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Global Responsibilities and Bioethics: Reflections on the Council of Europe's Bioethics Convention

EIBE RIEDEL*

INTRODUCTION

Dale Jamieson's article raises the ethical challenges facing humankind in relation to global climate change.¹ His thought-provoking analysis also raises the need to confront other ethical challenges facing public health in the global era. This article focuses on the current controversies surrounding bioethics, and concentrates on how the Council of Europe's Bioethics Convention, adopted in November 1996 and signed in April 1997, handles these ethical controversies.² While global climate change and destruction of ecosystems may have adverse impacts on the world's genetic resources, human manipulation of genes generates many different ethical concerns that people approach with often fundamentally opposite perspectives. The Bioethics Convention provides an excellent case study of the ethical difficulties states and peoples will face in coming to grips with the moral implications of the advances in scientific technologies.

Generally, bioethics concerns the reasoned comments and evaluation of human interventions of all kinds into life processes, be they plant, animal, or human. Bioethics does not consist of a school of ethics, or even of special rules and principles for physicians and biologists. Bioethics combines ethical questions relevant to interventions into life processes of all kinds. Thus, it embraces the classical categories of biomedical ethics, animal ethics, and environmental ethics, but also ethical questions relating to gene technology. The recent successful cloning of Dolly the sheep in Scotland in 1997 brought

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1. Dale Jamieson, *Global Responsibilities: Ethics, Public Health, and Global Environmental Change*, 5 *IND. J. GLOBAL LEGAL STUD.* 99 (1997).

2. Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine, Apr. 4, 1997, Europ. T.S. No. 164, 36 *I.L.M.* 817 [hereinafter Bioethics Convention].

many bioethical issues to the surface and provides a good example of the comprehensive moral challenge genetic engineering poses. Naturally, all these ethical dimensions cannot be discussed in a brief comment, nor for that matter within the context of the Bioethics Convention itself. Instead, I will focus my comment on human gene technology and reproductive medicine.

I. ETHICAL BACKGROUND TO THE BIOETHICS CONVENTION

More than ten years of intensive debate by experts preceded the adoption and signing of the Bioethics Convention, which illustrates how controversial this topic has become. In this section, the two fundamentally conflicting views that provide the context for the negotiations of the Bioethics Convention are briefly outlined.

From the outset of the debate about the negotiation of the Bioethics Convention, states divided into two camps: the conservative or fundamentalist position; and the gradualist or liberal position. Conservatives followed the lines propounded by philosophers like Hans Jonas, who pleaded that the application of gene technology to human embryos or germ cells be forbidden. Lax ethical standards, in connection with human gene technology, would cause a moral dike to break. Jonas argued as follows:

Modern technology has produced new capabilities of such magnitude, with such novel objects and novel consequences, that the framework of earlier ethics no longer fits. The Antigone Choir about the horrific, about the stupendous might of humankind today would have to be reformulated . . . we will have to re-learn reverence and shuddering, to protect us from the aberrations of our own might, such as from experiments with the human constitution. The paradox of our situation consists in that we will have to regain lost reverence from shuddering, the positive from the imagined negative: reverence for what human beings were and are, and shuddering from what they might turn into and might stare at us from an anticipated future.³

3. HANS JONAS, *THE IMPERATIVE OF RESPONSIBILITY* 11 (12th ed. 1995). For an overview, see also Eibe Riedel, *Gentechnologie und Embryonenschutz als Vernassungs- und Regelungs Problem*, in 13 *EUROPÄISCHE GRUNDRECHTE-ZEITSCHRIFT* 469 (1986).

Many Europeans, and particularly Germans, accepted Jonas' emotional arguments against human gene technology. According to this view, reverence for the image of man would represent the core principle of moral responsibility.

The gradualist, or liberal, counterposition starts from the premise that human beings have changed and from the beginning have altered their surrounding environment in order to secure survival, subsistence, or a better way of life. Every technological innovation—from the invention of flint as a tool or weapon to the atom bomb and peaceful uses of nuclear energy—brought with it chances and risks. The negative side of technology should be reckoned with, but it should not be allowed to cut off possibilities to use new technologies for human betterment.

