetic modification of embryos will enhance babies to create designer babies that will only be affordable for the happy few? Is the future that we want? It is definitely not the future that I want. Are we really all going to be cyborgs in a century, with bionic limbs and increased brain content? Of course, we will then edit our own genome and help human evolution. Is this the future of mankind? It is definitely not the one that I would want to see.[55]

The human rights challenge that I anticipate will be cast differently. It will ask why the resistance to all humans becoming cyborgs should mean that an individual who could benefit from genome editing must continue to be confined to a wheelchair, or be prohibited from overcoming a memory problem? From the perspective of an individual bearer of human rights, the aspiration to protect an abstract concept of human dignity will look like an example of the 'interest of society' prevailing over the welfare of the human being. They might suggest is therefore in direct conflict with Article 2 of the Oviedo Convention. The assumption set out in the Explanatory Report on the text of the Convention in paragraph 14 that individuals 'had to be shielded from any threat resulting from the improper use of scientific developments' would appear to such a human rights claimant to be a patronising

right and that this right should be respected by the state.' This is not to say that the English Courts have not always found it necessary to resolve such Art 8 claims, see e.g. R (M) v Hum*an Fertilisation and Embryology Authority* [2016] EWCA Civ 611, [34].

[54] *Costa & Pavan v Italy*, *Pretty v UK* Application no. 2346/02, ECHR 2002-III, judgment of 29 April 2002 .

[55] Ms de Sutter, p 28 of 48 in the English transcript of the debate of 12 October.

and paternalistic prejudice. On this view, the enthusiasm is not from scientists but from patients and they are entitled to be shown why the ban on germline interventions is a legitimate and proportionate restriction on their right to choose the therapies that they want.[56] The human rights challenge requires us to articulate an answer and satisfy ourselves that it is true to the values that drove the creation of the Conventions (both Oviedo and the European Convention on Human Rights).

Time for 'broad and informed public debate'

The Oviedo Convention itself recognises that it was not to be understood as an inflexible and eternally fixed document. If that had been the intention, then there would have been no need for public debate and consultation (Article 28), nor for protocols to elaborate the principles in particular contexts (Article 31), nor for a process to enable amendments (Article 32), nor the specific commitment for the Convention to be monitored against scientific developments within five years of agreement and then at intervals determined by the Committee charged with oversight (Article 32(4)).

Nor would engagement in further reflection on the ethics of germ-line interventions bring the institutional machinery of bioethics in the Council of Europe into conflict with religious traditions. The Roman Catholic position, in the Instruction *Dignitas Personae* approved by Pope Benedict XVI in 2008, does not propose an absolute ban on germ-line intervention as a matter of principle.[57] Rather, it concludes that on the state of science at that time there were no licit forms of germ line cell therapy. The Instruction recognizes the general moral appropriateness of gene therapy. In such therapy, 'actions seek to restore the normal genetic configuration of the patient or to counter damage caused by genetic anomalies or those related to other pathologies'. It concludes that it follows that 'procedures used on somatic cells for strictly therapeutic purposes are in principle morally licit.' Two problems were identified with germ-line modifications. First, it was anticipated that therapies then proposed to be performed on embryos would have been done in the context of in vitro fertilization 'and thus runs up against all the ethical objections to such procedures'. Second, and more generally, the Roman Catholic objection to germ-line modification was expressed to be based on safety concerns. Thus, there was no fundamental concern that there was something intrinsically different about germ-line interventions.

Further, the conclusion was specifically noted to be contingent on the contemporary scientific understanding:

[56] This is not to say that access to experimental therapies cannot be carefully regulated; see *Gard v UK* Application no. 39793/17, Admissibility decision 27 June 2017, *Hristozov v. Bulgaria* Applications nos. 47039/11 and 358/12, ECHR 2012, judgment of 13 November 2012.

[57] Unless otherwise indicated, the extracts are taken from Para 26.

