

# Eubios Journal of Asian and International Bioethics

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<i>Contents</i>	page
Editorial: Eubios Ethics Institute as ABA secretariat	45
Eubios Declaration for International Bioethics	46
Understanding Morality as a Ground for Exclusion From Patentability Under European Law	48
- Sivaramjani Thambisetty	
9-11: Experiences and Reflections	53
- James Dwyer	
Commercial Introduction of Transgenics in developing countries - Some points to ponder	57
- S. Seshadri, K. Kathiravan, S. Ignacimuthu and S. Janarthanan	
To what extent should Animal Cloning be Permitted?	59
- Maurizio Salvi	
Human Cloning – A Reaction to Verma	63
- Tade Matthias Spranger	
German Parliament Paves the Way for ES Cell Research	63
- Tade Matthias Spranger	
Genotype and Mana	64
- K.K.Verma and Rashmi Saxena	
Commentary on Verma and Saxena	65
- Masahiro Morioka	
An Essay on the Principle of Informed Consent versus the Significance of Trust for Subjects of Biomedical Research	65
- Jon Vegar Hugaas	
Best wishes from medical students	71
- G.Sivagnanam, M. Rajasekaran, P. Thirumalaikolundusubramanian, K.Namasivayam, C.Jayashree and C.Ravindranath	
Hope and Fear in Genetics	72
- Vijay Rajput	
<b>News in Bioethics and Biotechnology</b>	75
Genetic Engineering of Plants, Animals, Designer Molecules, Biotech & Public, Regulation of GMOs	75
Vaccines & Diseases, AIDS & STDs, Bioremediation, Environmental Issues, Biodiversity,	
Animal Rights, rDNA products Food Safety	76
Disease Risks, Patenting and Business, Birth Control, Embryo Status, ART, Fetal environment	77
Genetic Disease Markers, methods, Privacy, Ethics & Genetic Screening, Gene Therapy, HGP, Medical ethics, Law, Scientific ethics, Euthanasia, Organ Transplants	78
Health Costs	
Internet, Genetics Network, Conferences	79
Orders	80

## Editorial: Eubios Ethics Institute as ABA secretariat

This issue comes after the successful completion of TRT7 meeting in Tsukuba, held from 15-18 February, 2002. 46 foreign researchers combined with a similar number of Japanese participants to discuss informed choice in Asia. One of the results of the conference was the agreement with the Eubios Declaration, which is open for comment and enclosed in the following pages (pp. 46-48). It is a living declaration, and open to improvement. We welcome your signature, and the next issue will include some of the discussion, and a list of signatories to it.

The abstract book for TRT7 is on-line, and papers will appear in coming issues of *EJAIB*. One of the results of the meeting was that the secretariat for the Asian Bioethics Association shifted to Eubios Ethics Institute, and researchers were encouraged to work together in developing bioethics in Asia, and beyond. In this context it is important to call for participants to the IVth Asian Bioethics Conference to be held 21-26 November, 2002, in Seoul Korea. Details are in the conference announcements section. Next year a meeting in China is expected. In this way we would like to encourage development of bioethics in the region, in the spirit of cross cultural dialogue.

This issue includes a number of papers on issues relating to bioethics and biotechnology, including topics of patenting, plant and animal biotechnology. There is also the issue of Mana and genotype. There are also two papers on medical ethics, one looking at the theoretical background of trust, and the other from a survey of Indian medical student's reasons to study medicine.

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Deadline for next issue is **30 April, 2001**.

Open for signature from 1 March 2002

# **Eubios Declaration for International Bioethics**

**[The Eubios Ethics Institute and the Tsukuba Bioethics Roundtable Declaration on International Bioethics]**

## **Preamble**

The life and medical sciences present many important educational, ethical, legal and social issues, which need to be considered at local, national and international levels. Following the closure of the Seventh International Tsukuba Bioethics Roundtable (TRT7), and the discussion at the preceding six TRT meetings, and consistent with the stated goals of the *Eubios Journal of Asian and International Bioethics (EJAIB)* and the decade of debate that has appeared in *EJAIB*, the members of Eubios Ethics Institute, and the further undersigned persons, wish to highlight the following principles for international bioethics:

## **Descriptions of Bioethics**

1. Bioethics is an interdisciplinary field that needs to be nourished by debate among all disciplines and people, not limited to any academic specialty or professionals.

2. There are a variety of definitions of bioethics, and this variety is part of the intrinsic value of the field of bioethics. We consider bioethics to be the process of reflection over ethical issues raised in our relationships with other living organisms; the consideration of the ethical issues in spheres including environmental ethics, health care ethics, social ethics, and in the use of technologies that affect life; and the love of life.

3. Bioethics has grown rapidly throughout the world, and should play a central role in professional and public discussions and debates, and bioethical issues feature prominently in legal, medical, scientific, and policy agendas worldwide.

4. Bioethical principles proposed by bioethicists may vary in their number, names, and organization, yet sufficient convergence exists to allow us to endorse the ethical values of respect for persons, doing good (beneficence), doing no harm (non-maleficence), and justice. Moreover, the virtues of the moral agent and his/her relationship to others and the environment are emphasized. The examination of these principles is part of bioethics.

5. There are different ways to view bioethics and in discussions of bioethics we should be clear which approach we are addressing. These include:

**Descriptive bioethics** – understanding the way people view life, their ethical interactions and responsibilities with living organisms in their life.

**Prescriptive bioethics** or normative bioethics examines what is ethically good or bad, or what principles are most important in making such decisions. It may also be to inquire into when to say something or someone has rights, and others have duties to them.

When one person tells another what is ethically good or bad they are prescribing bioethics. If prescriptive bioethics leads to paternalistic elitism, then we reject it.

6. There are at least two essential approaches to bioethics:

**Interactive bioethics** is discussion and debate between people, groups within society, and communities about descriptive and prescriptive bioethics.

**Practical bioethics** is action to make the world more bioethical, for example, health projects for medically deprived populations, and environmental activism.

## **Personal and Global Bioethics**

7. Every person has a lifelong responsibility to develop his or her own bioethical maturity and values. We could define bioethical maturity as the ability to balance the benefits and risks of ethical

choices, considering the parties involved and the consequences. At the societal level, public policy and law need to be developed, which requires a social mechanism for balancing conflicting ethical principles.

8. International cross-cultural bioethics should be developed, including studies and discussions, which respect individual cultures as long as they do not conflict with fundamental human rights, as outlined in the United Nations Declaration of Human Rights. Nations and members of every society (communities) should honestly reflect on the bioethical lessons of the past. Honest reflection on the bioethical lessons of the past should be encouraged together with efforts to promote reconciliation on all levels.

9. Research on the thinking and reasoning of all people should be more emphasized in order to understand the diversity of people's thinking. This is necessary for determining the degree of universality that is possible, and should be used to complement other research approaches in bioethics. There is no inherent reason to believe a priori that the views of one person are intrinsically more valuable than another, based on gender, age, educational background, physical, mental, or psychological condition or life experience.

10. Such ethical understanding is necessary to develop international cross-cultural bioethics, and no one culture should claim to be the dominant source of the concept of bioethics.

## **Freedom of dialogue**

11. Freedom of discussion is necessary for bioethical reflection and an essential feature of democratic life. We uphold the value of free, open and reasoned discussion, so that any position is worthy of consideration. In public discourse, no individual or group can claim to have exclusive knowledge of the right ethical solution. Only open discussion can lead to justifiable conclusions.

12. All nations and communities are encouraged to vigilantly defend the basic freedom of open discussion and disagreement. Often, this freedom is imperiled and there is widespread reluctance to discuss problems openly, the reasoned solution of which may run counter to received opinions and traditions.

## **Life as a Whole**

13. We recognize the dependence of all life (biota) on intact, functioning ecosystems, and the essential services that ecosystems provide. We urge action to halt environmental damage by humans that reduces biodiversity or degrades ecosystem processes.

14. Whereas wildlife provide numerous free services that make our life possible and pleasant, cleaning the air, water, and the soil of pollutants, providing food, medicines and a beautiful place to live, wildlife are in grave danger from the loss of habitat, the spread of exotic species, pollution, and direct consumption by humans. Wildlife often cannot protect themselves from humans, so without our help they cannot survive. The presence of humans greatly reduces the usefulness of a habitat to wildlife. Wildlife reserves act as sources for replenishing our supplies of animals and plants. Therefore, we urge all nations and peoples to make the protection of wildlife and wildlife habitat a top priority. In particular we urge them to set aside a large portion of their territory, interconnected by the wildlife travel corridors, for the exclusive use of wildlife, off limits to humans.

**Intellectual Property**

15. We believe that life is the common heritage of life, and no one group of persons can claim to own a living organism so as to stop others growing similar organisms.

16. No part of the human body (DNA, gametes, genes, cells, tissues or organs) should be exploited as a source of profit. We oppose exploiting people from some countries or groups to do things that are unacceptable in other countries, for example trade in human organs, unethical or dangerous drug trials, or dumping of hazardous wastes, including nuclear wastes.

**Technology assessment**

17. We applaud the development of science and technology if for the betterment of all, and urge the better sharing of the benefits of technology with all. Practical methods for appropriate technology (both new and traditional) transfer should be effected, together with mechanisms to assess the cultural, environmental, ethical, social and health impacts of such technology. Encouraging simpler technologies can often be preferable to transfer of advanced scientific technology.

18. In particular, we call upon all those in the research community to use any appropriate technology to reduce the burden of diseases and afflictions, both mental and physical, that afflict persons in all societies, and in particular in developing and least developed countries.

19. We do not think that any one technology with the same general goals, like feeding hungry people or curing a given individual patient, should be singled out for more critical examination, rather that bioethical principles should be applied to protect the interests of living organisms today, and the future generations.

**Ethics Committees and Consent**

20. In order to effect this, ethics committees with full community and ethnic representation, for the purpose of reviewing research proposals, and monitoring the impact of science and technology, should be established immediately.

21. In principle, all research on humans that has the rational potential to harm should be validated by the documented, informed consent from competent participants, which is voluntary and noncoerced. There are important issues to discuss regarding consent from communities, and we urge further study on these issues. We must devote more research to the topic of research on human subjects who lack the capacity for fully informed consent, such as in pediatric and psychiatric medicine.

**Human reproduction and genetic heritage**

22. Somatic cell gene therapy for treatment of disease is a useful medical therapy and may be used when needed and chosen by patients. However, germ-line gene therapy should not be attempted until it is technically safe, and a truly international public consensus has been sought and achieved for what specific cases would be considered ethical.

23. Therapeutic cloning, for example of tissues or organs, may be a useful medical therapy and may be used when needed and chosen by patients. However, human reproductive cloning should not be attempted until it is technically safe, and a truly international public consensus has been sought and achieved for what specific cases would be considered ethical.

**Duties to all persons**

24. We respect the life of all living organisms, When considering organisms we have to think of not only those on the planet Earth now, those that will be brought back to alive from the state of being extinct, those made in the future through natural or deliberate creation, and those that exist in other places. We should consider all persons, no matter their body or mental composition, for their intrinsic value and not their makeup. Society should consider the use of technology to reintroduce extinct species or introduce new species to the ecosystem.

25. We urge reflection on the way that we will treat non-organic (e.g. robots) or hybrid (e.g. cyborgs) persons, before they are made. All persons who work towards the love of others should be valued as a member of the moral community. Many persons in this world are not valued because of speciesism and we uphold the rights of all Great Apes and other beings capable of loving others and conscious thought.

**Bioethics Education**

26. To work towards a social consensus requires participation of informed citizens, which requires education about issues of bioethical importance. We applaud the public discussion on bioethics that has started to emerge in a number of countries, but these efforts need further support.

27. In order to achieve the above goals, greater effort is required to educate all members of society about the scientific and clinical background, and the ethical principles and social and legal problems involved, in the life and medical sciences. This will enable the active collaboration of all individual members of society, many academic disciplines, and the international community.

28. Education of bioethics is to empower people to face ethical dilemmas. Ethical challenges come to everyone. The process of debate and discussion is important for developing good minds to face bioethical dilemmas. It also develops tolerance and respect of others. In these troubled international times, it is very important to develop tolerance of others, and to learn that everyone as a human being is the same regardless of race, sex or religion. Same in this sense means equally diverse, it does not mean identical.

29. The process of debate and discussion in classrooms is particularly valuable and we urge all persons, organizations, institutions and countries to take appropriate measures to promote the principles set out in the Declaration, through promotion of education in bioethics.

**A call to practical ethics now**

30. States and institutions should take appropriate measures to encourage all forms of research, training and information dissemination conducive to raising the awareness of society and all of its members of their responsibilities regarding the fundamental issues relating to bioethics, in an open international discussion, ensuring the free expression of various socio-cultural, religious and philosophical opinions.

31. These goals require the cooperation of all, particularly in those with more resources, such as multinational corporations, and rich countries. We urge all to work together for all.

**Open to improvement and signature**

32. We note that progress towards reflection of bioethics can be made by every person, in both official and unofficial ways, and the undersigned endeavour to help all who want to progress the development of bioethics through the social network of members of the ever diverse, growing and non-exclusive Eubios family.

33. This Declaration will be open to signature and text agreement until a period two months after the publication of the draft Declaration in *EJAIB* (March issue), when the Declaration will be published. Further persons and organizations are welcome to endorse, second, or otherwise use the principles in this Declaration to promote bioethics in the spirit of this Declaration. This Declaration will also be known by its simple form, the *Eubios Declaration for International Bioethics*. As knowledge and experience progress, this Declaration will always be open to revision. We invite the world to participate.

Declared on the 1 March 2002, and open to signature. On-line: <http://www.biol.tsukuba.ac.jp/~macer/eeidec.htm>

Please return your comments and support by Email to:

Dr. Darryl Macer, Director, Eubios Ethics Institute, Japan and New Zealand (Macer@biol.tsukuba.ac.jp)

A list of signatories will be published in the next issue, together with a summary of comments.

# Understanding Morality as a Ground for Exclusion From Patentability Under European Law

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There is a common presumption that patent law, at least up until its encounter with biotechnology, was hermetically sealed and closed from external considerations. Some commentators have thus said that patent law is morally neutral (1), and the grant of a patent a non-ethical event (2). From this follows the belief that to ask patent examiners to consider moral issues is a novel approach (3). This is a fallacy (4) that arises from an incorrect understanding of two notions: nature of the monopoly grant in a patent, and significance of the legislative provision for exclusion from patentability on grounds of morality and public order.

## Nature of the Monopoly Grant

Firstly, patents, it is argued, do not in themselves grant anything; all they do is provide a legal means by which the holder can prohibit another from using the invention. Just as issuance of a patent says nothing about the practicality of the invention (5), the grant of a patent does not confer the right to produce the invention. The product may be regulated so that approval is required before it is released, or the patent may be derived from another patented invention so that permission is required from the first holder. Secondly, it is also clear that exploitation of an invention is not exclusively dependent on whether an invention is patented or not.

The moral neutrality is thus justified by the description of the patent as a negative right to prevent third persons from exploiting the subject matter to which the right is attached. It should therefore not be seen as equivalent to the moral acceptance of the subject matter to which the legal right is attached (6). The argument that the patent is 'only a negative right' is extended to imply that any restriction upon exploitation of the invention should be dealt with by other regulatory bodies and not through the cumbersome and indirect means of patent laws.

The European Biotechnology Directive (7) (hereafter the Directive), reinforces this view. It emphasises that substantive patent law is not the forum to make judgements on the desirability of certain kinds of research or commercialisation of the results of that research. European and international law continue to apply as do the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with ethical standards. According to the Recitals of the Directive these will continue to be effective in restricting, prohibiting, and monitoring research and the use or commercialisation of its results (8).

Despite the above argument, the effect of the patent right is to create a zone of non-interference, in which the patent holder may exercise the right of commercial exploitation. The holder of this right can, as a result of this zone exercise the right unless for some contingent reason a restriction is placed on this right (9). It is thus a more accurate to define a patent not as a negative right but as a positive and a negative right, where the positive part is not unconditional. To recognise the significance of a grant of patents is not to undermine the importance of regulatory bodies. But the patent office, being the port of first call, has an undeniable onus to assess the desirability of

granting property rights and associating legitimacy with a morally objectionable invention. Apart from the fact that the patent is an asset that can be traded and licensed and potentially used to attract investment, the symbolism in the grant of a patent is not an insignificant one (10). There may well be general reluctance on the part of legislators and other regulatory bodies to restrict opportunities for exploitation once a patent has already been granted.

It is also commonly asserted that the denial of protection may often widen the use or dissemination of the contentious subject matter. This rests on the argument that with the grant of a patent the commercial exploitation of it is restricted to the patent holder alone, not so if the patent is not granted. This argument was presented by the patentee in the onco-mouse opposition. It was claimed that the absence of patent protection will in fact encourage more exploitation because the ability to exploit it is then not dependent upon a license. Put another way, paradoxically the very objections being raised on grounds of morality could, if successful have the side effect of greater numbers of onco-animals being generated than would otherwise be the case.

This is a weak argument. If the moral worth of an invention is debatable, then the degree in which it is exploited should not temper the law's attitude to it. To accept this is to acknowledge the failure of the law to regulate scientific research and the degree of its exploitation. The determined profiteer who intends to manufacture his morally objectionable invention is not going to care about the approval of the patent office, but the more conventional inventor is likely to be deterred by a show of disapproval.

## Significance of exclusion from patentability

The argument that there is no link between the grant of a patent and exploitation of an invention if accepted, subverts the very existence of Article 53(a) in the European Patent Convention (and correspondingly of Article 6 of the Directive). This provision clearly establishes a link between the exploitation of an invention and the grant of a patent for that invention. The wording of the provision is 'if the *exploitation* of the invention *would be* contrary to morality', a patent shall not be granted. The wording 'would be' in fact indicates that whether an invention is actually exploited or not is irrelevant. Thus if the exploitation *would be* contrary to morality, it is sufficient ground to make it an unpatentable invention (11).

The statutory backing for taking account of moral and socially (un)desirable features of an invention dates from the Statute of Monopolies of 1623. This was largely declaratory of existing common law and made all monopolies null and void, except as recognised by the Act itself. S. 6 of the Statute (12) expressly limits the ambit of patentable subject matter. An initial reading shows up three prohibitions in the proviso- '*so also they be not contrary to law, nor mischievous to the state (by raising prices or hurt of trade), or generally inconvenient*'. These clauses have never been regarded as capable of illumination solely by strict etymological assessment and literal statutory interpretation. In a later commentary this section is said to have 'established as a rule that all prerogatives must be for the advantage and good of the people, otherwise they ought not to be allowed by the law' (13).

*The patent grant must not be contrary to law.* The phrase refers to common law as well as the patent statute itself. It has to be so, for it would be absurd if, one law may grant patents that serve as a reward to persons for providing the means of violating any other law (14). *Generally inconvenient*, interpreted in the nature of 'prejudicial' makes this the first immorality clause. A patent text written in 1841 cites as falling within the proviso an invention 'contrary to religion and public morals'. Another written in 1851 declares that the law would not protect an invention 'immoral in its very nature' (15). It may thus be taken as a settled notion in the latter half of the 19<sup>th</sup> century that an invention contra *bonos more* would probably be 'generally

inconvenient' and that an invention to be patentable must be 'consonant with the general enactments of the law and with public morals' (16).

Although it may seem that this section was of considerable significance, it was not often resorted to. But this does not diminish its importance as the statutory source of the exclusion of immoral and illegal subject matter from patent protection. The only occasional resort may be explained by the very existence of an express statutory prohibition. This may mean that inventions likely to be hit by it were not presented as deserving of patent protection in the first place. It could also mean that the particular technological era did not throw up as many morally ambiguous inventions, and not many of those that would test the limits of the prohibition. Certainly not like biotechnology has done.

Australia retains Section 6 of the Statute of Monopolies. Specifically, a patentable invention under the Patents Act of 1990, Section 18(1)(a) is one that is 'a manner of manufacture within the meaning of Section 6 of the Statute of Monopolies'. Genetically engineered organisms will only therefore be patentable if they are within the scope of a 'manner of manufacture' (17). A leading commentator suggests that the grant of such patents may be 'generally inconvenient' (18).

It would appear that moral concern and public good was always intended to be part of the patent system, right from its conception in the Statute of Monopolies. One of the earliest cases, *Darcy v Allen* (19) is part of English legal folklore spelling out the circumstances that called for grant of a patent monopoly. Darcy was given a monopoly grant for the sole manufacture and importation of playing cards. Among the arguments in favour of the validity of the patent was one that based it on the peculiar social benefits that such a monopoly grant could achieve by reducing the undesirable incidence of card playing among the servant class (20). Here considerations of public policy and morality were being called upon in order to support a patent rather than to attack its validity (as is more typical). So in the case of patent law, the task is not of introducing a morality clause, but is rather of maintaining and exploring its limits.