This brief description of the conservative and liberal positions illustrates the ethical divide into which the negotiations for the Bioethics Convention ventured. Conservatives focused attention on the negative potential of human gene technology, saying that it could ultimately and adversely change the genetic heritage of humankind by irreversibly altering the gene pool. One such negative is the potential for pathogens to emerge or reemerge that prey on a more susceptible human gene pool. Moreover, our conception of the human being might be affected in the core areas of personal identity if embryonic or human germ cell genetic engineering were allowed or cell cloning on human beings became a real possibility. Liberals or gradualists stressed that genetic engineering and fertilization, in the context of reproductive medicine, still concern different fields that in practice are separated, and from an ethical standpoint, might be viewed differently. The most recent advances in microbiology, particularly soma cell reproduction in animals, make it probable, however, that the convenient distinction between gene technology and biomedicine found in the books will no longer be sustainable.

The ethical divide between the conservative and liberal outlooks on human gene technology beset the negotiators of the Bioethics Convention from the very beginning of the process. In addition, national legislative realities and the processes of globalization factored into the equation. Most Western European states have fairly liberal laws on human gene technology; only in Germany and in some southern European countries do the laws reflect a more rigorous ethical position. The German national position induced German pharmaceutical and biochemical firms to invest in countries with more

favorable climates for human gene technology, thus illustrating that globalization plays a role in coming to grips with bioethical concerns. As a Canadian colleague once said to me: "You Germans provide the morals and we do the business."

Against this background of liberal gene technology in Britain, France, Belgium, and other European states, the Bioethics Convention had to strike a balance that probably cannot be found. If the treaty provisions were too liberal, Germany would not ratify. If the provisions were framed too strictly, Britain and other science-oriented states would not ratify. As so often happens in international relations, formal compromises eventually were devised, where the stark differences of opinion were glossed over by recourse to abstract clauses, open to different interpretation. Yet the Bioethics Convention tried to establish a general setting, by presenting itself as a framework treaty, where only a few concordant principles are laid down, while specific and sanctionable rules are left for future protocols to be negotiated at a later stage.

II. ANALYSIS OF THE BIOETHICS CONVENTION

The Bioethics Convention began by relating bioethics with the human rights approach of the European Convention on Human Rights and Fundamental Freedoms of 1950 (ECHR)⁴ in an attempt to tie in the inherent value of the human being into the bioethics debate. While the ECHR focuses on the human being and his/her dignity in the context of a holistic personality-identity framework, the Bioethics Convention enlarges this concept by extending respect to human substances capable of human protection. The Bioethics Convention excludes animal and plant biology. In effect, the Bioethics Convention covers all medical and biological applications concerning human beings, including preventive, diagnostic, therapeutic, and research applications.

Article 1(2) of the Convention mandates that each party give effect to its provisions in its internal law. It is formulated in such a way that it amounts to a non-self-executing obligation. However, some articles are framed in such a way that they may be regarded as self-executing and can thus be applied directly at the domestic level. This applies in particular to those provisions of the Convention that formulate individual rights, such as the rights of data

4. Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 4, 1950, 213 U.N.T.S. 221 [hereinafter ECHR].

protection, as stipulated in Article 10.⁵ Article 2 stresses the primacy of the human being and that the welfare interests of the human being shall prevail over the sole interest of society or science.⁶ The word “sole” was the compromise formula by which the negotiators sought to muster the consent of those wishing to restrict bioethical research altogether. Research, thus, is allowed, but only under conditions stated in Articles 15-18.⁷ Articles 3 and 4 lay down non-self-executing obligations regarding equitable access to health care and define professional standards.⁸ “Health care” means the services offering diagnostic, preventive, therapeutic, and rehabilitative interventions, all geared to alleviate a person’s suffering or maintaining or improving a person’s state of health.⁹ Continuous quality assessment is a prerequisite for health care, as the Explanatory Report to the Convention points out.¹⁰ The term “intervention” as used throughout the text means all medical acts performed for the purpose of preventive care, diagnosis, treatment, or rehabilitation measures, or in a research context.¹¹ The Convention then focuses on six major problems:

- (1) questions of consent to interventions in the health field,¹²
- (2) protection of the human genome and scientific research,¹³
- (3) research on embryos,¹⁴
- (4) transplantation medicine,¹⁵
- (5) data protection issues,¹⁶ and
- (6) economic consequences of biogenetics.¹⁷

With regard to the consent question, the Convention glossed over the underlying controversies and now provides that medical research may not be carried out on persons not able to consent unless: it is for their own immediate

5. Bioethics Convention, *supra* note 2, at art. 10.

6. *Id.* at art. 2.