> Because the risks connected to any genetic manipulation are considerable and as yet not fully controllable, in the present state of research, it is not morally permissible to act in a way that may cause possible harm to the resulting progeny.[58]

Importantly, the Instruction also explains linking restrictions to their moral basis: 'the legitimacy of every prohibition is based on the need to protect an authentic moral good.'[59] It is therefore entirely consistent with this Roman Catholic teaching to revisit the conclusion reached in 2008 that 'in its current state, germ line cell therapy in all its forms is morally illicit' to see whether scientific knowledge and possibilities suggest a more nuanced position based on distinctions that were not available for consideration in 2008.

Other denominations are also supportive of such reflection. Earlier in 2017 the Council of the Community of Protestant Churches in Europe published a guide to the Ethics of Reproductive medicine, *"Before I formed you in the womb…"* that concludes

> that an ethic of love, freedom, justice and responsibility could in principle support the use of germline therapy as a way for parents to take responsibility for the identity and well-being of their children.[60]

It raises concerns about the use of the technologies for enhancement, and in particular about 'a grandiose "transhumanist" agenda for the transformation of humankind into a new (and supposedly better) species.'[61] However, even here, it suggests that 'enhancement projects with more modest aims, theological suspicion might stop short of blanket rejection'.

The section of this report dealing specifically with human genome modification argues that two distinctions are key to the ethical discussion, First, that between somatic and germline modifications and, second, that between therapy and enhancement. It suggests that the assumption that germ line modification would not be a reality for a long time 'has at times lent a rather speculative character and an air of unreality to ethical discussions', but as this has changed with the development of CRISP/Cas9 'it is timely, therefore, for Christian churches to take these developments seriously as areas of current concern that call for careful deliberation and response.'[62] For the Council, 'the most obvious ethical issues are concerned with safety, efficacy, and the balance of intended benefits against the risks of harmful consequences.'[63] They note that views are spilt on whether these concerns justify a moratorium.

The conclusion that I draw from this analysis of two contributions from the Christian faith tradition is that to treat the ban on germline interventions as an inviolable sacred line would be to abandon our responsibility to take seriously the ethics of medical advances. As the

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[58] Ibid. para 26.
[59] Ibid. para 36.
[60] Council of the Community of Protestant Churches in Europe, *"Before I formed you in the womb…"* (2017) p 17.
[61] Ibid.
[62] Ibid. p 150.
[63] Ibid p 150.

creators of the Convention anticipated, there is a need to re-examine the provisions of Article 13 to see whether the terms that were agreed in 1997, based on contemporary scientific possibilities and understanding, continue to reflect the values that it was intended to promote.

Conclusions

The reasons why we need to refresh our understanding of Art 13 are captured in the observation from Hans Joas that the preciousness, in his terminology the 'sacrality', of human rights is built on subjective self-evidence and affective intensity.[64] I have shown that it was not self-evident in the preparation of the Convention that modification of the human genome could never be compatible with human rights. It was a matter of recognising multiple values in a specific scientific context. The regulatory solution was not obvious but complex. The obviousness of the ban on genome editing seems even less now. We should be wary of conflating 'affective intensity' with strong feelings. If nothing else, the violence of anti-abortion activism should remind us that passion can eclipse reasoned debate. Indeed, I am doubtful that we should ever respect an affective response to a prohibition itself, rather than to values on which it is based.

In the case of Article 13, the reference to aim encourages us to reflect on the purpose of the prohibition not merely its letter. Joas ends his discussion by noting that if values are to be effectively codified into rights that all can invoke, then we need 'an argumentational justification of the universal validity claim'. He suggests earlier that such a case can only be built on a narrative that explains how the values are 'appropriate articulations of the experiences that we or others have been through; we embrace new ones not through a decision but because we have encountered an articulation experienced as even more appropriate.'[65]

What we need, recognising this affirmative genealogy, is to recreate the deliberative process from which Article 13 emerged. We need to see whether experience now suggests a new articulation of the way in which the relationship between the advance of science and respect for human dignity calls for a response. This might be no more than an elaboration of the meaning of the words, in the manner of a revised explanatory report. It might lead to an elaboration of the Conventions' values in the context of germ-line therapies, perhaps as a protocol. It could mean a revision of the text itself. The human rights challenge is to reassure ourselves that we have not lost sight of the primacy of the rights of the individual by creating an idol of the words that were adopted in 1997.

[64] Joas p 5.
[65] Joas p 137