In the Directive, ethical and moral principles (21) are acknowledged as being supplemental to the standard legal examinations under patent law irrespective of the particular technical field under scrutiny. 'Indeed, patent law, contrary to other laws, traditionally excludes from patentability, inventions which would be contrary to 'public order or morality' (22). The Directive 'in view of the potential scope of inventions in this field and their inherent relationship to living matter maintains specificity of such concerns for each member state' (23). Questions of *ordre public* and morality are addressed, in particular in relation to TRIPs, and the need to exclude from patentability inventions whose commercial exploitation offends those principles (24).

The Directive is a mixture of specific exclusions as well as a general provision reflective of Article 53(a), EPC. Examples of excluded inventions are given in the operative part of the Directive to provide national courts and patent offices with a general guide to interpreting the reference to *ordre public* and morality in Article 6. This list is not exhaustive (25). Processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, uses of embryos for industrial or commercial purposes are excluded from patentability. So also the human body, at various stages of its formation and development.

The Directive expands on the general exclusion in the EPC, but even the specific references to excluded subject matter are ambiguous. On the one hand this may be seen as allowing scope for changes in conventional morality as determined judicially. But on the other hand, the range of controversy in the subject matter would seem to require greater specificity of

guidelines. The latter would be in the interests of harmonised patent standards.

#### Article 53(a) of the European Patent Convention

The technical criteria in Article 52(1) (26), EPC is to be read in conjunction with the exclusionary provisions of Article 53. Article 53 (a) provides that patents shall not be granted for -

'Inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the contracting states.'

The various terms in this exclusionary provision have given rise to interpretative difficulties in the case of biotechnological applications. One of the most common is that of the meaning associated with 'ordre public' and 'morality' and the way they relate together.

It is clear that 'ordre public' cannot translate into public order directly as this would render superfluous the effort at retaining the original French word in the Convention as having no equivalent term in English. However, this is what is indicated in section 1(3) (a) of the English Patents Act, 1977 which provides that a patent shall not be granted 'for an invention the publication or exploitation of which would be generally expected to encourage offensive, immoral, or anti-social behaviour'. The Guidelines for Examination in the EPO provide that the purpose of Art 53 (a) is to 'exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour' (27). The effect of this seems to be to identify 'ordre public' as akin to the English idea of public order.

The two concepts *ordre public* and morality are both interpreted in different ways in the context of national patent law in the United Kingdom and the EPC. Thus 'As far as national patent law is concerned, doctrine and courts agree that *ordre public* as opposed to morality is a body of positive law. The only question being what kind of legal provisions qualify as pertaining to this body called *ordre public*, rather than being simple laws or regulations, the contravention of which is no obstacle to the grant of a European patent' (28).

But such a reading along with the proviso would make Art 53 (a) self contradictory, as certain statutory or common law rules, if expected to be violated, would then constitute sufficient ground to deny a patent. A favoured reading seems to be that of equating 'ordre public' with 'public morality'. This simple 'translation' also meets with the same objection above, but cannot be regarded as wholly misguided. If this is taken to be correct, then together with the proviso, it is recognition that morality is not coextensive with law or regulation.

The Directive appears to settle this ambiguity in Recital 39, where *ordre public* and morality are said to correspond in particular to ethical or moral principles recognised in a Member State. So it would appear that the specific exclusions refer to those for which a certain degree of 'European' consensus can be gathered, while the general is open to interpretation by Member States according to their own 'ethics or morality'. A general provision is essential in so far as it is inadvisable to 'freeze' morality as per any particular time in history.

There are different ways in which an invention may be offensive to ethics or morality. When a patent is granted a number of things follow. Information on the invention is publicised and put in the public domain. The patentee is empowered to exclude third parties, and is potentially entitled to monopolistic profit. Also the invention normally is manufactured and used. The terms 'publication or exploitation' in Article 53(a) seem to enfold all of these consequences. If patent examiners are to have a moral jurisdiction at all it must focus on the *use* to which particular inventions are being put. The *use* may be read into 'publication'. If it is immoral to publish information about a particular invention, the immorality does not reside in the

knowledge itself but the use to which such knowledge might be put

The issue of the development of the invention is not so easily dealt with. It would appear that since research and development takes place before a patent application is made, it is not of concern to the Examiners. But if blatantly illegal behaviour like use of bonded labour went into the invention, granting a patent would put the manufacturer in a position to benefit from his immoral/illegal behaviour. More subtle scenarios come to mind. What if it can be shown that data collected in concentration camps with humans as experimental subjects had gone into a particular application?

In the case of human biotechnological inventions informed consent and the ethicality of research protocols are of great concern. Incorporating *development* within the moral responsibility of the EPO is highly controversial and likely to be resisted (29). The Biotechnology Directive in Article 26 suggests that consent to the removal of genetic material, while a desirable prelude to patentability, is a matter for national governance.

Informed consent amounts to procedural resolution, and is not itself any statement on the morality of using human tissue or cells in a particular way. To that extent it should be easier to incorporate in the regular practice of a patent granting authority. Not to do so is to ignore the entire history of safeguards on human experimentation put in place in the aftermath of the Nuremberg trial. The trial provided the occasion for substantive analysis of standards of ethical research and international human rights (30).

It would be very unfortunate if the Patent Office were disclaim responsibility for the development of inventions for which it grants protection. Substantive criteria of morality or public order may need special expertise, but contravention of well-established principles of research ethics if brought to the notice of the patent office should result in a revocation. Every applicant should be in a position to vouch for the ethicality of procedures followed. Each consequence should be tested against the standard for exclusion. The alternative, where one or more of the developmental, use, access, or monopolistic questions maybe ignored by the Examiners is in effect an acceptance that immorality in one or more of these aspects is irrelevant to the morality of granting a patent (31).

While the state as granting authority cannot disclaim responsibility for the inventions for which it grants protection the power to refuse a patent on grounds of morality or public policy must be used cautiously. Balancing the two imperatives is the vexed problem of biotechnology especially when uncertainty about the effects of the technology abounds. Given the fact that technology cannot yet be called mature, very often fear of the unknown is couched in moral terms. The objections to human biotechnological inventions, as with other aspects of genetics, blurs disagreement on facts with the moral significance of the facts.

How can the legal system take the uncertainty of a rapidly maturing, but little understood technology into account? Specifically excluding those inventions that are thought to cause 'absolute amounts of harm' is one effective way. For example processes that seek to change the germ line genetic identity of humans. But for the most part, at this early stage, effort should concentrate on formulating methods of evaluation. Foundational methodologies would include decisions on leaving exclusions on ethics to the legislature or judicial determination, the manner of weighting that will calculate costs and benefits to humans as opposed to say animals, a decision to follow analogous jurisprudences (say human rights and dignity) or a democratic decision to take public perceptions of biotechnology into account.

#### **Exclusionary criterion: Formulating a fair test**

Interpreting Article 53(a), EPC involves identifying a threshold reference point mandated by the provision. This can

be a 'low-threshold precautionary' approach, in which case patents will be excluded at the slightest doubt as to their moral acceptability, or a 'high threshold permissive approach', where patents may be excluded only where granting one seems inconceivable (32). The Guidelines for Examination in the EPO signal a narrow approach to Article 53 (a) that is likely to be invoked only in 'rare and extreme cases' (33). The EPO itself has observed that 'the function of this article has to be seen as a measure to ensure that patents would not be granted for inventions which would universally be regarded as outrageous' (34).

The EPO has repeatedly found that any exception to the general rule should be construed narrowly (35). In the *Onco-mouse/Harvard* (36) case the Technical Board of Appeal censured the Examining Division for having deviated from a narrow construction of Article 53 (b) without convincing reasons. The *onco-mouse* case included very broad claims relating to a method for producing a transgenic non-human mammalian animal with an increased probability of developing cancer and to the transgenic non-human mammalian animal as such. The examining division (ED) refused the application on grounds of the subject matter being excluded from patentability under article 53(b).

The Board of appeal allowed the appeal but remitted the application to the examining division to decide whether the invention was contrary to ordre public or morality under Art 53(a). Following the decision of the Technical Board of Appeal the examining division granted a patent, stating that the patent does not give a positive right to its proprietor to use the invention but only confers the right to exclude others from using the invention for a limited period of time. It was up to each contracting state to enact appropriate legislation if the state wanted such technical knowledge to be used only under limited conditions.

In this case the attempt to balance advantages and disadvantages of the patent to society was tackled as utilitarian reconciliation of competing interests. Thus usefulness to mankind was scrutinised against two broad ethical considerations: environmental (37) and animal welfare. The former includes the possibility of escape into the environment and the idea that evolution was being manipulated. The latter includes, viewing animals purely as a means to an end, the detrimental effects of the tumours on the animals themselves and the possibility of conducting such research without the animals.

A utilitarian calculus was used to balance the moral and environmental factors involved. Although it was acknowledged that the experimental animals had to suffer there was little danger of environmental damage since the animals could not reproduce their artificial genetic makeup (38). Of the advantages of the invention, the animals were highly useful for medical research. It was this that justified grant of the patent. Also the provision of a test animal useful in cancer research would reduce the amount of testing on animals.

The various interests in the decision that had to be balanced were a mixture of known and unknown quantities. Thus on the 'known' side of the equation, there is the element of suffering to be inflicted on the cancer-mice, on the 'unknown' are risks to the environment. This is weighted against the possible advances in the treatment of cancer in human beings. The criticism of the utilitarian calculus focuses on the fact that the examiners give a discounted weight to cost items, and undiscounted weight to benefits irrespective of whether they are known or unknown quantities. Thus 'the known suffering to mice, whilst not ignored, is talked down, partly on the strength of speculative (and value laden) predictions about a net reduction in cruelty to animals; and the uncertain advance in medical knowledge is talked up (39)'.

Utilitarianism always, selectively chooses to ignore certain consequences and the above criticism is one of choice of values, and not of methodology. Thus, the general approach of

attempting a legitimate balance with respect to specific moral problems is an useful one, and will serve well beyond the present case. This has found approval in the Directive in Article 6(d) where suffering of animals is to be weighed against medical benefit to man or animal.

Also the *onco-mouse* case pared down moral considerations to specificities. One of the objections was that transgenic animals in general pose an unethical interference with evolution (40). The opponents were calling for an assessment on an all encompassing moral agenda that would be thoroughly analysed at all levels, not just confined to the exploitation/publication of the invention, which are the practical public aspects addressed by the decision. This concern was ignored by the ED, and correctly so, given that the objection is generic. The patent system is incapable of dealing with such broad issues.

Another method of approach to Article 53(a) is to see if the invention is so far to one end of the moral spectrum as to make the grant of a patent the likely receptacle of public outrage (41). EPO Examination Guidelines and the UK Patents Act are cited in support of this view (42). They indicate that a 'fair test' is whether public consensus would determine that granting a patent would be abhorrent. This is sometimes described as the 'unacceptability test' or the 'public abhorrence test'.

The Technical Board in *Greenpeace v. Plant Genetic Systems NV* (43) relied on 'unacceptability to the norms of European culture'. It also stated that 'a fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable'. The attempt to use the 'inconceivability test' in the *Relaxin* opposition was founded on the premise that there is an overwhelming consensus amongst contracting states that the patenting of human genes is abhorrent and hence prohibited under Art 53(a) (44).

There is a circularity to the above tests that detracts from its utility as a means of judging moral permissibility. The composition of the notional body that expresses this is unclear. Does it incorporate a diversity of thought or opinion, or is it an attempt to approximate homogenous 'European' values? Beylveld and Brownsword tease out this approach in the following manner.

The tests necessarily represent both quantitative and qualitative thresholds. Simple 'cultural morality' has no quality threshold, and relies on general feelings of repugnance or acceptance in the public. These attitudes are not put through a critical process, whereby positive or negative perceptions are evaluated and critically processed before being accepted as moral judgements. A critical cultural morality would on the other hand, have to pass through tests of sincerity and rationality and hence are more sustainable as moral judgements (45). This critical process is one that would encourage discourse as well as tolerate disagreement.

Thus 'the inconceivability test apparently speaks to consensus more than to the quality of the consensual view' (46). But when this 'consensus' view is applied on a correct appreciation of the science and is consistent with other positive evaluations, (as it was in the *Relaxin* case,) only then will it amount to a quality check. This quality assessment may be further extended. The inclusion of environmental concerns in the *onco-mouse* case as well as in the Biotechnology Directive, is one such necessary extension. The authors go on to elaborate a very promising critical cultural morality that has found a degree of acceptance in subsequent literature on the subject. The commitment to human rights among the contracting parties to the EPC (47) makes it one of the principal features of critical cultural morality. 'In short, Art 53(a) must be read as a charter for human rights in the specific field of patent law' (48).

This argument fundamentally derives from the fact that the EPO must employ certain substantive moral requirements because they are part of the constitutional arrangements that

institute the contracting states as a single legal community (49). To recognise the existence of human rights is to recognise that individuals have rights from which the state itself cannot derogate. No person or body can then be granted authority to do anything that violates that right. Therefore none of the contracting states to the EPC can regard a determination by the EPO that violates human rights, as valid. In consideration of a prior commitment the contracting states would be acting ultra vires if they purported to license the European patent system to act in violation of these commitments. In order 'to view the European Patent System as a single legal order (or sub order) it is necessary to impute to the contracting states the common intention to found a patent order with the European Convention on Human Rights as its central provision' (50)

An acceptance of this is indicated in Recital 43 of the Directive. This refers to the constitutional obligation of member states under Article F (2) of the Treaty on European Union wherein fundamental rights as guaranteed by the European Convention for the protection of Human Rights and Fundamental Freedoms constitute general principles of community law. Further, as per Article 16, the European Commission has to review the relationship of the Directive to international agreements on the protection of human rights to which the member states have acceded. In this regard it is expected that other international declarations, will also provide guiding principles (51).

Any balancing approach, on the lines adopted in the *onco-mouse* case must on this view incorporate consideration of human rights and dignity. In what manner these would be weighted is a challenge to the moral commitment of the EPO, specifically with regard to human biotechnological inventions. Advocating a utilitarian calculus as the correct methodology of application of Article 53(a), may seem inconsistent with a rights-based approach. This will not be problematic if the calculus gives primacy to the preservation of human rights. So the rights issue can be addressed if we prioritise the methodologies of the provision.

Human rights jurisprudence in Europe consists of well-established principles that lend themselves to easy adaptation by the patent office. There are a number of occasions in which such resort may become essential in the case of human biotechnological inventions. One such, is the manner of 'taking' of human tissue and samples without prior informed consent. Clearly, the patent office cannot be seen to reward an invention, the material for which was obtained in an unethical manner that offends against human rights.

Where the invention is based on or uses biological material of human origin, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto (52). The information of this person has to be complete and specific, in particular of the potential patent application for the invention made from the use of an element taken from him (53). It is not clear from a reading of the Directive whether the consent must be to the taking, or to the filing of the patent application.

The difference is crucial, as only the former can hit at patentability itself. This may be gathered from opinion 8 of the GAEIB (54), paragraph 2.4 of which says, 'An invention based on the use of elements of human origin, having been retrieved without respecting the principle of consent will not fulfil the ethical requirements.' (55) On the other hand, A notification on DG XV web site says "the free and informed consent of the person from whom the material concerned was taken is required in order to file an application for a patent on the use of such material' (56).

A related issue is dealt with in Recital 27. If an invention is based on or uses biological material of plant or animal origin the patent application should where appropriate, include information on the geographical origin of that material, if known. There is no indication given of what is 'appropriate'. There is also no obligation to 'know' 'which might encourage ignorance' (57).

Under the Convention on Biological Diversity, to which the European Community is party, states enjoy the sovereign right to exploit their own resources, and to determine access to genetic resources (58). The States are also asked to ensure that intellectual property rights are supportive of and do not run counter to the convention's objectives (59).

These provisions have obvious international policy significance. If natural occurring genes are patentable, why should countries (or individuals) hosting organisms containing potentially important genes make them freely available for scientific purposes? In order to fulfil the obligation under the Convention on Biological Diversity, a patentor state will have to prove that prior informed consent of the state concerned was taken for plant or animal genetic resources. Also that a mutually agreed, fair and equitable sharing of the results of research which is carried out on the genetic resources of the source state is facilitated (60).

As it stands, the Biotechnology Directive does not exhibit sufficient sensitivity to the concerns of bio-prospecting that has plagued research on human genome diversity since its inception. This attitude is likely to be counter productive, as countries and peoples would be justified in the face of such insensitivity to deny access to their genetic resources (61). The legal regime should aim to preserve human dignity as well as leave avenues of research open. The EPO doubtless has the textual backing to take a bold stance in judicial determinations. Whether it does so remains to be seen.

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## References

- 1) Noonan M D 'Patenting Medical Technology' II Journal of Legal Medicine 263 (1990) at 318.
- 2) Ho C M 'Building a Better Mousetrap: Patenting Biotechnology in the European Community' 3 Duke Journal of comparative and International Law 173 (1992) at 195. See also Miller J and Tramosch A G in 'Playing God? : We've Done it for Centuries' *New York Times*, 26 Apr 1987, s.3 p.2 'Lawyers have no obligation to discuss ethical matters. Indeed it could be argued that law and ethics should be kept apart' Lewelyn M 'Animal Patents: Lawyers Call the Tune', *New Scientist*, 1Dec 1990 p 18.
- 3) Lane M J 'Patenting life: Responses of Patent Offices in the US and Abroad', 32 *Jurimetrics Journal* 89 (1991) at 98.
- 4) See David Kell 'Treatment of Immoral Subject Matter Under Patent Law: A Historical Analysis' DPhil Thesis, Oxford University 1995.
- 5) At least two thirds of all patented inventions are never produced. The actual number of non-exploited patents is close to 70-90 percent in developed countries. Taylor and Silberston, *The Economic Impact of the Patent System* (CUP, 1973) p.20.
- 6) This argument was offered in *PLANT GENETIC SYSTEMS / Glutamine synthetase inhibitors* [1995] EPOR 173 at 373. This patent was granted 10<sup>th</sup> Oct 1990. During opposition proceedings instigated by Greenpeace, the biotechnology company offered the argument that 'Neither the patent at issue nor any other patent confers upon a patentee a right to exploit, let alone a 'monopoly' right to exploit his patented invention. Exploitation of a patented invention is always subject to governmental regulation and control in each of the contracting states of the EPC. Nothing in the EPC diminishes or restricts the ability of the Contracting states to control or prohibit by law or regulation the exploitation of a patented invention. Hence, although a patentee has a right to exclude others from using his patented invention, a patentee does not have a right actually to exploit his invention.'
- 7) 98/44/EC Directive on the Legal Protection of Biotechnological Inventions.
- 8) Recital 14, the Directive.
- 9) Peter Drahos, 'Biotechnology Patents, Markets and Morality' [1999] *EIPR* 441, at 443.
- 10) David Kell (n 122 above) cites how grant or denial of a patent exerts economic pressure. Powerful stigma may be associated with a court or administrative body finding that particular subject matter is contrary to morality or ordre public. There are reports of considerable criticism from the industry on the apparent immoral nature of the 'baldness mouse' patent. The Upjohn company's patent attorney in response to the EPO's examination report said 'The applicant regrets having included features considered to be immoral or contrary to public order. The applicant is pleased to say that they have not transformed any mammals with oncogenic reporter genes'.
- 11) Sigrid Sterckx, 'European Patent law and biotechnological invention' in Sterckx (ed) *Biotechnology, Patents and Morality* (Ashgate, 1997) p10.
- 12) Section 6 of the Statute merits quotation in full as the clause on which the patent system came to rest: 'Provided also and be it declared and enacted that any declaration before mentioned shall not extend to any letters and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any new manufactures within this realm, to the true and first inventor and inventors of such manufactures, which others at the time of making such letters patent and grants shall not use, so also they be not contrary to law, nor mischievous to the State, by raising prices of commodities at home, or hurt of trade, or generally inconvenient; the said fourteen years to be accounted from the date of the first letters patent, or grant of such privilege hereafter to be made, but that the same shall be of such force as they should be if this Act had never been made, and of none other'.
- 13) Bacon M A *New Abridgement of the law*, VI, 7<sup>th</sup> Dodd C E (ed) (A Strahan, London 1832 ) at 384, as cited in David Kell, ( n 125 above)
- 14) Hindmarch W M A *Treatise on the law relating to patent privileges for the sole use of inventions* ( V R Stevens & G. S Norton & W Benning and co, London 1846) at 142. As cited by David Kell (n 125 above).
- 15) The former is quoted from Webster T *On the subject matter, title and specification of letters patent for inventions and copyright of designs for articles of manufacture* F Elsworth, London, 1848 at 40. The latter is taken from Tanner, *The law of patents and registration of invention and design in manufacture* (John Crockford, London 1851) 10, as cited by David Kell, *supra* n 5.
- 16) Campin F W *Law of patents for inventions* (Virtue and co, London 1869) at 6.
- 17) Section 18(2) explicitly excludes human beings and the biological processes for their generation from patentability.
- 18) Ricketson, *Cases, Materials and Commentary* (Butterworths, 1994) p 631-640.
- 19) 72 ER 830.
- 20) 72 ER 830 at 883.
- 21) The European Commission has also established ELSA, Ethical Legal and Social Aspects of the Life Sciences and Technology. This is a common research sub area for three specific programs in the field of life sciences and technologies, Biotechnology (BIOTECH), Biomedicine and Health (BIOMED) and Agriculture and Fisheries (FAIR).
- 22) Recital 1.6, Opinion of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission, No: 8, 25.09.96.
- 23) Recital 39.
- 24) Recital 36.
- 25) Recitals 38,40.
- 26) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.
- 27) C-IV, 3.1.
- 28) Ulrich Schatz 'Patents and morality', in Sterckx (ed) *Biotechnology, Patents and Morality* (Ashgate, 1997) pp 159-170, at p 161.
- 29) In the context of the *Hormone Relaxin* case one commentator is of the opinion that 'even if the cell line in this case had been obtained in a dubious fashion about which the patent Examiner was aware, provided the information was not part of the application it would not be caught by the morality criterion. The moral prohibition, even without publication, cannot centre on a retrospective analysis of methods, since to sanction at this point would be redundant and outside the remit of legislation.' See Amanda Warren 'A Mouse in Sheep's Clothing: The challenge to the Patent Morality Criterion Posed by "Dolly"'. [1998] *EIPR* pp 445-452, at 446.
- 30) See Arthur Caplan 'The Doctor's Trial and Analogies to the Holocaust in Contemporary Bioethical Debates', in Annas and Grodin (eds) *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation* (OUP, 1992) pp 258-277.
- 31) Beyleveld and Brownsword, Mice, Morality and Patents: The Onco-mouse Application and Article 53(a) of the European Patent Convention (Common Law Institute of Intellectual Property, 1993) p 50.
- 32) These are terms used by Beyleveld and Brownsword in 'Patenting Human Genes: Legality, Morality and Human Rights' in J W Harris,

(eds) *Property problems, from genes to pension funds* (Kluwer International, 1998) pp 9-24, at p 9-10.