7. *Id.* at arts. 15-18.

8. *Id.* at arts. 3-4.

9. *Id.*

10. Explanatory Report to the Convention for the Protection of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Apr. 4, 1997, 36 I.L.M. 826, 829 [hereinafter Explanatory Report to the Bioethics Convention].

11. *See id.*

12. Bioethics Convention, *supra* note 2, at arts. 5-9.

13. *Id.* at arts. 11-18.

14. *Id.* at art. 18.

15. *Id.* at arts. 19-20.

16. *Id.* at art. 10.

17. *Id.* at arts. 21-22.

benefit,¹⁸ or under the restrictive exception that no other alternatives of comparable effectiveness to research on humans are available;¹⁹ a careful risk-benefit assessment for the individual concerned is carried out as a prerequisite;²⁰ an independent examination (usually by ethics commissions) relating to its scientific merit and multidisciplinary review of its ethical acceptability has been carried out;²¹ and that “the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection.”²²

The most disputed clause of the Convention concerns the acceptability of embryo research. Article 18 states:

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.²³

Originally, embryo research was to be allowed until nidation, or the fourteenth day after conception, if allowed by national legislation. Germany passed the Embryo Protection Act in 1990, which categorically forbade any genetic interference with human germ cells. Most other European states saw no need for such a comprehensive ban; or, if they did enact specific prohibitions, they allowed generous exceptions for research purposes, without even requiring a nexus with prophylactic, diagnostic, or therapeutic purposes. The final version of the embryo research clause in Article 18 attempted to hide this conflict. It is up to the state concerned to define what is meant by “adequate protection of the embryo,”²⁴ and thus Article 18.1 is quite unacceptable to many conservatives. Even Article 18.2, providing that “the creation of human embryos for research purposes is prohibited,”²⁵ does not allay qualms about the

18. *Id.* at art. 6(1).

19. *Id.* at art. 17(1)(iii).

20. *Id.* at art. 17(2) (referring to art. 16 (i, iii, iv, and v) and requiring additional assessments). Article 17(2)(i) provides: “the research has the aim of contributing, through significant improvement in the scientific understanding of the individual’s condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned” *Id.* Article 17 (2) (ii) provides: “the research entails only minimal risk and minimal burden for the individual concerned.” *Id.*

21. *Id.* at art. 16(iii).

22. *Id.* at art. 16(iv).

23. *Id.* at art. 18.

24. *Id.*

25. *Id.*

protection value of this prohibition. Where human embryos stored for in vitro fertilization purposes are used for diagnosis, by analyzing and thereby destroying one embryo cell, before others are implanted in vitro, it cannot be said that these embryos have been created solely for gene technology research purposes. Consequently, liberal gene technology practice remains possible, if national legislation does not put a stop to it. The formula compromise contained in Article 18 on embryo research is mitigated for countries like Germany by the "wider protection clause" of Article 27, which stipulates: "None of the provisions of this Convention shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in this Convention."²⁶ This "better law approach" is a technique often tried in environmental law in the European Community,²⁷ in the ECHR, or in other human rights treaties.²⁸

As far as genome analysis is concerned,²⁹ basically three types of problems have to be distinguished: (a) pre-implantation diagnostics; (b) perinatal diagnosis; and (c) postnatal genome analysis. Pre-implantation diagnostics is concerned with the proof of certain inheritable traits or of the sex of human embryos, procured for in vitro fertilization. Research on "excess embryos" opens up the possibility for comprehensive genetic changes. For example, it makes positive and negative eugenics possible. Negative eugenics involves selecting which embryos should not be implanted because they bear inheritable diseases. Positive eugenics is the accelerated breeding of "genetically more valuable human beings," by developing each cell of a morula cell cluster—a six to twelve cell partition—into a genetically identical individual, into twins, or clones. Basically, the genetic pool is thereby not touched or changed, only a new quantitative dimension is reached. The Bioethics Convention does not outlaw such experiments. The German Embryo Protection Act of 1990 tried to prohibit such experiments, but it remains to be seen whether that will work in the future, particularly as artificially managed soma cell reproduction in higher animals becomes a real possibility. That Germans should be particularly engaged in this issue is understandable, bearing in mind Nazi

26. *Id.* at art. 27.