- 33) EPO Guidelines C-IV, 3.1
- 34) *Howard/Florey Relaxin* 1990 OJ EPO 388 at 398.
- 35) *Lubrizon Genetics Inc/Hybrid Plants LUBRIZOL* 1990 OJ EPO 71 at 76. This referred to the construction of Article 53(b). This is an exception that excludes patents for plant and animal varieties, and essentially biological processes for the production of plants and animals other than microbiological processes and the products thereof.
- 36) OJ EPO 476 at 486.
- 37) The Directive mentions, for the first time, in Recital 36 that inventions that cause 'serious prejudice to the environment' will be excluded from patentability.
- 38) Here, the calculus deems welfare of different entities to be the sort of thing that can be added together so that total states can be compared. The demand that outcomes always be ranked in terms of the sum of welfare they contain is problematic. Ethically, it is objectionable to sacrifice the interests of any given person with the aim, not just of protecting but of increasing the aggregate welfare. This is problematic with respect to rights, it can also be seen as an objection to the consequentialist character of utilitarianism.
- 39) See generally, Beyleveld and Brownsword, n 31 above, Chapter 3.
- 40) OJ EPO 10/1992, 588 at 593.
- 41) Armitage and Davis *Patents and morality in Perspective* (Common Law Institute of Intellectual Property, 1994) p 47.
- 42) Guidelines for Examination in the EPO (IV, 3.1), explaining the purpose of Art 53 (a). 'The purpose of this is to exclude from protection, inventions likely to induce riot or public disorder or to lead to criminal or other generally offensive behaviour' S 1 (3) (a) of the 1977 Patents Act says that 'A patent shall not be granted (a) for an invention the publication or exploitation of which would be generally expected to encourage offensive, immoral or antisocial behaviour'.
- 43) [1995] EPOR 357, [1995] OJ EPO 545.
- 44) [1995] OJ 388, Para 6.4.3
- 45) The authors use Dworkin's criteria that make any position a moral one. The reasons that are given for positions must be ones that exclude prejudice, mere emotional reactions, rationalisation, or parroting. It is one that is held sincerely and is supported with other relevant beliefs, and is not held arbitrarily.
- 46) In J W Harris (ed) *Property Problems to Pension Funds* (Kluwer Law International 1997) at p 21.
- 47) As evidenced by the European Convention on Human Rights (ECHR) and other international human rights instruments, notably the Universal Declaration of Human Rights, 1948.
- 48) J Harris (n 46 above) at p 13.
- 49) The European patent convention is a contract entered into by a number of states. All of the contracting states (with the exception of Monaco) are signatories to and have ratified the European Convention of Human Rights.
- 50) Mice, Morality and Patents, p 70.
- 51) For eg UNESCO's Universal Declaration on the Human Genome and Human Rights. Article 11 states that 'Practices which are contrary to human dignity, such as reproductive cloning of human beings shall not be permitted' See <http://www.unesco.org/ibc/uk/genome/project/index.html>
- The provisions of the European Convention on Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, 1997, are also significant in this respect.
- 52) Recital 26.
- 53) Para 2.4, Opinion of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission, No: 8, 25.09.96.
- 54) European Commission's Group on Ethics in Science and New Technologies.
- 55) Ethical Aspects of Patenting Inventions Involving Elements of Human Origin, GAEIB (25.09.96) No:8.
- 56) <http://europa.eu.int/comm/dg15>
- 57) Robin Nott 'You did it. The European Biotechnology Directive at last', [1998] EIPR, pp 347-352, at 348.
- 58) Article 3 and Article 15.
- 59) Art 16(5).
- 60) See Andrew Scott 'The Dutch Challenge to the Bio-patenting Directive', [1999] EIPR pp 212-215, at 214.
- 61) See n 109 above.

## 9-11: Experiences and Reflections

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I live less than two kilometers from the World Trade Center. You know what I mean: less than two kilometers from the site where the World Trade Center stood until September 11. Now it's a pile of rubble, a mass grave for 3,000 people. Although the acrid smoke still drifts through my window at night, it is not too early to reflect back on the events. Indeed, it may be too late.

Whether or not it's too late, I want to describe some experiences and offer some reflections. I want to say something useful for my colleagues who teach bioethics in other places, but I'm not sure I can. At my best, I never feel very articulate and insightful, and now I'm quietly depressed. When I try to read or write, I have trouble concentrating. When I walk by a fire station, my eyes fill with tears. When I hear a siren, my stomach tightens. Such is my state of mind, and I'm one of the lucky ones. A colleague of mine was not so lucky. His wife is missing, presumed dead, buried in the rubble.

### The Hospital's Response

Now, less than a week after the attack, when I meet with other people living in New York, we often try to situate the event in our lives. No one even needs to pose the question: "Where were you when ...?" But we all need to give our answers. In fact, I need to give two different answers.

I was giving a talk in the surgery department at NYU Downtown Hospital. This hospital is located in lower Manhattan, between the financial district and Chinatown, about 500 meters from the World Trade Center. Since 60% of the patients at the hospital are Chinese immigrants, the surgeons and I were discussing what to do when immigrant families ask the staff to withhold the truth from the patient. We were considering ways to reconcile the desire to be culturally sensitive with the desire to be truthful, when we heard a loud explosion. We went outside, took one look, and went back inside to prepare for the casualties.

As we rushed back into the hospital, we heard the announcement over the public address system: Code Yellow Alert! The hospital was putting into effect its disaster plan. The surgeons knew what to do: cancel all elective surgery, free up the operating rooms, prepare for trauma surgery. I didn't know what to do. As I walked around looking for a job, I saw the disaster plan in action.

The administrators set up a command center on the first floor. The residents discharged patients who were in for elective procedures. The nurses prepared equipment, medications, and intravenous solutions. The emergency department freed up all available beds and created makeshift beds. Doctors and nurses set up triage areas. Young men and women, dressed in scrubs, waited outside with gurneys. They were focused and alert, full of adrenaline and anxiety.

I was at a loss, so I went to the command center and asked for a job. They sent me to the hospital blood bank. I gave blood – that was something I knew how to do – and stayed to help screen potential donors. All kinds of people showed up to donate blood: big and small, young and old, business people in suits and cooks in aprons, people who spoke English and people who spoke other languages. The hardest part of my job was screening out people who wanted to help but did not meet the qualifications to be a blood donor. Soon the line to donate blood grew so long that the nurse asked me to go through the line and pick out the people who knew they were o-negative.

As the morning wore on, we knew something was wrong. There were plenty of donors, but little demand for the blood that was already available and tested. The two towers had collapsed. The people standing outside the hospital were covered with smoke, ash, and concrete dust. We could imagine what happened to the people in the towers. Few survived. The hospital did treat about 400 people, including more than 100 police and fire personnel. Most of the people were treated for eye problems, respiratory problems, or lacerations, and then released. Only about 30 patients needed to be admitted to the hospital.

By nighttime there was nothing for me to do at the hospital, so I walked home. As I walked along the deserted streets and past the police barricades, a thousand thoughts came into my mind. Three of these thoughts might be of use to colleagues in other places.

"Competence is the first kindness," someone once told me. I don't know whether competence is really a form of kindness, but it can be extremely valuable, even life-saving. People need to know how to do things well, what things to do, and how to do those things in a coordinated manner. All that takes study and practice.

My second thought was about the spirit of professionalism. After the attack, healthcare professionals of all kinds put aside risk and inconvenience to themselves in order to respond to people in need. An ideal of responsibility, of responding to people in need, still resonates in healthcare professionals. Societies need to encourage this spirit of professionalism and to temper the economic forces that distort it.

My third thought was about the value of a system of public health. The crisis made so clear the value of hospitals, disaster plans, professional training, medical stockpiles, surge capacity, and public awareness. But I fear that privatization, free markets, and deficit reductions are eroding systems of public health all over the world.

### **My Response**

"Where were you when ... ?" My first answer to that question was false. Everything I said about the hospital was true, but I was not at that hospital that morning. My talk there was the month before. I made up my role that morning because I wish it had been true. I wish I had been involved and useful, but I was not.

I was sitting at my desk at home, preparing a talk for the ethics committee at another hospital, when I heard a loud explosion. I thought it was a sonic boom, so I went back to work. A little later my wife called and told me that a plane had hit one of the towers at the World Trade Center. I turned on the radio to hear the news. By the time I went outside to look, a second plane had hit the second tower.

I spent the rest of the morning watching the towers, listening to the news, and trying to make sense of what was happening. When I saw the first tower collapse, I felt little emotion at all. I assumed, in a naive and self-protective way, that almost everyone had made it out of the building by the time it collapsed. Little did I know or want to feel.

About noon, I walked over to the nearest hospital to give blood. More than 300 people were in front of me in line. The staff picked out some donors from the front of the line and sent the rest of us home. I couldn't even give blood – that's how useless I was! My training in philosophy and ethics was of no immediate use. What could I say, that the attack was unethical? Few people in New York doubted that. I did say that I thought a military response would be both ineffective and unethical, but perhaps the course of events will prove me wrong.

In the days and weeks that followed, I fell into my characteristic response to the world: quiet depression mixed with wide reflection. Other people are more action-oriented, but I often get caught up thinking. Maybe my proclivity to depression was there all along, just waiting for its chance. Now

it had its chance, and one of the things I was depressed about was my own reaction and feeling.

I reproached myself for not feeling enough. I was so close to so much death, destruction, and suffering, but I had not felt any deep emotional response. I felt some confusion, a desire to understand, forebodings about military responses, a concern for Muslim-Americans, and some sorrow for the families of the missing. But I had not felt the great rage, deep sorrow, or remarkable empathy that moved so many other people.

But how much should we feel? And what exactly should we feel? These are ethical questions, not just psychological questions. Philosophers like Epictetus, Spinoza, and Nietzsche were critical of a whole range of human emotions. They criticized certain emotional responses and urged people to work to eliminate or modify those responses. Another group of philosophers, the classical utilitarians, emphasized the need to cultivate deep and wide-ranging sympathies. I have always admired this part of the utilitarian tradition. I certainly see the need to use experience, reflection, imagination, and literature to cultivate a wide sense of sympathy.

At first I wasn't trying to cultivate sympathy; I was just trying to get to work. I teach two days a week at Bellevue Hospital. Along the entrance to the hospital stands a long wooden wall, erected to separate the entrance from a construction site. In the hours and days after the attack, people came to the hospital looking for missing relatives. They taped posters of the missing on the wall. Soon the whole wall was covered with posters of missing persons. Each poster had a picture, some vital information, something about where the person worked, and a plea to contact the searching family member.

The posters were snapshots of the different people who live and work in New York: men and women; white, black, Asian, and Latino; Americans and foreigners; stockbrokers and firefighters. The photographs captured people at different moments: a woman in a wedding dress, a young man at graduation, two sisters at home, a father with his child, a firefighter in uniform.

Soon everyone began to realize that the posters of the missing were the faces of the dead. What was a plea for help became a memorial for the dead. The wall became a shrine. People placed candles and flowers at the base of the wall. Children wrote letters of gratitude and sorrow, and their teachers attached the letters to the wall. An elderly Chinese woman put a bowl of rice on a small box and stuck chopsticks into the rice – an Asian symbol of death.

I made myself look, at the posters of the missing, at the faces of the dead. Two Irish-American sisters, pictured back to back, both worked for Cantor-Fitzgerald. A Chinese-American man, with a caption under the photo: "We miss you, Daddy." An African-American firefighter from Brooklyn: "He ran into the building as others ran out." A young Japanese banker, with a plea to contact his family in Japan. A woman who was trapped in the elevator in Tower #2; she had called her sister on her cell phone. A tall woman in a wedding dress, with a description of the tattoo on her back. A handsome 26-year-old man who worked for Starbuck's; he was delivering coffee when the attack occurred.

Looking at the wall, I felt a sense of people's lives – of how hard they worked, of how intimately they were connected to other people, and of how deeply they were mourned. I wiped the tears from my eyes and went into work. But each day, on my way to and from work, I stopped and lingered at that wall. I studied the faces, read the information, and imagined lives, here and abroad. I feared that a military response would kill innocent people, people who worked very hard, who were intimately connected to others, and who would be deeply mourned.

### **Communities and Countries**

Everyone was deeply impressed by the courage, discipline, and sense of duty that the firefighters showed. But I was also impressed by how ordinary people behaved. Ordinary people

displayed concern, discipline, a great willingness to help, and a real sense of community. People volunteered to help in the rescue efforts, to work at hospitals, to counsel people who lost a relative. People collected and donated money to help the survivors. Children baked cookies to take to the fire stations in their neighborhoods.

I have never seen New Yorkers behave so well. In their daily interactions with each other, they showed more civility, concern, and kindness. People in public waited more patiently in line and deferred to others. People at work asked about coworkers and their families. People inquired about their neighbors and offered to help in small ways. People in elevators even seemed less guarded, more willing to look at and talk to others. There was, at least for a while, a much stronger sense of community.

I reflected on the sense of community that emerged. I think it was a recognition of three things: (1) that we are all vulnerable; (2) that we all need the concern and support of others; (3) that we all depend, in our endeavors to live worthwhile lives, on the work and activities of many other people. Maybe I am waxing too philosophical, but I really did sense a dim recognition of these basic aspects of community.

Will this sense of community last? Probably not. When people feel attacked and vulnerable, they often come together, but when the immediate danger passes, they revert to their old patterns of behavior. How people respond in a crisis and how they behave in the long-term probably have to be different, but I do not want to accept the usual base line of behavior as normative. I want to at least pose some questions. What should the base line sense of community be in modern cities in pluralistic societies? Can a sense of community be strong and effective without being intolerant and undemocratic? Is there any ethical value to a sense of national community, to a sense of patriotism?

I cannot answer these questions in an adequate way, but I can try to outline the problems we face. First of all, we need to recognize that a robust sense of community is not always a good thing. Some communities are united in their hatred of those who do not belong. We all know of tight-knit communities that share a deep hatred for people of other races, ethnic groups, religions, places, and customs. Because tight-knit communities can be so hateful, exclusionary, and provincial, some people have welcomed modern forces that tend to erode communities. Forces like industrialization and individualism have worked to erode, displace, and unsettle local communities and associations. The problem is that the good aspects of community are often eroded along with the bad.

Some writers have suggested that Internet communities, professional associations, and interest groups will fill the void left by the erosion of more local communities. Although these new associations can be valuable and helpful, I doubt that they can replace local communities. People develop vital attachments, strong dispositions, and basic characteristics in families, neighborhoods, schools, and other forms of face-to-face communities. In the best of communities, people even develop into citizens who are concerned, critical, and tolerant. John Dewey once said that democracy "must begin at home, and its home is the neighborly community" (Dewey, 1954, page 213).

At least the problem is clear. We need to foster face-to-face communities that are tolerant, inclusive, and democratic. Somehow we have to foster daily and local associations but infuse them with wider and deeper ethical meaning. That's no easy task, but there are hopeful signs. One hopeful sign is the renewed interest in social capital and civil society (Putnam).

Although I see the need for a sense of local community, I am more skeptical about a sense of national community. Patriotism scares me. Love of country often becomes entangled with nationalism, jingoism, imperialism, and narrow economic interests. During the cold war, American politicians often invoked national security and relied on a reservoir of patriotism

to curtail dissent at home, support dictators abroad, fuel destructive wars, and further economic interests.

So the patriotic response to the attacks on September 11 filled me with anxiety. I have heard so many patriotic songs. I have never seen so many flags. People wore flags on their lapels. Shopkeepers put flags in their windows. Drivers put small flags on their cars, trucks, or taxis. People hung flags on buildings. I even saw a huge flag hanging in the atrium of the university library. When I saw a flag there, I felt like someone had hung a national flag in a church. But others felt differently – about libraries and flags.

I am afraid of nationalism, jingoism, imperialism, and the way economic interests disguise and assert themselves, but I don't think that patriotism will go away. The only realistic hope is to transform it. If patriotism takes the form of pride in military prowess, a love of self-assertion, and a desire for revenge, then we're all in trouble. When people want their country to be great and powerful, rather than good and just, then we're all in trouble. So it behooves us to consider the nature and form of a proper love of country.

In the present historical circumstances, the most likely alternatives to countries are not tolerant communities in a world democracy, but economic enclaves in a global plutocracy. At least for a while, countries may be necessary units. Of course, the borders between countries are rather arbitrary. They are often the product of historical contingencies, expansionistic wars, and political compromises. But even if the borders are arbitrary, they may serve a justifiable function (Rawls, page 39). Borders serve to define a territory in which the people may be able to form a representative and effective government. And a territorial government has legitimate functions: to protect the natural environment, to promote the well-being of the human population, to cultivate just political and social institutions, and to deal fairly with peoples in other territories.

But what role should love of country have? In the opening paragraph of *Achieving Our Country*, Richard Rorty writes: "National pride is to countries what self-respect is to individuals: a necessary condition for self-improvement. Too much national pride can produce bellicosity and imperialism, just as excessive self-respect can produce arrogance. But just as too little self-respect makes it difficult for a person to display moral courage, so insufficient national pride makes energetic and effective debate about national policy unlikely. Emotional involvement with one's country – feelings of intense shame or of glowing pride aroused by various parts of its history, and by various present-day national policies – is necessary if political deliberation is to be imaginative and productive. Such deliberation will probably not occur unless pride outweighs shame." (page 3)

It may be that people like me have too little national pride, too little emotional involvement with country. Of course, others have a blind and uncritical attachment. The task is to combine emotional involvement with critical assessment. That's no easy task.

The task is even harder now. When people or countries feel attacked, they are not in the mood for self-examination and self-improvement. Yet most people and countries have a lot of room for self-improvement. My own country has a long way to go to realize meaningful political liberties for all citizens, to achieve active participation in civic life, to provide equality of opportunity, to ensure economic well-being and basic health care for all members, and to develop foreign policies that respond to the real needs and aspirations of others.

### Terrorism and War

After the terrorist attack, classes at my university were suspended, the surrounding neighborhood was closed to traffic, and some student dormitories had to be evacuated. When classes resumed the next week, the students in my ethics class were eager to hear what I had to say about terrorism. I have never felt so inadequate as a teacher. I do not have any keen

insight into the root causes of terrorism or the ethical responses to it. I had some vague ideas about how colonialism, modernization, corruption, the cold war, bad foreign policy, mass media, and fundamentalism all contributed to the growth of extreme Islamic movements. But I didn't have a sound understanding or a clear thesis to articulate. All I had was two small points to make – one ethical, the other historical.

First of all, in speaking to my class, I tried to counter the facile and naïve form of relativism that was implicit in the remarks of a number of expert commentators. Listening to interviews on the radio, I often heard commentators say something like the following: "One man's terrorist is another man's freedom fighter."