27. European Community Treaty, Mar. 25, 1957, art. 100(a)(iv), 298 U.N.T.S. 3, 54.

28. ECHR, *supra* note 4, at arts. 17, 60.

29. Bioethics Convention, *supra* note 2, at arts. 11-14, 18.

experiments in concentration camps and the gross abuses of medical ethics during the Nazi era.

However, the sensibility of a total ban on all gene technology concerning human beings may be questionable. At least critics ought to know about the medical treatment and economic potential in gene technology before ruling it out. The public debate in Germany for many years only focused on risk assessments but hardly at all on the positive prospects of these new technologies. It seems that fundamentalists have won the day and that the scientific research community has moved abroad to where better science conditions prevail. Globalization gave the German scientific and research communities an outlet for further exploration of the potential of human gene technology, and at the same time undermined the German national prohibition on pre-implantation diagnostics.

The Bioethics Convention, at any rate, does not resolve the issue one way or the other, nor could this be expected. It leaves vital questions to be resolved either in subsequent protocols or leaves it up to national laws to determine the scope and extent of gene technology and bioethics. This makes a mockery of the attempt by the Council of Europe to set common standards through treaties. Typically, Council of Europe conventions have the object not of creating completely new codified law, but of harmonizing the differences existing in the various European legal systems. While in effect, the Bioethics Convention produced little consensus on this issue, it did however, raise the level of consciousness and awareness of ethical dimensions to these new technologies.

As far as perinatal diagnosis is concerned, the Convention provides a relatively clear answer. Article 12 states:

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.³⁰

Article 14 continues by strictly outlawing selection on the basis of sex, except where serious hereditary sex-related diseases are to be avoided. Ethically, perinatal diagnosis can be justified on at least four grounds: (1) in order to

30. *Id.* at art. 12.

calm down worried parents with late first child expectancy; (2) in order to inform at-risk patients who previously had to live in fear until birth whether a genetically caused deformity existed; (3) to prepare parents for an expected sick or handicapped child; and (4) to develop therapies, for example, in cases of early detection of treatable mucoviscidosis. In 1987, the Roman Catholic Church strictly laid down the instruction "*donum vitae*", that the perinatal diagnosis is only permitted if it "respects the life and integrity of the embryo and is geared towards its individual protection and healing intention."³¹

Postnatal genome analyses seem to be ruled out by Article 12 if they concern genome analysis on employees or for insurance purposes.³² Postnatal genome analysis for health protection purposes raises many difficult questions, many of which are beyond the scope of this brief article. Paramount among these questions is the protection of privacy rights of individuals. Presumably, a special protocol will have to deal with the problem of privacy rights in connection with postnatal genome analysis. The general philosophy behind the Bioethics Convention as a framework treaty is that the right to know or not to know embraces the human right of informational self-determination, and thus precludes ulterior motives and purposes for genome analysis. Biological and genetic monitoring or screening is generally viewed with great skepticism in Europe, while industrial firms seek to utilize biological and genetic monitoring, especially in high-risk technologies. The Convention, by contrast, is liberal in relation to genetic fingerprints and other uses for the benefit of society as a whole, such as criminal law detection, public health issues, or protection of the rights and freedoms of others.³³

Article 10 of the Convention addresses the problems of privacy and the right to information or "informational self-determination," as it is called in German jurisprudence:

- (1) Everyone has the right to respect for private life in relation to information about his or her health.
- (2) Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

31. 74 SEKRETARIAT DER DEUTSCHEN BISCHOFSKONFERENZ 15 (1987) (citing ECCLESIA CATHOLICA, CONGREGATIO PRO DOCTRINA FIDEI, DONUM VITAE (1987)).

32. Bioethics Convention, *supra* note 2, at art. 12.

33. *Id.* at art. 26.

- (3) In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.³⁴

Article 10 thus establishes a right to privacy of information in the health sector, reiterating the principle laid down in Article 8 of the ECHR and the European Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data.³⁵ The right to know or not to know is, however, subject to restrictions under Article 26.1 of the Bioethics Convention, which are, in fact, narrower than those contained in Articles 8 through 11 of the ECHR. Thus, a judicial authority may order a test to be carried out on persons suspected of committing a crime, or to determine whether a filiation link exists. The wording of Article 10 leaves doubts as to the precise scope of the provision. Presumably, much will depend on domestic law. A doctor, when faced with the problem of whether to inform a patient who really does not wish to be informed, but in the interest of others thinks it necessary to do so, will have to rely on domestic law whether he should inform. Article 26.1 of the Convention may be cited as well, in that the possibility for prevention of risks to third parties might warrant that the privacy right is valued less than the risk prevention right of third persons. The Explanatory Report is vague about this solution, and refers the problem back to domestic law.³⁶ Such intrinsic vagueness and uncertainty will not promote quick ratification of the Convention.

Economic utilization of biomedical findings is addressed in the Bioethics Convention as well, but merely in general terms. Article 21 stresses that “the human body and its parts shall not, as such, give rise to financial gain.”³⁷ This, again, can be read narrowly or widely. Under a narrow construction, patents on human substances are prohibited. On a wider reading—which seems to underlie the Article—human substances are not to be made the issue of patents and the like, but all technological processes that produce change in human substances remain marketable and, therefore, open to patents. This view, in my opinion, will ultimately prevail. I cannot see a “public domain” situation

34. *Id.* at art. 10.

35. Explanatory Report to the European Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data, Sept. 12, 1981, 11 I.L.M. 342.

36. Explanatory Report to the Bioethics Convention, *supra* note 10, at 31.

37. Bioethics Convention, *supra* note 2, at art. 21.

gaining ground here, even if ethical responsibility criteria supported this position.

CONCLUSION

The Bioethics Convention attempts to address a pressing question of moral responsibility toward others, or social responsibility. Jamieson's "prevent harm paradigm"³⁸ neatly captures the nature of the social responsibility states and nations face in connection with human gene technology. I agree with Jamieson that those who are in a position to prevent anthropogenic health problems have a strong moral obligation to prevent them and that this responsibility extends to helping those most vulnerable to the problems already existing and looming on the horizon. While dealing with climate change requires a macroscopic perspective on moral responsibilities, the Bioethics Convention addresses an ethical question from a microscopic angle—human manipulation of the human genome. The global implications of the bioethics controversy are not, however, microscopic because they portend potential changes in the human genetic pool that could have foreseeable and unforeseeable adverse consequences for the human race.

However, I do not think that the European Bioethics Convention will fulfil the hopes of the framers of that treaty. The harmonization goal will not, in the short or medium term, be met. In addition, it is not a good sign that the European Parliament, after heated debates, could not agree on a joint text, let alone a directive or recommendation on the Bioethics Convention. The utilization of the framework convention method, while attracting more and more diplomatic support, seems in the bioethics context ill-judged: laying down general and generic principles first, to which all can agree, while leaving the specific and often costly details to later protocols, only works when there is substantial consent about the underlying main principles. Fundamental dissent on substantive issues, as in the Bioethics Convention, cripples the harmonization goals of such treaties, and subsequent reference back to domestic law merely indicates that the desired consent does not exist. So it seems doubtful that the Convention will be in force quickly, and equally doubtful that more detailed protocols might be forthcoming rapidly. Sovereignty still reigns strongly. However, in the light of increasing global challenges, we will have to work out global responsibility strategies and

38. Jamieson, *supra* note 1, at 117.

develop public interest norms that transcend the classical notion of state sovereignty; these public interest norms open up like an umbrella above states. In international environmental law ever since the Earth Summit of Rio in 1992, we have witnessed the emergence of such global norms of responsibility, such as sustainable eco-development, the right to development, and other notions of intergenerational equity.³⁹ All are geared toward Jamieson's prevent-harm paradigm, the responsibility to those in need. Perhaps the Bioethics Convention is the first frustrating step in the needed effort to develop global public interest norms in the area of bioethics.

39. Eibe Riedel, *International Environmental Law. A Law to Serve the Public Interest?*, in NEW TRENDS IN INTERNATIONAL LAWMAKING - INTERNATIONAL "LEGISLATION" IN THE PUBLIC INTEREST, 61 (Jost Delbrück ed., 1997).