What does that statement really mean? I suspect that it is a glib truism, a trivial form of perspectivalism, or a naïve form of ethical relativism. If the statement means that people endorse different causes and disagree about justifications for violence, then the statement is true but obvious. We hardly need an expert to tell us that people disagree about what causes to pursue and how to pursue them. If the statement means that people's judgments and perspectives are often influenced by where they stand, by their experiences and histories, then that statement is also true but rather trivial. We don't need an expert to tell us that.

If the statement means that justifications for violence are merely matters of opinion, then the statement is a very naïve form of ethical relativism. To counter this naïve relativism, and to make room for meaningful discussion, I told my students about Michael Walzer's account of terrorism. In *Just and Unjust Wars*, he writes: "The systematic terrorizing of whole populations is a strategy of both conventional and guerrilla war, and of established governments as well as radical movements. Its purpose is to destroy the morale of a nation or a class, to undercut its solidarity; its method is the random murder of innocent people" (page 197). This account helps to focus attention on several key points.

First of all, terrorism involves the random murder of innocent people. Walzer notes that terrorists ignore the moral difference "between aiming at particular people because of things they have done or are doing, and aiming at whole groups of people, indiscriminately, because of who they are" (page 200). People are killed simply because of their collective identity. They are killed because they are Protestants, Catholics, Israelis, Palestinians, or Americans. They are killed because they happen to be delivering coffee in the World Trade Center.

Terrorists, like all fanatics, ignore moral differences and erase moral distinctions. Because the cause seems so important, anything goes. Whether a particular cause is just depends on complex ethical and political judgments; it is not merely a matter of taste. But even if we assume that a particular cause is just, there are always moral limits. The particular limits may depend on particular situations, but these limits are not merely matters of taste. Everyone is not equally guilty; there are always relatively innocent people, and they are often the ones who are killed.

Another advantage of Walzer's account is that it focuses our attention on the ways that established governments employ terrorism. Walzer makes this point explicit: "Tyrants taught the method to soldiers, and soldiers to modern revolutionaries. That is a crude history; I offer it only in order to make a more precise historical point: that terrorism in the strict sense, the random murder of innocent people, emerged as a strategy of revolutionary struggle only in the period after World War II, that is, only after it had become a feature of conventional war." (page 198)

Many examples come to mind. The biological warfare that the Japanese conducted in Manchuria, the British bombing of German cities, the American fire bombing of Tokyo, the atomic attacks on Hiroshima and Nagasaki – all these targeted innocent people.

Established governments ignored moral differences and erased moral distinctions. They developed and used conventional and nuclear weapons to target innocent people. They also developed and used chemical and biological weapons to target innocent people. The Japanese used biological weapons in Manchuria. After the war, the Americans granted immunity to General Shiro Ishii and colluded with the leaders of Unit 731 in order to secure their results and methods (Harris). During the war, the Americans and British studied and developed ways to produce anthrax bombs. After the war, the Americans experimented with fungi that destroyed wheat and rice crops – even though General Eisenhower had condemned the German military for flooding and destroying agricultural fields in the Netherlands. After the war, and even after the 1972 Biological Weapons Convention, the Soviets worked to develop sophisticated biological weapons. In 1979 more than sixty people died of inhalation anthrax near a research facility in Siberia. And the list goes on. The Iraqis, with their own rationalizations, produced and used chemical weapons.

And then smaller groups adopted the idea of biological and chemical terrorism. The Aun Shinrikyo cult tried to use anthrax and then settled for Sarin. The result: 12 people died and thousands became ill in the Tokyo subway attack in 1995. And now we're all worried, but no one wants to take responsibility. We're worried about groups of terrorists who might be capable and willing to use anthrax, small pox, plague, botulism, tularemia, toxic chemicals, and nuclear devices. Given the way that established governments have behaved, they bear a special responsibility for the state we are in.

### Reflection and Action

The problem I began with, and the problem I still have, is that I wanted to be helpful but I really wasn't. So I responded by reflecting on events and issues – on the state of public health, the spirit of professionalism, the practice of sympathy, the need for communities, the dangers of patriotism, the nature of terrorism, and the conduct of established governments. Of course, one can always say that reflection itself is helpful work. But in my case I'm not so sure.

In its most natural form, reflection is a phase in the course of conduct (Dewey, 1960). What naturally happens is that we are going along, engaged in some activity, when we encounter difficulties; we then pause, disengage temporarily, reflect, and come up with ideas or meanings to put to work in further activity. But my reflections don't seem to find their way back to action. For me, thinking often becomes a familiar resting point rather than a phase in the course of conduct.

I rarely find the right balance, the right relationship between engagement and reflection. I'm not alone. I think the whole society needs to work out a better relationship between reflection and practice. I'll give one example. At one of the hospitals where I work, the director of social work asked me if I would meet with the two social workers who are assigned to the transplant unit. The director said that these two social workers, Kate and Carla, face a lot of ethical issues, especially now that the unit had begun to do more transplants from living donors.

Because Kate and Carla were so busy, a week passed before we were able to meet. When we finally met, we worked together to articulate some of their felt concerns and to focus attention on some of the ethical issues. We even came up with some ways to approach some of the issues. Kate and Carla were very grateful, even relieved. They sensed they were dealing with complex ethical issues, but they never quite had the chance to make them explicit and to try to address them directly.

I thought that Kate and Carla were a bit too grateful – I hadn't really done that much – and I wanted to see how our ideas worked in practice, so I suggested that the three of us meet sometime for lunch for a follow-up meeting. When I saw the hesitancy in their faces, I wondered what I had done wrong. I was just trying to suggest a friendly meeting so we could see

how things were working out. Then Kate explained: "We never have time for lunch. We just grab a sandwich between family consultations."

"Wow," I thought to myself, "what a privileged position I have!" I have so much time to reflect that I spend time reflecting on other people's problems. Indeed, I'm a kind of professional reflector. But there is a great imbalance and unfairness in this system. All workers should have time to reflect on what they are doing and how to do it in an ethically better way. Most people just need a regular time and place, some encouragement, and a little guidance in order to reflect more thoroughly on the ethical issues implicit in their work.

The working lives of Kate and Carla are out of balance, but so is mine. Their problem reflects the larger social problem. My little problem is exceptional, but it is a real problem. I find it so difficult to put reflection into practice that I often stop trying. I just think about the issues we face and try to be kind to people in my daily life. But I need to do better, especially now.

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# Commercial Introduction of Transgenics in developing countries - Some points to ponder

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Slowly transgenics have been finding their way into the agricultural fields of developing countries. After some debate India has approved use of Bt cotton. Planting of transgenics, ostensibly, are reported to reduce the pesticide use and save much money. There are for<sup>1</sup>and against<sup>2</sup> groups on the introduction of Bt crops, which are commercialized now for the control of insect pests in fields. Howsoever the decision of the countries in introducing transgenics may be, there are some points still, on which the world is still debating. Recently the Ecological Society of America has called for greater scrutiny of genetically modified organisms (GMOs) than those of organisms produced by traditional breeding practices citing the risks including creation of new or harder pests, harm to non-target organisms and loss or changes to biodiversity. They lay stress on the need for more peer-reviewed research on the potential environmental effects of GMOs<sup>3</sup>. We hereunder present some of those points that would be useful for discussion and further refinement.

## 1. Bt crops kill only target pests

The world is divided and is yet to come to a conclusion that Bt crops do less harm to the non-target insect pests. In the *Bacillus thuringiensis* toxin spray trials most of insects viz. *Ploidia interpunctella*<sup>4</sup>, *Heliothis virescens*<sup>5</sup>, *Plutella xylostella*<sup>6</sup> are reported to acquire resistance. This kind of resistance cannot be ruled out in case of transgenics. Examples of highly

effective plant pest systems are Bt maize and the European corn borer<sup>7</sup>, Bt potato and the Colorado beetle<sup>8</sup> and Bt oilseed rape and the diamond back moth<sup>9</sup>. However, especially the Bt cotton had come under criticism where in Bt cotton reduction in expression resulted in survival of lepidopteran pests of intermediate Bt sensitivity in cotton fields<sup>10</sup>. Some reports<sup>11</sup> indicate that lepidopteran pests are less or not sensitive to Bt. Most of the publications regarding the non-target insect studies are reported from laboratory trials only. But there is an argument that there may not be a threat to non-target organisms on use of Bt crops. Some are of the opinion that the cotton cultivars with boll specific ICP expression might need the aid of chemical insecticides when pest densities are very high.

## 2. Gene pollution

Even though it is said that there will be no gene pollution, there is a fear that genes may find their presence in the soil, in turn would be taken up by the soil living bacteria, which would find its way into the gastrointestinal tracts of human beings and cattle. A recent report on the presence of tetracycline resistant genes in groundwater as far as a sixth of a mile downstream from swine facilities producing antibiotics<sup>12</sup> can well be considered for transgenics cases. According to the authors, the evolution of genes are there due to use of tetracycline in farms, which are transferred to bacteria that can travel a long distance in the environment. The finding of horizontal transfer of genes in *in-situ* conditions is the significant report in this present context.

Even though they are succumbed to various pest problems, most Bt crops still have antibiotic resistant genes, promoter, terminator and other marker genes like GUS, etc that may lead to various unexpected problems. Some are of the opinion nullifying this as trivial and gene transfer does not happen in nature citing the short half life of the plant DNA, the checks mouted by nucleases in gastrointestinal tracts, restriction enzymes and other digestion enzymes produced by gut bacteria. As the effects are yet to be studied in detail there arises the need to address this in utilitarian point of view.

## 3. Refugia

Scientists recommend the use of refugia while planting transgenics<sup>13,14</sup>. The advantage of 'refugia' discussed are to delay the development of Bt resistance in the target pest population<sup>13</sup>. For Bt maize, in US, refuge areas of 4-30% of non-Bt maize area has been recommended<sup>15</sup>. Scientists have started debating on the percent of refuges required for each Bt crop<sup>14,16,17</sup>. But unlike West and US large areas may not be possible in developing countries where the per capita land availability is less and smallholdings dominate the agricultural scenario. If introduced in the small apportioned fragmented cultivable plots, this may result in the loss of more farmers lives, where the benefactor will be the transgenic planter and the loser will be the farmer planting non-Bt crops surrounding the transgenic plots. In agriculturally dependant developing countries one cannot expect more than 10 acres of solid plantation unless all the farmers in an area are convinced on the advantages of transgenics. If not so, what would be the alternative? This has to be answered immediately. Another case is the planting a transgenic by a small farmer. If farmers with a land of 2 or three acres opt to transgenic and the area of refugia has to be worked out differently to a huge US farm. It was also reported that, the contribution of refuges would depend on several aspects of their management including their proximity to GM crops and the extent to which they are treated with conventional pesticides<sup>18</sup>. Hence a convincing area required for plantation and the set of package of practice for each and every area (Bt crop dominating area, mixed cropping area and non-Bt dominating area etc.) has to be worked out and promulgated effectively for a successful implementation.

## 4. Insect resistance

Insect resistance is a great mishap in any plant crop that is planted as monocrop and in mass scale. In the past, chemical pesticides application had come under attack and the emphasis was implied to the routine and direct use of pesticides in higher amounts. More than 500 species of insects have become resistant to conventional insecticides and there is empirical evidence that they can also adopt to *Bt* toxins<sup>19</sup>. Thus the loss of *Bt* toxin to pest resistance could have significant environmental consequences<sup>20</sup>. Cotton pests selected for resistance to one or more *Bt* toxins include *Heliothis virescens*<sup>21</sup>, *Spodoptera exigua*<sup>22</sup> and *Helicoverpa Zea*<sup>23</sup>. Even in field conditions, a significant number of cotton growers have experienced damage equivalent to control, due to *H. armigera* in *Bt* cotton fields<sup>24</sup>. *Plutella xylostella* has been found to show higher resistance in field conditions<sup>14</sup>. In this line some of questions that can be debated are 1) The half-life of the introduced gene against target insect pests (this will help us to select or introduce a new gene for incorporation before 100% breakdown occurs in field conditions) 2) Their specific targets and implications there upon 3) The remedy if insect breaks down the resistance 4) The consequential pyramiding effects if the insect breakdown occurs, etc.

### 5. Economy

Where farmers find it difficult to afford the cost of traditional seeds and related agricultural practices, it is utmost important to workout economy on using the transgenics and it is also worthier to think the cost-benefit particulars on planting them in large scale. The issue and procurement price, market trend in leniant and flooded market scenario are to be taken into account for a better appraisal. The crop promotion cost should be less when compared to the conventional methods. Some reports say, transgenics (mustard) can yield 20-25% more than average. It is a known fact, most of the farmers in developing countries do not nourish their crops according to the prescription. There needs a fair comparison of proper ecoagrotechnology vs transgenic technology. For successful implementation of transgenics working out of the comparative cost-benefit ratio is a must.

### 6. Environment and health

The soil bound toxins are reported to retain greater insecticidal activity than the free toxin. Reports indicates, binding of *Bacillus thuringiensis* subsp *kurstaki* toxins in the clays, humic acids and clay humic acid complexes, after harvest of *Bt* crops, which reduces their susceptibility to degradation by microbes<sup>25</sup>. These may have ecological effects that need reevaluation under mass scale planting of *Bt* crops.

Allergies are reported to be a predominant problem associated with the transgenics. The Starlink case in US is the best example. The Starlink gene protein found in American taco shells were attributed to cross-pollination or mixing through silos or transporation that had cost the producer, *Aventis* to pay around \$100 million as compensation. Nobody knows the resultant allergy related problems that may crop up on using transgenics in a long run. This needs to be addressed immediately considering the poor laws that support the farmers's cause in compensating the farmers in distressed conditions. In this scenario, these countries must draw foolproof transgenic related laws to monitor and control the producers and protect the end users.

Most of the traditional farmers have the habit of saving the seeds for their future purpose. The most important question to be answered is, what if, if farmers saves and reuses the seeds (the seeds may have been pollinated by pollens from adjacent non-*Bt* crops or through inbreeding and may lose the traits) for further use.

### 7. Traditional vs. Transgenic

Almost all the developing countries lack an organized marketing sector for selling their produce and the grains markets are being controlled by the traders only. With this, the consumers never had the chance of identifying the right preferred quality of grain from these markets. There is also a lack of regulations to streamline the market to function fairly. Recently the spurt is there from consumer societies alerting the public on the right of knowing the quality, origin etc. Given the transgenic contamination in the traditional varieties even in the developed Western markets and US, it may be highly difficult in the developing countries to provide pure transgenic and traditional products separately to the consumers. These countries even do not have sophisticated testing procedures or can employ such sophisticated gadgets for the purpose. Moreover, the US experience says, the contamination is mainly from the cross-pollination in the field from one field to another. Considering the fragmentation of farm plots and poor availability of other resources, it is highly unlikely that we may have pure transgenics or non-*Bt* varieties in plots or markets. This will in a long run ruin the farmers' independency in planting a variety of will, but will force them to take up the dictated varieties only.

### 8. Poverty vs. Science

Most of the economists say, the poverty in the world countries is not due to poor availability of food grains. According to Amartya Sen, the root cause of the famine is not the non-availability of resources of food materials but the inability of people to earn money due to joblessness created by unemployment. It is nothing but the purchasing power of the poor and not the physical shortage of food<sup>26,27</sup>. For example, if the stocks in godowns are considered, India should be largest producer of grains in the world. Against the required minimum stock (as on January 2001) of 16.8 million India has the stock of 45.7 million tonnes, which is roughly three times higher than the requirement<sup>28</sup>. Hence, poverty should not be cited as the only reason, if India like countries prefers to go for transgenics.

When Green Revolution was at full swing, William C. Paddock<sup>26</sup> wrote, "To many the green revolution is a turning point in man's long war against the biological limitations of the earth." Some of his observations include, 1) The new varieties require irrigation, water, fertilizer, and additional labor. All are expensive. For the farmer, this means financial risk that may

lead to debt. 2) To feed the world population requires the use of agricultural chemicals, the pollutants of which will have a deleterious effect on our children and on their children and 3) The governments of hungry nations will once again turn their thoughts away from the No. 1 problem of solving the agricultural and rural problems of their countries and resume their emphasis on pacifying the cities and worshipping the idol of industrialization.

Apart from increased food grain production what we see now, as a consequence of Green revolution, is the polluted dead soils, putrefacted lagoons and river and ocean pollution and alteration of aquatic flora and fauna due to indiscriminate use of pesticides and fertilizers. We must be cautious in our every positive move, that we do not allow one to think that we again rehearse the same conditions due to transgenics introduction. Issues that warrants are input requirements, farmers's financial risk, purchasing power, economy, deleterious effects, and the unknown risk that may accrue in future. One has been pushed to the state of thinking the post introduction pest breakdown and the suitable alternatives. Moreover, the implementation of IPM has also suffered due to economic conditions, availability of resources, availability of small farm plots, varieties used, assorted cropping patterns, that made IPM adoption poor.

Hence, a thorough risk assessment of every GM plant to be released is essential and, in addition, post approval monitoring of natural enemies should also be employed once insect resistant GM plants are grown on a large commercial scale<sup>18</sup>. We suggest, the farming system and farmers' plight, consumers and their awareness and markets also should be analysed for a successful sustained implementation of the Bt crops. In addition, people's perception also plays a great role in deciding a technology to be adopted. New Zealand shows the way for this in obtaining public opinion on introduction of GM, where it has made a broad and well focussed consultation. The Royal Commission established by New Zealand on Genetic Modification as applied to research, medicine and agriculture<sup>29</sup> is a new line of thought in this direction. This will help the countries to face the immediate challenges on introducing the transgenics. This kind of surveys and commissions also can be instituted at least to make aware of the public and to draw more consultations from various groups from their own country.

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## To what extent should Animal cloning be Permitted?

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### Introduction

In 1996 the birth of 'Dolly', the first mammal cloned, has opened discussions among biologists and the public about the desirability of such a technology (Terragni 1999, Dijck 1998). The public has played a decisive role in decisions associated to cloning both in the US and Europe (Simon 1999). This is surprising when we think that cloning was not a new technology. The first experiments of nuclear transfer with amphibians (*Rana pipiens* and *Xenopus laevis*) were performed in the United States and Britain during 1950s (Gordon & Colman 1999: 743-746) to study the irreversibility of the modification of genetic material of differentiated cells from adult animals. Nuclear transfer experiments were performed in amphibians in the 1960s, in mice in the 1970s, in sheep in the 1980s, and in monkeys in the 1990s. They have provided evidence that fully differentiated somatic cells retain all the genetic material of the early embryo, and that differentiation is almost entirely achieved by reversible changes in gene expression.

In this paper I will deal with implications arising from animal cloning. It is not my intention to minutely report the history of cloning (see Gordon & Colman 1999:743-746) or to analyse legal implications that such a technology may involve. Here I will explore is both the biological and ethical implications that animal cloning may rise if performed in animal breeding programmes.

### Dolly Superstar

'Dolly' is a well-known name among scientists. She is the first mammal to develop from a cell derived from adult tissue (1). Dolly derived from cells that had been taken from the udder of a 6-year old Finn Dorset ewe and cultured for several weeks in a laboratory. These cells were then fused with unfertilised eggs from which the genetic material had been removed. Biologists cultured 276 of these reconstructed eggs' for 6 days in temporary recipients. Twenty-nine of the eggs that appeared to have developed normally up until the blastocyst stage were implanted into surrogate Scottish Blackface ewes. Dolly's birth drafted a revolutionary way for producing engineering animals. In fact, the normal sexual reproduction (the fertilisation of an egg by a sperm and the inter-parental chromosomes fusion) was substituted with a reproductive system by which "DNA is removed from an unfertilised egg and the egg fused with a diploid cell containing a full set of paired chromosomes"

(Wilmot, April 1997). Successively, the obtained eggs had been implanted in a surrogate mother, in whose womb they developed into lambs (2).

The successful experiment performed by members of the Roslin Institute offered a new technique for producing genetically modified animals. Instead of pronuclear injection, which leads to the production of 2-3% of transgenic animals, the nuclear transfer technique leads to an easier and more successful production of GM animals (3). To summarise, Dolly's birth has achieved the following scientific goals: (1) The complete genetic material from an adult mammalian cell has been used in the development of a new individual for the first time; and (2) donor cells, induced to exit the growth phase and become quiescent before being used for nuclear transfer, are more susceptible to reprogramming by the recipient egg cell and result in the normal development and birth of cloned offspring (Wilmot et al. 1997).

After the successful experiment with Dolly, several laboratories have begun to work on different applications of animal cloning. In 1997, Dr. Pennisi announced the cloning of a transgenic lamb (*Polly*) cloned from cells engineered with a marker gene and an undisclosed human gene. Dr. Pennisi's experiment showed that "foreign DNA can be introduced to a genome without disrupting the genetic interactions that guide a lamb's development" (Pennisi 1997). Successively biologists have also begun to clone goats, cattle (4) and monkeys (see Revel, 2000:43-59). Currently a number of experiments are taking place to check whether all animal species are clonable (Cohen 2000:4).

#### Why clone animals?

According to the Roslin Institute in Edinburgh animal cloning can achieve a number of scientific goals: 1) Human therapeutic proteins; 2) Organs and tissues for transplants; 3) Nutraceuticals; 4) 'Humanised' cows milk Animal models of disease; 5) Cell therapy agents. In April 1997, Dr Wilmot has summarised the applications of animal cloning as follows:

#### Applications in Medicine

Human Therapeutic proteins	Transgenic sheep, goats and cattle can be used as bioreactors to produce human protein in milk (for example: alpha-1-antitrypsin). Cloning could reduce the number of animals needed for creating a transgenic line
Xenotransplantation	NTT could lead the production of pigs in which pigs' proteins inducing rejection are removed and replaced by their human counterparts.
Nutraceuticals	NTT ought to produce transgenic cows producing human proteins
Animal models of disease	Transgenic animals can be produced by using different animal species than the used ones. This extension might allow the creation of better models for testing treatments for human pathologies
Cell therapy	NTT could solve immune rejection problems. We could use cells removed from a patient and successively reintroduce the patient's cells (bioengineered) in the organism

#### Applications in Biological Research

Ageing & Cancer	NTT avoids DNA replication's mistakes – somatic mutations- and subsequent ageing and cancer processes
Alternatives to Embryo Stem Cells	Embryo stem cells have only been recovered from two specific strains of mice (and not from any livestock species). Nuclear transfer would allow gene targeting in other strains of mice and in other laboratory species such as rabbits and rats.
Cloning	The ability to produce large numbers of genetically identical animals would have important benefits in experimental design. The advantages of genetic uniformity have been

amply demonstrated in studies with inbred lines of mice. Nuclear transfer from cultured cells could provide alternative approach in species where repeated inbreeding is impractical or prohibitively expensive.

#### Gene Targeting in Farm Animals

Improving Transgenic Animal Production	NTT can substitute a procedure called 'pronuclear injection'. The limits of this technique were: 2-3% of GMOs are transgenic, only a portion of transgenic animals completely express the modified exogenous DNA.
Opening new Possibilities	NTT opens the possibility of specific genetic manipulations that are currently impossible, such as the substitution of a single base in DNA (typical of many human genetic diseases)

These potential applications of the nuclear transfer technique show that both medical research and industrial biotechnology have an interest in animal cloning. In this paper, however, I will focus on animal cloning for breeding program purposes.

The extremely high similarity between clones' genotypes, in fact, would allow manufacturing organisms having improved strains of livestock. One of the major benefits of cloning, then, is the possibility of creating populations of genetically determined organisms responding to the needs of both the animal breeding industry and the research community.

#### Biological implications of cloning

Contrary to the common perception, a clone is not a carbon copy of its ancestor. Gene plasticity, environmental factors, and neural topography structures differentiate clones from their parents. Even if clones have a high genetic similarity compared to their parents, the claim that a clone is a carbon copy of another individual is biologically false and it refers to genetic determinism (5). A number of biological factors deny the claim that clones are carbon copy of their ancestors (Revel 2000): 1) Dolly's mitochondrial DNA comes from the egg donor (usually mitochondrial DNA comes from the mother); 2) Dolly's immune system genes are not developed at the embryo stage (Dolly has a different immune system from her mother).

The above mentioned differentiation-factors are reinforced by the influence that environmental factors have towards the phenotypic expression of a genotype. "Phenotypic identity requires identity between genotypes, which cloning can ensure, and identity between environmental interactions, which it cannot ensure." (Eisemberg, 1999). A cloned DNA, thus, will express differently in the phenotype of different clones. Nevertheless, the similarity between two clones is so high as to show two identical individuals. This coincidence is only apparent, since two clones have a range of constitutive qualitative dissimilarities (Kolata 1998).

In 1997, Hubbard has explained in an editorial published in *The Nation* (1997) the non-coincidence of cloned individuals. He underlined that "Dolly has the same DNA (or genes) in the nucleus of her genes. But, although embryologists have a way of forgetting it, an egg is not an empty bag containing nothing but a nucleus, transplanted or not. Eggs also contain structural and metabolic equipment, including a complement of extranuclear DNA specific to that individual. The second ewe did not contribute her nucleus, but she did contribute the rest of contents of her egg. The reconstituted egg was than gestation in the uterus of yet another ewe. Dolly is, indeed, a nuclear DNA clone, but there is more to life than DNA for sheep."

Biologically speaking, animal cloning involves a number of implications (6). We may distinguish two levels of implications: implications for the cloned organism (individual specific consequences) and implications that such a technology may cause at a species-specific level. Let us start with the first kind of implications.

Scientists observed that the mortality of clones is high. Currently, 50% of clones perish during pregnancy (perinatal mortality). This abnormal perinatal mortality rate may suggest that cloned individuals have physiological weakness (7) (Cohen 1998:4). Another implication of cloning refers to sexual reproduction mechanisms. A clone develops from a cell derived from an adult tissue. It is not resulting from a chromosomal fusion (maternal / paternal chromosomes) but it derives from a cell of only one organism. As such, clones are anomalous biological individualities since their genotype is a copy of the nucleus of a donor.

In parallel, clones do not have a definite age and we cannot say what parental relation exists with their genitor. As Wilmut noted "One of the more interesting questions about Dolly concerns her age. As far as her DNA goes, is she one year old or seven? And will she age prematurely? The premature death of a number of clones seems to suggest that biologically speaking clones' biological clock runs faster than other animals (Cohen 1999).

At the species-specific level cloning leads to a number of biological implications (ecological and evolutionary implications). The first consequence of cloning would be the impossibility to foresee the long-term consequences that may arise from the use of such a technology. The affirmation of bioengineered gene pools, in a repetitive number, could interact with mechanisms of population genetics by causing the affirmation of specific allelic frequencies that may lead to epidemics or deleterious outcomes towards the Natural evolution (adaptation). We have no ideas about consequences that such a pressure on the Natural evolution may cause. As Eisemberg has said, "genetic homogeneity is compatible with adaptation to a very narrow ecologic niche; when that niche is perturbed (...) extinction may follow" (Eisemberg 1999:472). Thus, cloning may cause an increase of pathogenic gene frequencies at a population level or the loss of adaptive capacities.

In parallel, a massive use of cloning may seriously damage biodiversity. The continuous mix of genetic data via sexual reproduction is a basic mechanism of natural evolution. The possibility of continuously recombining genetic data allows adaptive processes (Gordon 1999). Biologically speaking, the advantage of biodiversity is without controversy. The primary source of genetic variations in living beings is genetic mutation 'and' cell division. The first one creates new genetic information that will be naturally selected over time. The second one reshuffles the random genetic changes created by mutations. Clearly a large-scale use of cloning may affect biodiversity and favour the consolidation of specific allelic frequencies at a population level having a negative impact towards the natural balances. Seen in this light, cloning is intrinsically hazardous.

To summarise, cloning causes a number of biological problems:

1) *Clones are not the carbon copy of their parents, but they have an unnatural similarity rate with them so high as to distort the population concept.* Members of a population are reproductively isolated from the others. This clause refers to species-specific similarities (genetic and phenotypic similarities) making the reproductive apparatus of species-specific individuals compatible. However, the reproduction-condition among members of a species does not involve their genetic coincidence. Cloning is biologically problematic since it may distort the species-concept.

2) *Clones can reproduce and start a cascade of events by which a modified gene lineage could be artificially consolidated at a population level.* Evolutionary mechanisms could be completely affected by cloning. Humans could cause the affirmation of gene pools that do not respond to adaptive mechanisms. Clearly, we have no ideas about the evolutionary response to these pressures. Subsequent mutational factors could consolidate gene frequencies (at a population level) that are different from the desired ones.

The above mentioned factors show that cloning is biologically problematic. Nevertheless, we should be aware that these implications concern also other applications of animal genetics (for example, transgenic animals or chimeras). Consequently, I claim that cloning does not posit different ethical implications than the ones of transgenic animals and chimeras. To what extent are we allowed to interact with the Natural evolution to create new-organisms responding to human needs? Are we under the obligation to consider unforeseeable long-term consequences of bioengineering Life as a 'reasonable risk to pay' in the name of the human progress (or economic benefits)?

### Animal Cloning

To date, a number of research institutes perform animal cloning experiments every day all across the globe. This means that this application of animal biotechnology has been considered morally legitimate. This is because, as I have already said, one of the main benefits of animal cloning is the more rapid dissemination of genetic progress from elite herds to the commercial farmer. Thus, animal cloning constitutes an ideal tool to optimise both the cost/benefit model and the effectiveness of animal breeding programmes. Let us start to analyse the ethical legitimacy animal cloning by considering the benefits that such a technology may bring forward.

According to Woolliams "The basic benefit for the biotechnology industry of cloning will (be) ... that it will lead to a high optimisation of engineering organisms' production. (...) Cloning could substitute artificial insemination and embryo transfer in breeding programmes. Farmers could receive cloned embryos of the most productive cows of elite herds. Biotechnology industries could create catalogues that describe the genetic merit of cloned organisms, their fertility, health and longevity (8) (Woolliams 1997)".

The first objection to the ethical legitimacy of Woolliams' hypothesis refers to the effectiveness of cloning. The mortality rate of cloning is high. (1 out 277 tries to clone Dolly.) At the present, both the percentage of implanted embryos that had a full-term development (2.5%, due to failure of genomic reprogramming or imprinting –Revel, 2000:45) and the incidence of perinatal mortality, make this technology really inefficient. However, although this ineffectiveness seems to impede the use such a technology in human genetics (human reproductive cloning), it does not represent a significant obstacle to obstruct animal cloning. We can assume that, in a future, animal cloning will be more efficient (Gordon & Colman 2000:743-746). Or we can argue that other techniques used in animal biotechnology (pronuclear injection, for example) do involve a high mortality rate as well (in transgenic animals production 95-98% of genetically modified embryos are usually damaged and only 2-3% of the animals born are transgenic). According to this, as we accept the high mortality rate of producing transgenic animals, we should not think of this side effect of cloning as a relevant problem. Otherwise we should be in opposition to both animal cloning and transgenic animals production for safety reasons.

From a philosophical point of view, the capacity to better derive live animals from cultured cells may be considered as a pro cloning argument. In fact, as we think ethically legitimate the production of transgenic animals in both animal industry and research, we should claim the usability of animals in the fields of animal cloning as well. We have seen that animal cloning can increase the effectiveness of transgenic animals production (9). As such it might be accepted by animal rights advocates as a way to decrease both the mortality rate of animals used in research and animal suffering (clearly in the respect of the animal welfare clause). Ontological approaches to the animal rights issues (Regan's theory, for example), should lead to similar conclusions as well. If animals have an intrinsic value (or a moral status as *subjects-of-a-life*) the production of newborn organisms (clones) should be considered legitimate in itself. Particularly in those cases where clones inherit a healthy

genotype that has not been modified to cause animal suffering (phenotypic expression of the cloned genotype). What arguments can we provide to discuss animal cloning, which differ from the ones posited to discuss the ethical implications of producing transgenic animals?

Can we say that two transgenes have a different moral status than two clones? Why? What difference would diversify the moral implications arising from the production of a transgene via pronuclear injection compared to the ones arising from animal cloning?

Cloning is only a technique! The ethical legitimacy of such a technology refers to the conceptual reasons by which biologists and regulatory bodies have justified the moral legitimacy of producing transgenic animals. This does not mean that animal cloning is ethically unproblematic. It simply means that the moral implications of animal cloning can be equated with the ones of manufacturing transgenic animals. Those philosophical theories that do not accept the instrumental use of animals for human purposes will automatically oppose animal cloning. On the contrary, those views that admitted such a use of animals will consider animal cloning as ethically legitimate.

In my opinion, the main problem of animal cloning refers to the ethical legitimacy of using animals for human purposes. And also in this case, my response to this puzzle does not differ from the one I have claimed elsewhere (Salvi 2001): animals are moral entities, but we can instrumentally use them in a restrictive way (in those cases in which the expected goals are so good to justify the use of animals, no alternatives are available and both the number and the suffering of animals is minimised). Then I do not oppose animal cloning, but I wonder whether we really need to clone animals. Industrial applications of cloning do not justify animal cloning, since already existing technique used in animal breeding programmes could be used to have improved strains of livestock. On the contrary, research applications of animal cloning having a clear and well-documented scientific goal (for example to explore the chemical process inducing specific cell differentiation of ES cells), should be allowed when no alternatives are available. This is not because animal cloning is ethically legitimate from a moral point of view, but simply because the value of the expected scientific goal is higher than the one of other industrial applications of animal breeding. Therefore it is the relevance of expected goal that reflects on the ethical implication of animal cloning and not the value attributed a priori to such a demonised technology (a value that does not exist to me).

I do know that some people will stress the relativity of the weighting system used to define the goodness of the chosen scientific goal. But I do think that people would accept that a clinical (or research) trial regulated by good clinical (or research) practice protocols and scientifically justified as the only tool to explore a scientific avenue which otherwise could not be followed, is not equivalent than an application of animal cloning performed to have a easier production of, say, goats with liver dysfunctions to produce higher quantity of 'pâté de fois gras'.

As I have said, we do know that cloning is a *technique* of molecular biology performed from long time. And we do also admit the possibility of animal experimentation for research purposes (regulated by 3Rs and animal welfare). Then, I do not see arguments to allow animal applications of other routine techniques of Natural sciences (such as the production of transgenic animals for research purposes) and reject cloning. If we follow the anthropocentric view that legitimates the first conclusion, we then should extend this claim to animal cloning as well. This means that I do disagree with the claim that both animals and human beings occupy the same position into a moral taxonomy. To me both the biological (linguistic and cognitive capacities) and the socio-cultural (human beings as moral-community makers) features of human beings justify the prevalence of human beings in a moral taxonomy and deny biocentric ethics. But this does not imply that I deny the moral status of non-human beings. It simply means that since human

beings define the moral relevance of the actions they do animal cloning needs to be absolutely unavoidable and strictly regulated. And, following this line of reasoning, I do not see moral arguments to oppose to animal cloning for research purposes but I also do not see any reason to accept cloning as a technique to use in animal breeding programmes when the expected goals are oriented only to maximise and accelerate the animal breeding industry- oriented process.

#### Notes

- 1) The invention is covered by two patent applications filed by Roslin Institute (Edinburgh) with a priority date of 31st August 1995: PCT/GB96/02099, entitled *Quiescent cell populations for nuclear transfer* and PCT/GB96/02098 entitled *Inactivated oocytes as cytoplasm recipients for nuclear transfer*. Roslin Institute (Edinburgh) does not expect any granted patents to issue for at least another 2-3 years.
- 2) The innovation of the nuclear transfer technique (NTT) was the use of unfertilised eggs and their fusion with a cell that contained the genetic endowment of only one organism.
- 3) "In cloning procedures generally, nuclei are extracted from cultured cells that might have come originally from an embryo, a fetus or an adult organism. The nuclei are inserted into egg cells which have had their original nucleus removed, a process called nuclear transfer. In the initial work at the Roslin Institute, the egg cells along with their transplanted nuclei were then implanted directly into a foster mother, where they developed and, in the case of Dolly, resulted in a viable offspring." (<http://www.sciam.com/explorations/090297clone/beardsley.html>).
- 4) The NTT technique is actually used in Denmark and Australia to clone cattle (Viborg Laboratories of Denmark's National Institute of Animal Science, and Monash University). The Danish team is using genetic material from dead cows. They emptied oocytes of their DNA, take adult cells from cows' ovaries, they fuse the empty oocyte with the empty cells and finally implant the obtained blastocyst in a surrogate cow. On this topic see Coghlan A., *New Scientist* 17, January 1998.
- 5) "Yet it seems clear that some of these concerns, at least, are based on false beliefs about genetic influence and the nature of the individuals that would be produced through cloning. Consider, for instance, the fear that a clone would not be an "individual" but merely a "carbon copy" of someone else -- an automaton of the sort familiar from science fiction. As many scientists have pointed out, a clone would not in fact be an identical copy, but more like a delayed identical twin. And just as identical twins are two separate people -- biologically, psychologically, morally and legally, though not genetically -- so, too, a clone would be a separate person from her non- contemporaneous twin. To think otherwise is to embrace a belief in genetic determinism - - the view that genes determine everything about us, and that environmental factors or the random events in human development are insignificant." (Wachbroit 1997)
- 6) A biological implication of cloning is that it has revolutionised the concept of totipotency. At present, we cannot think of germ cells as the 'only' totipotent cells anymore because NTT allows somatic cells to originate a new organism. (ES cells have this capacity as well.) In the light of this, we can think of totipotency as a capacity to differentiate into nearly any cell type.
- 7) This mortality rate may decrease in a future when biologists will get a better understanding of what determinants cause the death of clones during pregnancy.
- 8) They could choose the sex of the embryo (male for beef and female for milk) and would be guaranteed a genotype of proven performance in either low or high input systems. The cloned embryo would be delivered to the farm in much the same way as semen straws are today, perhaps from breeding companies based overseas. (John Woolliams, *Cloning in farm animal production*, 1997, RIO)
- 9) The claim the cloning does involve a high mortality rate would offer a strong argument against cloning. However, new discoveries of biological sciences (the possibility to use embryonic stem cells rather than eggs -*New Scientist*, 29 January 2000) can offer technical solutions for this problem.

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## Human Cloning – A Reaction to Verma

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In his commentary Prof. Verma (see the January 2002 issue of *EJAB*) pointed out an aspect, which is of paramount importance for the further discussion on reproductive human cloning. His reflections refer to the question whether cloned human beings would be exposed to the risk of discrimination so that human cloning could lead to a violation of human dignity. However, one should make a distinction between three initial positions. First of all, the existence of cloning techniques as such cannot disobey the rights of future human beings, as law only empowers existing individuals. Secondly, in case a human clone already exists, it must be clear that he or she is a full member of mankind, i. e. protected by all human rights. Third, as any discrimination requires public's knowledge of the fact that he or she is a clone, confidentiality in view of the medical treatment is a crucial condition to avoid discriminatory acts.

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## German Parliament Paves the Way for Embryonic Stem Cell Research

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Human Stem Cell research, i. e. research on cells which possess the capacity to differentiate into cells of different degrees of specialisation, is one of the most promising fields of modern medicine. However, in many countries, the legal status of stem cells remains uncertain. Last year, President *Bush* of the United States voted for a public funding of research on existing stem cell lines. As a result, private programmes are not restricted in any way, although opponents insist on their point of view, according to which any kind of embryonic stem cell research leads to a violation of human rights, especially human dignity. In December 2001, the Ethics Committee of the Japan Society of Obstetrics and Gynecology approved a revision to its

guidelines to allow the use of supernumerary fertilized eggs to obtain stem cells. Israel allows human stem cell research too, as the Jewish religion does not qualify stem cells and embryos as human beings.

Now, on 30 January 2002, after the so-called Study Commission on Law and Ethics in Modern Medicine as an interface between politics and science submitted its first report on the issue (1), the German Parliament (Bundestag) made its decision on stem cell research. In a free vote, the Members of Parliament had a choice of three inter-fractional motions.

The first proposal (2) aimed at a total ban of production and import of human embryonic stem cells and called for an improved promotion of "ethically harmless" alternatives, i. e. research on adult stem cells or animal stem cells.

The second draft (3) followed a conciliatory approach. In general, it emphasized the therapeutic potential of human stem cell research. Nevertheless, as the end does not justify any means, the prohibition of the production of human embryos to obtain stem cells should maintain. On the other hand, the import of human embryonic stem cells should be allowed as an exception if the following six requirements are fulfilled: A lack of research alternatives (e. g. research on adult stem cells) calls for an import of embryonic stem cells; the import is restricted to stem cell lines which already exist; the embryo's parents' informed consent must be obtained; the research purposes must be high-ranking; the ethical acceptance has to be examined by a high-level ethical committee; an authorizing authority must license the import.

The third motion (4) underlined the freedom of science and the interest of future generations' in the development of new medical treatments. Therefore, the import of embryonic stem cells for research projects examined by a scientific and ethics committee should be allowed. In case that research on imported stem cells does not lead to the expected progress, the legislator should take additional measures into consideration.

On the first ballot, none of the three proposals achieved the necessary majority: 263 MPs called for a total ban, 226 MPs - including Chancellor *Schröder* - supported the mediatory approach, and only 106 MPs favoured an unrestricted import. On the second ballot, the third motion dropped out and majorities changed. 340 representatives pleaded for the possibility of a restricted import, 265 delegates voted for an absolute ban. The prevailing point of view serves as a draft bill. The new law regulates public research as well as private research projects and shall be enacted within the next few months.

In general, the Parliament's decision is to welcome as it paves the way for an outstanding and very promising field of technology which has the potential to help millions of peoples suffering from various and very serious diseases. Nevertheless, the mediatory approach seems to be inconsequent and too narrow. The solution described above gives the impression that Germany wants to participate in the advantages of stem cell research without carrying the burden of producing stem cells itself. The Parliament's decision tries to respond to this reasonable doubts by restricting the import to stem cell lines which already exist. However, this does not alter the fact that even if stem cell lines already exist, they do not come from out of nowhere. Hence, although the German legislator considers the production of embryonic stem cells unethical und unlawful, it wants to benefit from such creations which have taken place in other countries.

Another objection refers to the suggested handling of supernumerary embryos, i. e. embryos produced in connection with in-vitro fertilisation which are left unused after fertility treatment. These embryos are doomed to die: Sometimes, they are destroyed by means of introducing pure alcohol, but usually, they are left deep-frozen until devastation. The draft bill fails to explain the necessity to protect these embryos from scientific measures. Certainly, it would be too simple to justify research on supernumerary embryos just because their death lies ahead.

Otherwise, one could even justify research measures on fatally ill adults. However, the relevant difference is that in case of supernumerary embryos death is the only reason for their existence. In an oversubtle wording: They live to die. With this in mind, scientific research on supernumerary embryos is at least worth considering.

In all, Germany did a first important step towards an improvement of scientific outline conditions (5), which aims at catching up with international developments. Only one day after the Parliament's decision, the Deutsche Forschungsgemeinschaft, which is the central public funding organization for academic research in Germany, announced to support research projects using imported embryos. However, it is uncertain whether the adopted motion really manages to adjust the regulation of scientific work to the international level. As already mentioned, the United States abstain from any regulation concerning private scientific research on human stem cells. Japan adopts the same course, and in the United Kingdom the Lower House and the House of Lords last year both voted to adjust the Human Fertilisation and Embryology Act regulations to the demands of modern human stem cell research (6). The German approach clearly falls behind these efforts to encourage scientific progress.

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- 1) For an English summary: [http://www.bundestag.de/gremien/medi/medi\\_2zwisch.html](http://www.bundestag.de/gremien/medi/medi_2zwisch.html) [31.01.2001].
- 2) German Parliament, Printed Matter No. 14/8101, 29.01.2002.
- 3) German Parliament, Printed Matter No. 14/8102, 29.01.2002.
- 4) German Parliament, Printed Matter No. 14/8103, 29.01.2002.
- 5) In view of the economic dimension, difficult questions arise from patent law, cf. Spranger, Patentability of Human Stem Cell Procedures in Accordance with EC Law, [2002] 11 European Intellectual Property Review.
- 6) 2001 No. 188, Human Fertilisation and Embryology, The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 (made 24<sup>th</sup> January 2001; coming into force 31<sup>st</sup> January 2001). In compliance with these provisions, so-called therapeutic cloning is permitted with careful monitoring, cf. *Civin*, Stem Cell Research: Back to the Future, [2001] 19 Stem Cells 356.

the Bali concept. In Sanskrit "mana" refers to inherent tendencies or desire or drive.

The following "shlokas" from Bhagwat Geeta, a sacred Hindu scripture in Sanskrit, will help in bringing out the meaning of "mana". The "shlokas" are being cited here in a translated form, and the authors are well aware of imperfection in the translation.

#### Chapter 6, Shloka 33. (Arjun speaks to Krishna)

*O Krishna, you have just said about "yoga", but I find it impractical, as "mana" is mercurial and unstable.*

#### Chapter 6, Shloka 34. (Arjun continues)

*"Mana", besides being unstable, is very strong and unbending. Hence to control it is as difficult as to control wind.*

#### Chapter 6, Shloka 35. (Krishna says in reply)

*O great warrior, undoubtedly "mana" is mercurial and very difficult to control. But, through practice and "vairagya" (= detachment from worldly pleasures and relations), harnessing of "mana" can be achieved.*

#### Chapter 6, Shloka 36.

(Krishna continues)

*If a man does not have his "mana" under his control, for such a person "yoga" is very difficult to attain. On the other hand, if a person keeps his "mana" under check and makes efforts, he can attain "yoga" quite easily.*

In these shlokas it has been pointed out that internal desire or inborn urges should not be allowed to be expressed in behaviour without rational screening, if one is trying to attain a healthy state of body and mind or "yoga".

## Genotype and Mana

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An extensive paper on this topic has recently appeared (Fleising, 2001). A parallel between DNA FUNCTIONING and "MANA" was first pointed out by Firth (1940). The present communication is about reexamining this parallel, keeping in view the original Sanskrit meaning of "mana".

#### What is "mana"?

Fleising (2001) has based his discussion on the meaning of "mana", as understood in Bali (Indonesia), and as described by Geertz (1980). According to this meaning "mana" refers to a special power or capacity present in a dominant and strong person, who generates respect as well as fear among the people around him, such as a tribal chief. This power has far reaching effect on conduct and behaviour of the person.

"Mana" as well as some other words, like "sekti" and "murti" mentioned by Geertz (1980), have been obviously inherited by the Bali people from Sanskrit, which was the language in the Indian subcontinent in ancient times. Much of the Bali mythology has its roots in the Indian mythology. But the meaning of "mana" in the parent language Sanskrit is considerably different from

**Analogy between genotype and “mana”**

Some notable analogy may be made out between the Sanskrit “mana” and genotype. The following is an attempt in this direction.

The entire set of genes or genotype includes all the genetic potential possessed by an individual, but all of it does not find expression in the phenotype. This is partly because of genetic dominance and epistasis, and in part due to effect of environment. Monozygotic twins have identical genotypes, but if one of them suffers from iodine deficiency in his/her diet, he/she will not grow up normally like his/her sibling. In fact it is a fundamental concept of the present day genetics that the genotype interacts with the environment to produce the observable characters or the phenotype.

Now let us turn to “mana”. As has been noted earlier, the Sanskrit “mana” refers to inherent urges or tendencies. A person normally does not give expression to all his urges and tendencies, because he has learnt from his cultural environment (constituted by his parents and other family members, his friends, his teachers, his religion and his society in general) that some of his urges may be harmful to the society or to himself, if expressed as such.

From the above discussion an analogy between “mana” and genotype may be readily made out, namely that in either case, because of interaction with the environment, the full potential does not find expression in observable features or behaviour.

This analogy, however cannot be reasonably stretched further. “Mana” is concerned with behaviour, whereas genotype controls development of various characters, including those of ontogeny, morphology, physiology, behaviour, ecological preferences etc.. “Mana” is related to consciousness and when consciousness appears in a human foetus is not known. Genotype, on the other hand, is functional throughout the lifetime of an individual right from the moment of zygote formation. Genotype is a scientific term, and it cannot be separated from its biological meaning. “Mana” has a spiritual aspect. When Fleising points out that the analogy between D.N.A. and “mana” is “demonstrating the resemblance of a scientific inference to a religious entity”, one has to agree with him.

In conclusion of the present discussion it may be said that development of behavioral pattern is influenced and modified by the environment in a developing human individual at two different levels, namely at the genotype / phenotype level and again at the “mana” level. This situation improves the chances of producing well adjusted and useful members for the intricate human society.

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**Commentary on Verma and Saxena**

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Verma and Saxena’s paper on the analogy between “mana” and genotype is stimulating. Probably a similar argument could be applied to our “human nature”, that philosophers have contemplated for centuries. This suggests that our “human nature” has some close relations to our genes, which has been the main argument from recent evolutionary sciences.

My question is: what happens if we apply our knowledge of genes to the concept of “mana”? For example, our DNA is modified and a new set of genes is created when an egg and a sperm meets. Do similar things happen to “mana”? Is it possible that one’s “mana” will get mixed with some other’s one and create a completely new “mana”? What about the natural selection of “mana”? When the phenotypes of a certain group’s “mana” is more adequate to the environment than other groups’ phenotypes, then, what happens? The evolution of “mana,” or the shift in the “mana”-frequencies in a population occurs?

The relationship between “meme” and “mana” also comes to my mind. Anyway, thank you for your thought-evoking article.

**An Essay on the Principle of Informed Consent versus the Significance of Trust for the Subjects of Biomedical Research [1]**

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**Introduction**

In this essay I will give a survey of the background, justification and meaning of the principle of *informed consent* and evaluate the significance of *information* (i.e. disclosure and understanding) versus *trust* for the subjects that give their consent to participate in medical research projects. The first part will be a general disclosure of the background, justification and meaning of the principle of informed consent. This will make up the major part of the essay. In this part I will mainly rely on the *Principle of Biomedical Ethics* (4<sup>th</sup> ed.) by Tom L. Beauchamp and James F. Childress.[2] My references will also be to the *Nuremberg code* and the World Medical Association’s *Declaration of Helsinki*. [3] In the second part, I will give a summary of an article presenting some of the results of the Advisory Committee on Human Radiation Experiments’ *Subject Interview Study*. [4] which I believe are of great relevance to the subject matter. Finally, against this background, I will try to give a short evaluation of the significance of the aspect of disclosure

and understanding *versus* the aspect of trust in the process of subjects giving their consent to participate in medical research trials.

The background, justification and meaning of the principle of *informed consent*

The Principle of informed consent is stated in *the Nuremberg Code* as follows with regards to permissible medical experiments: "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." [5] The World Medical Association likewise states in *the Declaration of Helsinki* that "In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participate at any time. The physician should then obtain the subject's freely-given *informed consent*, preferably in writing." [6] These two quotations are a documentation of the fact that the development in biomedical research ethics has taken a new turn in the second half of this century. [7] This new turn is partly due to the experiments of *the nazi-doctors* during the Second World War, but it also has to do with the disclosure of a continuing violation of human rights in the name of medical science in the decades thereafter. [8] The following survey of the meaning of, and the relation between, the three principles of *respect for integrity*, *respect for autonomy* and *informed consent* may illustrate what this new turn in biomedical ethics is all about, and provide an understanding of the *justification* and *function* of the principle of informed consent in medical ethics and medical research ethics regarding research involving human subjects.

### Integrity, autonomy and informed consent

A definition of the principle of informed consent will be given later, together with a survey of the meaning and different elements of informed consent. At this point, I will focus on the meaning of the principles of respect for *integrity* and *autonomy* and the relation between the two principles and the principle of informed consent. This means that I will focus on the *justification* of the principle of informed consent. The *principle of respect for integrity*, as I intuitively conceive it, has to do with the idea that each human being is unique as a person, and that each human life therefore is of unique value and therefore must not be violated or humiliated in any way, and the basic principles of the Declaration of Helsinki, expresses this principle in the following way with regards to medical research involving human subjects: "The right of the research subject to safeguard his or her *integrity* must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental *integrity*, and on the personality of the subject." [9] However, we may ask what this word "integrity" really means?

In Webster's Encyclopedic Unabridged Dictionary, we find the word *integrity* explained in the following three ways: (1) soundness of and adherence to moral principle and character; uprightness; honesty; (2) the state of being whole, entire, or undiminished; and (3) a sound, unimpaired or perfect condition. [10] A much similar explanation is found in The Oxford English Dictionary. [11] This means that the word *integrity* may be used with reference to at least three different notions. However, not all of them are of relevance to the principle of informed consent in medical ethics, as we shall see. E. D. Pellegrino describes *the relevant meaning* of the word integrity for medical ethics, as follows: "Integrity has two senses of

significance for medical ethics. One sense refers to the integrity of the person, of the patient, and of the physician; the other refers to being a person of integrity. In the first sense, integrity is a moral claim which belongs to every human simply by virtue of being human. In the second sense, integrity is a virtue, a moral habitus acquired by constant practice in our relation with others. Integrity belongs to all persons as humans, but not all are persons of integrity. Each sense of integrity has important implications in medical ethics." [12]

It is the first of Pellegrino's two notions of integrity (i.e. the notion of integrity as a *moral claim* which belongs to every human simply by *virtue of being human*), that is of importance for the justification of the principle of informed consent. This indicates that a person's integrity has to do with his or her *dignity* as a human being: What ever violates our experience of dignity, and perhaps also other people's conception of it, also violates our integrity. Of course, there is a difficulty in explaining in more detail what this mean, but even though we may not be able to give a full explanation of the essence of the *concept* of integrity, it is still possible to get an adequate understanding of the *principle* of respect for integrity, merely by focusing on examples of what kind of actions that may violate a person's integrity. It has, for instance, been pointed out that a person's integrity is linked to his *identity*, and that these two concepts are closely related to each other in such a way that when a person interferes with another person's identity, he may also violate the integrity of this person. [13] The same can in many cases be said for the relation between the integrity and the autonomy of a person.

The principle of respect for integrity as described in the passage above, lies at the foundation of the principle of respect for autonomy. I hope, therefore, that by explaining the meaning and function of the principle of respect for autonomy, I will shed some further light upon the function of the principle of integrity as well. It is normally held that the principle of respect for autonomy is morally justified with reference to the principle of respect for integrity, even though one cannot say that the first one is logically derived from the second one. This means that one ought to respect a person's autonomy in order not to violate his or her integrity. But what is meant by the word *autonomy*? The word derives etymologically from old Greek and is a compound of the word *autos*, which means 'self', and the word *nomos*, which means 'law', 'rule' or 'governance'. Today the word "autonomy" is used in quite diverse meanings, and does not refer to a univocal concept. Tom L. Beauchamp and James F. Childress have therefore pointed out that "like many philosophical concepts, 'autonomy' acquires a more specific meaning in the context of a theory." [14] However, in an essay of this kind, I do not find myself at liberty to go in detail on this question, and will therefore focus merely on the common conditions that most of the theories of autonomy can agree upon.

It is then possible to say with the words of Beauchamp and Childress that "virtually all theories of autonomy agrees that two conditions are essential: (1) *liberty* (independence from controlling influences) and (2) *agency* (capacity for intentional action)." [15] But it should at the same time be noted that Beauchamp and Childress also points out that "disagreements exists over the meaning of these two conditions and over whether some additional condition is needed." [16] In addition to the two conditions of liberty and agency that are common to most theories of autonomy, Beauchamp and Childress also adds a third one as essential: "We analyze autonomous action in terms of normal choosers who act (1) intentionally, (2) *with understanding*, and (3) without controlling influences that determine their action." [17] This means that a person is autonomous when this person to a substantial degree is able to act according to these three conditions, *liberty*, *agency* and *understanding*.

We then may say that *the principle of respect for autonomy*, asserts that one ought to respect a person's choice and actions

when they are not harmful to others and, in addition, performed according to these three conditions.[18] If this is not done, then one violates the person's integrity. Beauchamp and Childress states this principle in both a positive and a negative form. In its negative form it merely asserts as a broad and abstract obligation that "autonomous actions should not be subjected to controlling constraints by others." [19] In its positive form, however, it asserts the more affirmative demand that "respect for autonomy obligates professionals to disclose information, to probe for and ensure understanding and voluntariness, and to foster adequate decisionmaking." [20]

In this formulation we recognize the three aspects of liberty, agency and understanding, which may be said to provide a link between the principle of respect for autonomy and the principle of informed consent, as we shall see later on. This means that the principle of informed consent may be viewed as a means to an end in relation to the principle of respect for autonomy, in the way that one has to respect the principle of informed consent, in order to respect the principle of respect for autonomy. [21] This is a similar relation to the one we find between the principle of respect for integrity and the principle of respect for autonomy, i.e. that one in most cases has to respect the principle of autonomy in order to respect the principle of integrity. The two principles of respect for autonomy and integrity and the principle of informed consent form a *triangle in biomedical ethics*, in such a way that if we accept one of them, we accept them all, and therefore we cannot turn down one of them without turning down the others as well. [22] However, the most fundamental of the three is the principle of respect for integrity, which serves as a justification of the next one, the principle of respect for autonomy, which together with the first one, in turn serves as justification for the principle of informed consent.

#### The definition and elements of informed consent

The *principle* of informed consent in biomedical ethics states in a simplified form that a patient should not be submitted to a medical treatment and that a subject should not take part in a research projects if this submission or participation is not based on the *voluntary* and *informed consent* of the person or the subject, or in the case of incompetent persons, [23] of their legal appointed guardians. According to Beauchamp and Childress, the term "informed consent" is surrounded by considerable vagueness, [24] and I will therefore in this section try to give a definition of *informed consent* and focus on the different elements which are compound in the informed consent, in order to cast some light on this *principle* of informed consent. There are at least two senses of "informed consent" that must be explained in this context. In the first sense, informed consent is analyzable in the light of *autonomous choice*. With regards to the contexts of medical ethics and research ethics, this means that "an informed consent is an *autonomous authorization* by individuals of a medical intervention or of involvement in research." [25] An informed consent in this sense "occurs if and only if a patient or subject, with substantial *understanding* and in substantial *absence of control by others*, *intentionally* authorizes a professional to do something." [26] Here we find that the three aspects of *liberty* (absence of control by others), *agency* (capacity for intentional action) and *understanding*, which earlier in this paper were said to provide the link between the principle of respect for autonomy and the principle of informed consent, are necessary and sufficient conditions for an informed consent. But there also exist another conception of informed consent, which in real life perhaps has greater significance for the decisions that are actually made regarding the subjects' participation in therapeutic procedure and research activities. Informed consent may also be analyzed "in terms of the *social rules of consent* in institutions that must obtain legally valid consent from patients or subjects before proceeding with therapeutic procedures or research." [27] "Informed consent" in this sense merely refers to the *institutionally* or *legally* effective authorizations determined by prevailing rules.

The relation between these two concepts of informed consent is of such a kind that an informed consent in the first sense need not be an informed consent in the second sense, and *vice versa*. For instance, in the case of incompetent patients one may have an informed consent from the patient's legally appointed guardian and not from the patient himself. This would then be an informed consent in the second sense, but not in the first sense, since the patient does not give the consent himself. This kind of informed consent is mentioned in the Declaration of Helsinki as follows: "In the case of *legal incompetence*, informed consent should be obtained from the legal guardian in accordance with national legislation." [28] This means that the three conditions of agency, liberty and understanding in these cases will have to be fulfilled by the legal guardian. We can also imagine cases where a minor, and hence legally incompetent person, are *capable* of giving an autonomous authorization, but *not legally authorized* to consent, and therefore not in a position to give an effective consent under prevailing institutional rules. This would then be a consent in the first sense, but not in the second sense. This is also mentioned in the Declaration of Helsinki, but as we see, the demands are stronger in this case: "Whenever the minor child is in fact able to give a consent, the minor's consent *must be obtained in addition* to the consent of the minor's legal guardian." [29] Even though there in some cases might be a gap between the two senses of informed consent, the legal and institutional rules are necessary, and cannot be dismissed. This does not mean, however, that they may be developed independently from the first conception of informed consent. Beauchamp and Childress "take it as axiomatic that the model of autonomous choice (the first sense) ought to serve as the benchmark for the moral adequacy of institutional rules." [30]

I will now turn to the question of which elements that are compound in the informed consent. A common procedure is then to divide the elements into *information* and *consent*. [31] The information component, is then explained as the disclosure of information and the comprehension of this information, while the consent component is explained as the voluntary decision, with absence of control by others, to be submitted to a recommended procedure. However, not all will be satisfied with this explanation. Beauchamp and Childress points out that it is possible to recognize not merely two, but *seven elements* in the informed consent. They divide these into the following three main groups: *threshold elements* (which constitutes the preconditions of the informed consent), *information elements* and *consent elements*. According to Beauchamp and Childress, then, the threshold elements are: (1) *competence*, to understand and make decisions and (2) *voluntariness* in deciding; the information elements are: (3) *disclosure* of material information, (4) *recommendation* of a plan, and (5) *understanding* of the information and the plan that is recommended; and the consent elements are: (6) *decision* in favor of a plan and (7) *authorization* of the chosen plan. [32] Later on I will comment on and give a short evaluation of the significance of the elements of information (i.e. disclosure and understanding) and the element of trust in the process of subjects giving their consent to participate in medical research trials. I will therefore in the following passages give a short survey of the elements of *disclosure* and *understanding*, starting with the element of disclosure.

According to Beauchamp and Childress, professionals are obligated to disclose a *core set of information*, that must include the following five elements: (a) "those facts or descriptions that patients or subjects usually consider material in deciding whether to refuse or consent to the proposed intervention or research;" (b) "information the professional believe to be material;" (c) "the professional's recommendation;" (d) "the purpose of seeking consent;" and (e) "the nature and limits of consent as an act of authorization." [33] They also add that *if research is involved*, "disclosures should generally be made as to the aims, methods, anticipated benefits and risks of the

research, any anticipated inconvenience or discomfort, and the subjects' right to withdraw from the research." [34] There are, however, some problems attached to the element of disclosure, such as the question of standards of disclosure and the need for *intentional nondisclosure*. [35] I will not comment on the first one, but the second one needs an explanation in this context.

Sometimes intentional or deliberate nondisclosure may be necessary in *clinical interventions* because it benefits the patient, for instance as in the case of therapeutic use of placebos. Likewise, the researchers sometimes may have to perform *types of research* that are incompatible with complete disclosure. For instance, could vital research in fields such as epidemiology not be conducted if consent from subjects were *required* to obtain access to medical records. Beauchamp and Childress therefore asserts four conditions that are essential in order to justify such a use of deception or intentional nondisclosure in research: Deception should be used only if (1) it is essential to obtain vital information; (2) no substantial risk is involved; (3) the subjects are informed that deception is a part of the study; and (4) the subjects give their consent to participate under these conditions. [36] According to these criteria, the subjects should always have an *understanding* of the possibility of being deceived when participating in research which include intentional nondisclosure.

I will now turn to the third information element in the informed consent, i.e. the element of *understanding*. Beauchamp and Childress have, with regards to biomedical ethics, said that "in recent years the focus has shifted from the physician's or researcher's obligation to *disclose* information to the quality of a patient's or subject's *understanding* and *consent*." [37] In the task of giving a definition of understanding one meets with several problems, and there exist no consensus among scholars about the nature of *understanding*. In this context, however, I will settle with the definition that "one understands if one has acquired pertinent information and justified, relevant beliefs about the nature and consequences of one's action." [38] It is commonly accepted that it is difficult to find procedures to make sure that the patients or subjects really understand the information they are given. Beauchamp and Childress points out that the professionals must in one way or another try to draw analogies between the specialized information and "more ordinary events familiar to the patient or subject." [39] This does not, however, mean that the patients or subjects have to be exposed to the total amount of information available regarding the treatment or research, the ethical demand is only that they are *adequately* informed and have an adequate *understanding* of the information concerning the treatment or research. In order to achieve this goal, the professionals will have to use all their imaginative, empathic and professional skills. This means that they should be aware of, look for, and try to prevent problems of different kinds that might cast shadows on the patients' or subjects' understanding. Such problems can be related to *the information processing*, [40] for instance to the possibility of so called *information overload*, i.e. that the understanding of the patients or subjects are prevented e.g. by the use of unfamiliar terms, or to the possibility of *underdisclosure*, i.e. that the information that is given is inadequate or not comprehensive enough. A third problem connected to the information processing, has to do with the language used when disclosing information about risks.

Besides the problems of information processing there also is the problem of *non-acceptance and false belief*, [41] and the problem of so-called *waivers*. [42] The first one can be explained as a "breakdown in the ability to *accept* information as true or untainted, even if the person adequately *comprehends* the information." [43] A waiver, on the other side, is a person that "voluntarily relinquishes the right to an informed consent and relieves the physician from the obligation to obtain informed consent." [44] In the last sections of this paper, I will look at the significance of the aspect of trust in the process of giving consent. I will then also try to show that the two problems of

non-acceptance and false belief and the problem of waivers in fact are closely linked to *the element of trust* in the consent process.

### The significance of *trust* for the subjects who consent to take part in medical research

I will now look at the significance of *trust* for the subjects who consent to take part in medical research, but first of all I will give some comments on the concept of research and the intention behind the use of the principle of informed consent in biomedical research ethics. It is normally accepted that society have to conduct research involving human subjects in order to solve several of it's major problems, and WMA *Declaration of Helsinki* therefore states that "medical progress is based on research which ultimately must rest in part on experimentation involving human subjects." [45] Normally, there are two kinds of research that involves human subjects, the first one is so called *behavioral research*, such as in psychology and sociology, and the second kind is so called *biomedical research*, which focus on the human body, that is, on the physical aspects of it. With regards to this second kind, the WMA has stated that "in the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially *diagnostic or therapeutic* for a patient, and medical research, the essential object of which is *purely scientific* and without implying direct diagnostic or therapeutic value to the person subjected to the research." [46] This means that there in principle also are *two kinds of medical research*, the one that are essentially diagnostic and therapeutic, which involves subjects who are ill, and the one that are purely scientific, which involves subjects that are healthy or subjects with an illness that are of no relevance to the experimental design. The principle of informed consent, however, is normative in all kinds of research involving human subjects and must in neither of them be omitted.

In this essay, the focus is said to be on the principle of *informed consent* and it's relevance for the subjects that consent to take part in *biomedical* research in comparison to the relevance of the aspect of trust. This does, however, not imply that the content and conclusions of this essay is of no relevance to behavioral research. A central part of the information that is provided in the processing of informed consent in biomedical and behavioral studies, is the calculations of risks *versus* benefits. The *intention* behind the use of the principle of *informed consent* is that the research subjects should be able to make an enlightened decision based on a reasonable calculation of *risks* and *benefits*. Potential subjects may be asked to participate in different kinds of research with different possibilities of harm and benefit for the subject. In a simplified way, we can say that there may be: (a) research which involves a possibility of harm, and no possibility of benefit for the subject, for instance in the case of students (i.e. healthy persons) that participate in research projects; (b) research which involves both a possibility of harm and a possibility of benefit for the subjects, for instance in the case of patients with incurable illness, such as persons that are tested HIV-positive; or (c) research which involves as good as no possibility of harm, but a possibility of benefit for the subjects. The first mentioned would then typically be a purely scientific and non-therapeutic research, while the second and third would be a therapeutic or clinical research. It should also be mentioned that even though there is no possibility of benefit for the subjects in the purely scientific research, there should always be a possibility of benefit for society, in order for it to be ethically justified, as stated in *the Nuremberg Code*: "The experiment should be such as to yield fruitful results for the good of society." [47] Persons that participate as subjects in research of this kind, then, ought to be motivated by altruism (but unfortunately for them this is not always the case, sometimes they hope for more than merely the good of society).

As already mentioned, the intention behind the principle of informed consent is partly to secure that the potential subjects get an adequate understanding of the potential risks and benefits connected to the research. However, Beauchamp and Childress points out that "clinical experience and empirical data indicate that patients and subjects exhibit wide variation in their *understanding* of information about diagnoses, procedures, risks, and prognoses." [48] One of the studies that may give empirical weight to such a judgement, is reported in the article "Trust - The Fragile Foundation of Contemporary Biomedical Ethics" by Nancy E. Kass (et. al.), [49] which contains a survey of the results of the *Subject Interview Study*, one of three projects examining contemporary human subject research, initiated by the Advisory Committee on Human Radiation Experiments in USA. The Subject Interview Study, which in itself is a behavioral study, "enrolled almost 1.900 outpatients nationwide to determine their experience with and attitudes about research," [50] and "approximately one hundred of the patients who enrolled in this study and reported having personal experience in medical research were interviewed a second time and in greater depth to gain further insight into their reasons for participating and their understanding of the research enterprise." [51] I will now give a short summary of the findings from these interviews and some of the conclusions that the authors of the article draws about the implications for conducting ethically sound research with human subjects. It should be noted that most of the patients in the Subject Interview study had experience from *therapeutic research* (65 of approximately 100 patients) and that this article focus predominantly on the experiences of this group. But this does not mean that the results are irrelevant to the ethics of purely scientific biomedical research, or even to behavioral research ethics, for that matter.

Based on the results from the Subject Interview Study, the article focuses on three questions: (1) Why do patients become research subjects; (2) how significant is the element of trust in the patients' decision to become subjects; and (3) what implications should the answer to these two questions have for the conduct of research? The answer to *the first question* is complex and may be divided into five parts. The Subject Interview Study showed that the patients became research subjects because: (a) they hoped for benefit; (b) they had resigned; (c) they had *trust* in the physicians recommendation; (d) they had *trust* in the hospital institutions; and/or (e) they had *trust* in the research activity. As for the first two, these were often closely connected: "The theme of hope was often wedded to despair." [52] In the last three reasons, we find that the element of trust reoccurs as a common factor. The Subject Interview Study also tried to map the impact of the *disclosure* of the benefits and risks and of the subjects' *understanding* of the benefits and risks on their consent. The results are described in the article as follows: "Comments about the consent process underscored the importance of trust in the experience of these patients. Many participants expressed that their decision to participate had been made before they had been given the consent form to sign. They knew they wanted to participate, they *trusted* that it was right, and the details described in the form, were not particularly relevant." [53] Apart from this the study also revealed that the consent in many cases were based on *false belief* concerning the potential benefits, that the subjects also tended to *voluntarily relinquish* (the problem of waivers) or ignore their right to an informed consent, and that they tended to consider the research as just another treatment option: "Through further discussion, however, it was evident that most respondents, while able to articulate the broad goals of research, viewed their own participation as simply another treatment option." [54] This indicates that the answer to *the second question*, must be that the element of trust in the patients' decision to become subjects are very significant, and that it in fact, *overshadows* the element of disclosure and understanding. The third question answered in the article asked

for what implications the answer to the two first questions should have for the conduct of research? As an answer to this question, I will point out that the authors of the article conclude as follows: (a) that the *clinicians* "should be mindful of the tremendous influence they have over their patients;" (b) that the *investigators* "should make it clear that their primary loyalty is to future patients;" (c) that *those who oversee research* "should be humbled by the trust patients-subjects have in the research enterprise," and "continue to do their best to live up to that trust;" and (d) that the *Institutional Review Boards* should "take measures to assure that investigators do not overrepresent the benefits of research and that all consequences of the research that relate to the patient's 'good' be explained." [55] On a more general basis the authors of the article also asserts that the stories of the patients in the Subject Interview Study "suggests that the current emphasis in research ethics on analyses of benefits and risks and on subjects' autonomous decisionmaking is insufficient," and that "*the paradigm* must be enriched with a *sensitivity to the profound trust* participants place in researchers and the research enterprise." [56]

#### Evaluation of the element of trust versus the element of information

I will now in the very last section of this essay sum up and evaluate the significance that I think ought to be given to the element of trust in comparison to the element of information in the paradigm of biomedical research ethics. We have seen that the potential subjects' consent to participate in research trials may be due to trust in the physicians, the hospitals, the researchers and/or the research institution. This means that the element of trust can not be excluded as a *motivating factor* in the process of potential subjects giving consent. However, I believe that the fact that this is so, not *necessarily* does constitute a problem. A consent based on trust is surely not a bad thing *per se*, and there need not be a contradiction between a consent based on trust and a consent based on information, disclosure and understanding. Only when the consent is based *exclusively* on *trust in the informants* and not in the *information* that is given, may there be a problem. Of course, this depends on what super-ordinate paradigm one chooses for one's bioethical reasoning. I belong to the group who wish to give patient autonomy priority in preference to friendly authoritarianism. An awareness on behalf of the researcher of the significance of the element of trust in the process of giving consent may help stress the importance of *informed* consent and the fact that the researcher not just should be looking for any kind of consent, but for an *informed* consent as explained in the first part of this essay. Through the process of disclosing *adequate information* the researchers have an opportunity to sort out the waivers, the false-believers and the subjects that are most likely to base their consent exclusively on trust in the *informant* as a person, rather than on the actual *information* provided, and as result most likely will have an inadequate *understanding* of what is going to happen. In order to do this the researchers needs adequate *guidelines* and *feed-back mechanisms* that may secure the process of informed consent and make it clear whether the patients have got an adequate conception of the risks and benefits of the trial, or merely have a profound trust in the persons that conduct the research project. This can be done in different ways. In the case of literates one may develop better informed consent sheets that actually are *understandable* for the common man and woman, with *questions* that have to be *answered* in order for the persons to be allowed to participate in the trial, in the case of illiterates and perhaps also in the case of literates, one may use video recording of meetings with oral *briefing* and *interviews*, which together with the answers from the informed consent sheets, in turn may be handed over to an *independent committee* for evaluation. In addition to this, one may also gather the potential subjects in groups, where they receive information and get the opportunity to ask questions in order to enrich each others

understanding. Of course, in some of the more simple and straightforward trials, this may seem like a much ado about nothing, but one nevertheless has to remember that the first principle of the *Nuremberg Code* states that "the voluntary consent of the human subject is absolutely essential" and that "the duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment." [57] Therefore, although it may constitute a temptation for the researcher that the subjects are inclined to trust the physicians/researchers more than relating to the information they receive, he or she has a *moral and professional obligation* not to take advantage of this, for instance by giving inadequate information or by giving the information in an inadequate way in order to get the consent that he or she wishes. When dealing with research involving human subjects one always has to remember that *it is far harder to regain trust, once lost, than to squander it in the first place.* [58]

## Notes

- 1] This essay is a re-write of a paper submitted on the Ph.D.-course Ethics and Research Policy at Department of Philosophy at University of Bergen, Autumn 1999. The aim was not primarily to establish new knowledge but to provide an account of an important topic within Western biomedical ethics. However, it may be of a certain interest in another cultural context.
- 2] Tom L. Beauchamp & James F. Childress *Principles of Biomedical Ethics*, New York 1994, 4<sup>th</sup> Ed.
- 3] *The Nuremberg Code*. From Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946 – April 1949. And *World Medical Association Declaration of Helsinki*, with amendments until the 48<sup>th</sup> General Assembly in the Republic of South Africa, October 1996. Both can be found in a copy of readings used in the course Ethics and Research Policy at Department of Philosophy at University of Bergen, Autumn 1999.
- 4] The article "Trust. The Fragile Foundation of Contemporary Biomedical Ethics" by Nancy E. Kass (et. al.) in *Hastings Center report*, September-October 1996, pp. 25-29. This article can be found in a copy of readings used in the course "Ethics and Research Policy" at department of Philosophy at University of Bergen, Autumn 1999.
- 5] *The Nuremberg Code*. From Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946 – April 1949, *op. cit.*
- 6] *World Medical Association Declaration of Helsinki*, with amendments until the 48<sup>th</sup> General Assembly in the Republic of South Africa, October 1996, *op. cit.* Basic Principle No. 9. Italics are mine.
- 7] Cf. K. E. Tranøy: *Medisinsk etikk i vår tid*, Bergen 1994, p. 32. In Norwegian.
- 8] Example given, as in the case of the Tuskegee Syphilis Study, cf. the article of Allan M. Brant "Racism and Research. The Case of the Tuskegee Syphilis Study" which was published in *Hastings Center Report*, December 1978, pp. 21-29. This can be found in a copy of readings used in the course Ethics and Research Policy at department of Philosophy at University of Bergen, Autumn 1999.
- 9] *World Medical Association Declaration of Helsinki*, with amendments until the 48<sup>th</sup> General Assembly in the Republic of South Africa, October 1996, *op. cit.*, Basic Principle No. 6. Italics are mine.
- 10] *Webster's Encyclopedic Unabridged Dictionary of the English Language*, Gramercy Books, New York 1996.
- 11] *The Oxford English Dictionary*, London 1989, explains the word as follows: (1) the condition of having no part or element taken away or wanting; undivided or unbroken state; material wholeness, completeness, entirety; something undivided; an integral whole; (2) the condition of not being marred or violated; unimpaired or uncorrupted condition; original perfect state; soundness; and (3) in a moral sense: (a) unimpaired moral state; freedom from moral corruption; innocence; sinlessness; or (b) soundness of moral principles; the character of uncorrupted virtue, especially in relation to truth and fair dealing; uprightness, honesty, sincerity.
- 12] E.D. Pellegrino "The Relationship of Autonomy and Integrity in Medical Ethics," in P. Allebeck & B. Jansson (ed.) *Ethics in Medicine*, New York 1990, p. 10. This quotation is borrowed from Margareta Andersson's *Integritet som begrepp och princip*, Åbo 1994, p. 30. In Swedish.
- 13] Cf. Tranøy, *op. cit.*, p. 38. In Norwegian.
- 14] Beauchamp & Childress, *op. cit.*, p. 121.
- 15] *Ibid.*, p. 121.
- 16] *Ibid.*, p. 121.
- 17] *Ibid.*, p. 123. Italics are mine.
- 18] In this context one often use the terms "competence" and "incompetence." Beauchamp and Childress explain these concepts in such a way that a person is competent if he or she is psychologically and legally capable of adequate decisionmaking, and incompetent if not. This means that competence judgements distinguish the class of individuals whose autonomous decisions

must be respected from those individuals whose decisions need to be checked and perhaps overridden by a surrogate. Competence in decisionmaking is therefore closely connected to autonomous decisionmaking and to questions about the validity of consent. However, competence is a threshold and not a continuum concept like autonomy. In biomedical contexts a person has generally been viewed as competent if able to understand a therapy or research procedure, to deliberate regarding major risks and benefits, and to make a decision in light of this deliberation. A person therefore has to be judged competent in order to give a legally accepted informed consent. Cf. *Ibid.*, pp. 132-137.

- 19] *Ibid.*, p. 126.
- 20] *Ibid.*, p. 127.
- 21] The picture will of course be more complicated in the case of persons who are judged legally incompetent. In these cases one does not have to respect the autonomy of a person in order not to violate his integrity. This does however not imply that it is justified to violate the integrity of the incompetent person.
- 22] By this I do not mean to say that the principle of informed consent and the principle of respect for autonomy are logically derived from the principle of respect for integrity. Cf. Tranøy, *op. cit.*, p. 41. In Norwegian.
- 23] Cf. note no. 17 and 20.
- 24] Beauchamp and Childress, *op. cit.*, p. 143.
- 25] *Ibid.*
- 26] *Ibid.* Italics are mine.
- 27] *Ibid.*, p. 144.
- 28] *World Medical Association Declaration of Helsinki*, with amendments until the 48<sup>th</sup> General Assembly in the Republic of South Africa, October 1996, *op. cit.*, Basic Principle No. 11. Italics are mine.
- 29] *Ibid.* Italics are mine.
- 30] Beauchamp and Childress, *op. cit.*, p. 144.
- 31] For instance, we find an example of this in Tranøy, *op. cit.*, pp. 41-42. In Norwegian.
- 32] Beauchamp and Childress, *op. cit.*, pp. 145-146.
- 33] *Ibid.*, p. 147.
- 34] *Ibid.*
- 35] Cf. *Ibid.*, pp. 147-157.
- 36] *Ibid.*, p. 157.
- 37] *Ibid.*, p. 142.
- 38] *Ibid.*, p. 157.
- 39] *Ibid.*, p. 158.
- 40] Cf. *Ibid.*, p. 159-160.
- 41] Cf. *Ibid.*, p. 160-162.
- 42] Cf. *Ibid.*, p. 162-163.
- 43] *Ibid.*, p. 160.
- 44] *Ibid.*
- 45] *World Medical Association Declaration of Helsinki*, with amendments until the 48<sup>th</sup> General Assembly in the Republic of South Africa, October 1996, *op. cit.*, introduction. Italics are mine.
- 46] *Ibid.* Italics are mine.
- 47] *The Nuremberg Code*, *op. cit.*, No. 6.
- 48] Beauchamp and Childress, *op. cit.*, p. 157.
- 49] *Hastings Center report*, September-October 1996, pp. 25-29. This article can also be found in a copy of readings used in the course Ethics and Research Policy at department of Philosophy at University of Bergen, Autumn 1999.
- 50] *Ibid.*, p. 25.
- 51] *Ibid.*
- 52] *Ibid.*
- 53] *Ibid.*, p. 26. Italics are mine.
- 54] *Ibid.*, p. 27.
- 55] *Ibid.*, p. 28.
- 56] *Ibid.*, p. 27. Italics are mine.
- 57] *The Nuremberg Code*, *op. cit.*, No. 1. Italics are mine.
- 58] Italics are mine. The words are originally uttered by Sisela Bok and quoted by Nancy E. Kass (et. al.) in "Trust. The Fragile Foundation of Contemporary Biomedical Research," p. 28 in *Hastings Center Report*, September-October 1996.

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## Best wishes from medical students

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### Abstract

There is a prevalent view that medical education is having a detrimental influence on values of students, leading to production of selfish and distrustful doctors. One can assess the motivation of individuals by eliciting and analyzing their personal wishes. A questionnaire in English, consisting of statements with examples of wishes, under 18 different headings (or to express their own wishes in writing) were completed by the third and final year undergraduate medical students, of both sexes (n=259; males=138, females=121; aged between 20 and 22 years), to assess their motivation. Fischer exact test was used to analyse significant gender difference if any. In pooled data, the three most popular categories of wishes were; self-esteem (41%), happiness (40%) and health (35%). Significant gender difference existed only for wishes pertaining to sex, power and self-esteem. The rank order of the three most popular wishes for males were happiness (42%), health (34%) and intimacy (33%), while for females they were, self-esteem (54%) happiness (38%), health / intimacy (36% each). In this study there is no evidence that medical students were money oriented. However poor preference for altruistic wish was highly discouraging, pointing to the need for shaping the students' personal and professional career towards a non-cynical, person oriented approach.

**Keywords:** medical undergraduates, money, altruism, questionnaire, India.

### Introduction

It is a great privilege to study medicine, a noble profession. It is expected that students who take up medicine not only be academically brilliant but also possess attributes like, unselfishness and courteousness, since they play a pivotal role in physician-patient relationship and patient care. Medical education has virtually no effect on attributes like; warmth, kindness, helpfulness etc<sup>1</sup>. Contrary to the general expectation, there are a few reports stating, medical students become money

Table 1: Rank order of wishes of medical students according to the total number (Proportion) expressing each wish.

Rank	Wish category	Example	Male	Female	Total
1	Self-esteem	To be more confident in the things I do	40 (29)	65 (54)**	105 (40.5)
2	Happiness	I want to be the happiest person always	58 (42)	46 (38)	104 (40)
3	Health	Healthy for ever - self and family	47 (34)	43 (36)	90 (35)
4	Intimacy	To have good relationship with those I care about	45 (33)	43 (36)	88 (34)
5	Knowledge	To answer any question in any subject	40 (29)	32 (26)	72 (27.8)
6	Achievement	To be a Nobel laureate	27 (20)	25 (21)	52 (20.1)
7	Altruism	To help the poor like mother Theresa	22 (16)	23 (19)	45 (17.4)
8	Donation	To donate my organs after my death	18 (13)	24 (20)	42 (16.2)
9	Affiliation	To have large circle of friends & relatives	25 (18)	15 (12)	40 (15.4)
10	Religious	One religion for the whole world	14 (10)	11 (9.1)	25 (9.7)
11	Travel	Travel across the world	9 (6.5)	15 (12)	24 (9.3)
12	Money	To be the richest person ever	16 (12)	7 (5.8)	23 (8.8)
13	Sex	Satisfactory sexual life till my last day of life	17 (12)	0 (0)**	17 (6.6)
14	Time	Need more time every day to do more work	9 (6.5)	5 (4.1)	14 (5.4)
15	Power	To be the ruler of the world	12 (8.7)	2 (1.7)*	14 (5.4)
16	Appearance	To be the most attractive/ beautiful person in the world	6 (4.3)	3 (2.5)	9 (3.5)

oriented during the course of their study<sup>2</sup>, though concern for patients and a tendency to help was also seen<sup>3</sup>. The personal wishes of individuals' relate to trait, and well-being<sup>2</sup> but more importantly throws light on underlying motivation<sup>4</sup>. To our knowledge there is no report of studies eliciting medical students' wishes in developing countries, hence the present study was aimed at obtaining the personal wishes of medical students and to see how they varied with reference to gender, in a country like India.

### Methods

The authors conducted the survey after getting due ethical clearance. An anonymous questionnaire was completed by 259 (94.5%) of the 274, third and final year medical undergraduate students, who were between 20 and 22 years. The sample comprised of 138 boys (53.3%) and 121 girls (46.7%), of two Government medical colleges, at Trichirappalli and Madurai cities, in the southern part of India. The questionnaire was completed at the end of the lecture and collected by the authors. The questions were in simple English and were structured based on a previous study<sup>4</sup> with modification to the effect, the students were given the option to tick any three wishes given under 18 different headings (quoting an example under each heading) or prefer their own wish under the corresponding heading or under different headings of their choice. Details like gender, age and year of study were also elicited.

The data were entered in Microsoft Excel spread sheet. GraphPad InStat version 3.05 was used for statistical analysis (Fisher exact test) to find out any significant gender difference.

### Results

The question of rating difference did not arise since either the students opted to tick three wishes, which were already quoted as examples or chose to write their wish under relevant heading. Table 1 shows the number of students with wishes under different categories according to the rank order. In the pooled data (total) the three most popular categories of wishes were self-esteem (41%), happiness (40%) and health (35%). When the results were analyzed gender wise the three most popular categories of wishes were different for boys and girls, which did not follow the same rank order. While boys wished for happiness (42%), health (34%) and intimacy (33%), girls were for self-esteem (54%) happiness (38%), health / intimacy (36% each).

Significant gender difference existed in wishes pertaining to sex; boys were more likely than girls to make sex wishes [17 (12%) Vs 0 (0%); OR (odds ratio) = 35, p < 0.0001], [power 12 (9%) Vs 2 (5.4%); OR = 5.67, p < 0.01] and it was the reverse with self-esteem [40 (29%) Vs 65 (54%); OR = 0.35, p < 0.0001].

17	Food	Want high quality free food for life time	3 (2.2)	2 (1.7)	5 (1.9)
18	Undoing	To appear and disappear as I like	2 (1.4)	1 (0.8)	3 (1.2)

n = 259 (boys 138; girls 121). Figures in the table represent the number of respondents and those in parenthesis are %.

p < 0.01; \*\* p < 0.0001 when boys were compared with girls (Fisher exact test). The rank order is for pooled data (boys & girls taken together)

### Discussion

In the present study there is no evidence that medical students were money oriented, since only about 10% of them had such wishes and rank wise it occupies the 12<sup>th</sup> position. One study has reported that happiness, money and altruism<sup>4</sup>, while another as achievement, affiliation, intimacy, power as well as happiness and money<sup>2</sup> as most popular wishes of medical students. The present study, agreed with respect to happiness; but not with others, instead they were self-esteem and health. It is heartening to learn that there was less preference for money wish, the reason may be, and unlike in developed countries where they may have to self-support, students of developing countries are not burdened by the economic stress since it is mostly taken care of by the parents.

A depressing aspect of the present study is, the poor preference for altruistic wish. This aspect denotes that qualities like empathy, trustworthiness and unselfishness are probably not nurtured during their career as a medical student or earlier when they were children. The differences between the present study and the earlier ones are hard to explain, though one has to bear in mind the age, socio-cultural cross-country variations.

In the present study the wish for self-esteem was high in girls (54%) as against boys (29%) which was extremely significant, while in a previous report women preferred, improved appearance, happiness and health<sup>2</sup>. This may possibly be because, girls are less poised compared to boys. However since a large proportion of both boys and girls wished for self-esteem, may mean that their counter parts in developed countries are better placed in that aspect. There is an urgent need to improve the psychosocial, communication skills of students and to instill values like altruism. This aspect, practically doesn't find space in medical curriculum. An earnest effort in this direction would equip the present & future generations to face professional challenges.

The preference for sex wishes exclusively by boys is in concordance with earlier reports<sup>2, 4</sup>, which has been explained on the basis of different adaptive problems during the process of human evolution<sup>5</sup>.

The prevailing socio-cultural factors, social security system, role model in living and learning environs and reinforcements due to religious beliefs, all shape the wishes of individuals, which in turn has a bearing on professional behaviour. In this context present study points to the need for shaping the students' personal and professional career towards a non-cynical, person oriented approach by driving ethical values in their mind.

### Acknowledgements

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## Hope and Fear in Genetics

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Those of us who write, read or talk about genetics and biotechnology inevitably encounter a barrage of legal principles under various guises that seem to suggest ways that the legal system ought to deal with advances in genetics. We must worry, we are told, about such things as biodiversity, the precautionary principle, the principle of future generations, the prevention principle, the common heritage of humankind, economic analysis, equal rights, privacy, and rights to information. Not only we do not know really what these things are- and, from the look of things, neither do those propose them-but their application to genetics obviously is not easy

Genetics revolution will likely to alter the way we carry on in business and our personal lives.

It will also play on the well-known slogan; will bring good things to life, literally. Through genetic manipulation we can hope for more nutritious and flavorful food that are easier to grow. This genetic revolution is unidirectional; in other words, the consequences of increased genetic knowledge and technology are irreversible. Thus, once we permit an activity to go forward, such as introducing a genetically altered plant or animal into the environment, we do so in perpetuity. It all depends on the choice that we, as society (in the large sense, including our neighbors around the globe), make. Although still in its infancy, biotechnology has already introduced before courts and tribunals worldwide such controversial issues as DNA typing, reproductive technologies, and patenting animals and genes.

In no other area of biomedical research there has been a greater concern for ethical issue than in the field of human genetics. It has also led to great deal of concern about our ability to handle the information derived. The knowledge about human genes and genetic diseases prior to fifties was so poor that there was hardly any genetic research or progress. There has been veritable explosion in knowledge that has culminated in Human genome project, gene therapy and genetic engineering. The human genome project (HGP) has also precipitated unprecedented concern for intellectual property rights. Recent experiments on cloning of sheep bring human cloning into realm of possibility, raising ethical, legal and social issues as important aspect of HGP. This will bring some guidelines or legal concern with least amount of ambiguity. It will also need to deal with special concern to curtail the potential harm without clamping a moratorium on research and service in this field.

Each of us is unique individual. Each of us has genome, consisting of three billion DNA bases inherited from our mother, plus and additional (very similar) three billions from our father. Each of us differs in DNA sequence by about one base in every thousand, for total of between three and six million differences. These differences underlie our uniqueness and individuality. It is important to make a point that there are other contributing factors as well, which are non-genetic. So it is necessary to be extremely cautious and alert to "genetic determinism", a trap of assuming that more is due to genetic inheritance than in fact is.

Some area of genetic medicine such as the effort to identify simple genetic etiology for complex disease and traits will plainly begin to fall away during next few years. One very important role of society and us is to think about how allocation of resources,

crafting of laws and education of children and professionals should be used to prepare for such a future.

Ethical and judicial system can be "institutional criticism" examining how the establishment and maintenance of different institute puts each society in a position to cope with issue in health and science. However history is very poor in this regard. Bioethics and law in this field is scarcely 40 year old. American and European law has grown out of reaction to big scandals, such as chronicled at the trials in Nuremberg, Tuskegee, and Henry Beecher's study of abuse in research. Bioethics knows how to react to Dolly the cloned sheep. It is not so great at predicting or laying the ground for new science or paradigms shift in medicine. It is clear from the public reaction to Dolly, and other scientific claims in the areas of developmental and molecular genetics. The danger is that when scandals about Viagra or Prozac or cloning finally grow tiresome, the public's uneducated fear is replaced by untutored acceptance of new technology. Without reconstruction of the institution of society to meet new challenges, there is little chance we will be prepared for the innovations that are coming. (1) Today's public fears of genetic diagnosis assume that the use of such technologies will be alien, impersonal and technologically difficult.

We will see many ethical, legal, and social implications of genetics in the future. Genetics involves shared familial information, and the diagnosis of one person has direct implication for his or her family members. It is extremely important that patients and research participants understand what information and future predictive insights about them may emerge from genetic studies, particularly when the latter involves genetic testing or screening for multigenic and predisposition diseases. What do you tell someone who test positive for a disease-associated allele when you can only be vague about its clinical implications? What responsibility do physicians or counselors have in the communication of risk information to the patients when the risks themselves are poorly understood? Can genetic information be "owned" and, if so, by whom and under what circumstances? These and other issues that arise from genetic information will challenge the courts and will be exacerbated, as we get better at "reading" and interpreting the content of genomes. The question of the "ownership" of DNA, still more the notion that genetic copies which belonged to human beings can be said to have propriety value, has already been well rehearsed in the debates over organ donation and the patenting of human genes. These issues are complicated by the discussions about the need to "reimburse" the population groups who have donated the material.

The problem raised directly in the academic literature but also indirectly through court decisions. (2) It involves the somewhat counter-intuitive notion that private property rights can impede, rather than encourage, innovation. This concern arises because of the way genetic information yields its effect on biological system. Granting private property rights to minute parts of this layered and interconnected system creates potential for the tragedy of the anticommons (inhibiting effect of patent protection). We may so split up rights to use genetic information that it will become prohibitively expensive for anyone to conduct meaningful research. So while our patent system was designed to promote through the granting of property rights (to prevent a tragedy of the commons in which no one would invest in research without having private property rights), its effect on the ownership of genetic information may actually be to stifle research. (3)

The essential belief of community is that the legal system can respond to any harm threatened by a new technology before that harm becomes severe. We can allow science to move the economy and our lifestyles forward. Only problem to that is biotechnology advances move far more quickly than the legal system. In fact, the slow pace of change is one of the inherent limits on the judicial power. Given that neither science nor the legal systems have proven they will be able to prevent the harm

that might result from gene therapy or genetically modified food product; this fear is far from reasonable. Nevertheless, having a reasonable basis for concern does not amount to a justification for paralysis. Genetics and genetic technology, whether anyone likes it or not, are reality. The real question is how to control it so that it is most likely to benefit us. It is too late to argue that we should abandon the enterprise.

A major challenge in the judicial arena is to introduce the most current and rigorous scientific information related to genomic in a form that is most useful and understandable to judges and juries. Molecular genetics, like some other sciences, can be complicated and often confusing, even to those with scientific background and training. Because molecular genetics is also changing continuously, one can easily pit one scientific "expert" against another, with no clear mechanism to adjudicate between the two. Most scientists are uncomfortable with what they perceive to be the rigid demands of judicial proceedings. And shy away from "beyond reasonable doubt" pronouncements. The all-to-frequent result is that the scientific perspective is represented by fringe elements of the scientific community that may distort the state of the science. Although such distortion is not unique to genetics, prominent and widely publicized examples have been witnessed during the last several years, and the future unfortunately holds the promise of many more. It will be interesting challenge to explore whether the IPCC (Intergovernmental Panel on Climate Change, organized by United Nations in 1988) model can be adapted for use of genetic information in the judicial area, especially since the 1993 Supreme court decision in *Daubert v. Merrell-Dow* places responsibility on the individual trial judges to determine the relevance—and the admissibility of scientific evidence (4).

#### Human Genome Diversity Project

The word eugenics (from the Greek eugenes or well born) was coined in 1883 by Francis Galton, an Englishman and cousin of Charles Darwin, who applied Darwinian science to develop theories about good or noble birth. (5) Central to our human rights obligation is the promotion of "respect for, and observance of human rights and fundamental freedom for all without distinction as to race, sex, language, or religion." (6) The Universal Declaration of Human Rights is founded upon the notion that there are universally recognized human values and that these values are inherent in the human individual. The international community requires that every member of the human family be treated as person, that "everyone has the right to recognition everywhere as person before the law." (7) As far as HGDP is concerned, its ethical safety is to be judged in accordance with the minimal agreed human values expressed as human rights that form part of international law, and in accordance with the ethical norms current in the culture.

Cavelli-Sforza delivered a paper at UNESCO in 1994 to demonstrate how the Project will help combat the scourge of racism He explained "...individual human are genetically quite diverse, but the average difference among human groups are small. They are much smaller than superficial skin-deep differences would lead us to believe and they are also relatively small compared with the difference existing among individuals within the groups." (8) According to him, racism will find no joy in the HGDP. But what bothers me the implied genetic reductionism that is at the heart of modern eugenics. Eugenics can be practiced within a population precisely on the basis of genetic reductionism that there are some lives that, it is popularly claimed, constitute a burden to the community, to the individual concerned, to that individual family, and whose quality of life is so low that these lives are not worth living. Such eugenics has nothing to do with race, but everything to do with disability.

The point is that eugenics is built upon an attitude that seeks its justification in science, just as racism is an attitude that may seek its justification in science. What we are dealing with are habits of mind and ways of thinking philosophically that are

hostile to the key notion of the inherent dignity of the human individual and the inviolable and inalienable human rights that arise from such a consensus about the value of human beings.

Diane Paul and Hamish Spencer have pointed out the strong role of that politics and social values have played in the ready acceptance of eugenics by geneticists. "Nearly all geneticists were enthusiastic proponents of a movement in the first quarter of century that is now generally held in contempt. In Germany, not one geneticist criticized the inter-war eugenics movement." (9) The point is that we need to be clear that with both eugenics and racism we are dealing with political, social and ethical attitudes, and that eugenics in the contemporary era is not necessarily linked with racism. Eugenics may be linked to the human distaste of person with disabilities to Nietzsche's idea of the threat that the disabled and chronically sick pose to the healthy, (10) and to the economic burden on the community comes from the provision of the long-term care for the disabled, elderly, and the chronically sick. That being the case, it is naive to imagine that scientific information in and of itself, can overcome or even significantly undermine race as political category or eugenics as political and social movement. (11) It is interesting to note that the People of Republic China has recently enshrined the new eugenics in law in which carriers of serious genetic diseases are allowed to marry only "if the couple agree to long term contraception or sterilization" (12).

Certainly it is morally objectionable for government or institute or any third party to compel or coerce anyone's reproductive behavior. The right to reproduce without interference from third parties is one of the fundamental freedoms recognized by the international law and moral theories from a host of ethical tradition. (13) However, the goals of obtaining perfection, avoiding disease, or pursuing health with respect to individuals need not involve coercion or force. No moral principle seems to provide sufficient reason to condemn individual eugenic goals. While force and coercion, compulsion and threat have no place in procreative choice, while individual decision can have negative collective consequences, it is not clear that it is any less ethical to allow parents to pick the eye color of their children or try and create a fetus with propensity to particular skills. It is hard to see what exactly is wrong with parents choosing to use genetic knowledge to improve the health and well being of their offspring

HGDP can be carried out in a way that is sensitive to the ethical obligations found in international law. However we should also be clear that those who seek to use the findings of the HGDP to support movements and ideas, which are hostile to fundamental human rights, would no doubt do so. The correct response to this is not to say that findings will prove the opposite but to recognize that what science finds, and these findings should be put in support of fundamental human rights which derive from the universal belief in the inherent dignity of the human individual. Such values cannot be "proved" by science and neither they can be "disproved" by science.

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## Abbreviations

AEM Applied & Environmental Microbiology; AJHG American J. Human Genetics; AJLM American J. Law & Medicine; AJMG American J. Medical Genetics; AJOG American J. Obstetrics & Gynecology; AJPH American J. Public Health; BME Bulletin of Medical Ethics; Biotech Biotechnology; BMJ British Medical J; CMAJ Canadian Medical Association J; CQHE Cambridge Quarterly of Health Care Ethics; EBN European Biotechnology Newsletter; EEN Eubios Ethics Institute Newsletter; EST Environmental Science & Technology; F&S Fertility & Sterility; GEN Genetic Engineering News; GMOs genetically modified organisms; HCR Hastings Center Report; HGT Human Gene Therapy; IDHL International Digest of Health Legislation; IJB International J. Bioethics; JME Journal Medical Ethics; JMG J. Medical Genetics; JRSM J. Royal Society of Medicine; KIEJ Kennedy Institute of Ethics Journal; MJA Medical J. Australia; NatBio Nature Biotechnology; NatGen Nature Genetics; NatMed Nature Medicine; NEJM New England J. Medicine; NS New Scientist; PCR Polymerase Chain Reaction; PNAS Proceedings of the National Academy of Sciences (USA); O&G Obstetrics & Gynecology; SA Scientific American; SSM Social Science & Medicine; TIBTECH Trends in Biotechnology; TIG Trends in Genetics.

## News in Bioethics & Biotechnology

Comments are written in text form together with recent references. This list continues from the last issue of *EJAIB* and will continue. This list is available on-line topic-by-topic (and the on-line topical files have been updated), at: <http://www.biol.tsukuba.ac.jp/~macer/NBB.html>

## Genetic Engineering of Plants

Papers on genetically modified plants are included in *RTD Info*, 31 (Sept. 2001), 24-34. A review of plant biotechnology in China is *Science* 295 (2002), 674-6. Chinese scientists have sequenced *Indica* rice genome, *AgraFood Biotech* 73 (29 Jan. 2001), 20. The creation of salt tolerant plants is discussed in *The Scientist* (4 March 2002), 26-7. On forest biotechnology, *Science* 295 (2002), 1626-9. Use of GM bacteria to fight livestock parasites is being developed in Australia, *Food Chemical News* (8 Oct. 2001), 27-8.

The genetic cost of reproduction in a self fertilizing plant is reported in *Nature* 416 (2002), 320-3. Microsatellites are preferentially associated with non-repetitive DNA in plant genomes, *NatGen* 30 (2002), 194-200. On plant stem cells, *Nature* 415 (2002), 751-4. The use of miniature plastids is discussed in *Science* 295 (2002), 258-9.

## Genetic Engineering of Animals

Protein production in transgenic animals is reviewed in *GEN* 22 (1 Jan. 2002) 20-1, 43. A comparison of genotype versus country for **cattle** growth is *J. Animal Science* 80 (2002), 330-7. **Pigs** that may be useful for low rejection **organ** transplants have been made, Lai, L. et al. "Production of alpha-1,3-galactosyltransferase knockout pigs by nuclear cloning", *Science* 295 (2001), 1089-91. On somatic nuclear transfer for pig, *Biology of Reproduction* 66 (2002), 642-50. **Herman** the famous Dutch GM bull has been given a stay of execution, *Science* 295 (2002), 437. **Columbia** has allowed the creation of transgenic animals, following release of regulations, to add to Brazil who allows GM animals, *AgraFood Biotech* 71 (25 Dec. 2001), 10.

A **cat** has been **cloned**, Shin, T. et al. "A cat cloned by nuclear transplantation", *Nature* 415 (2001), 859; *NS* (23 Feb. 2002), 6; *Science* 295 (2002), 1441-2. **Monoclonal mice** have been generated from nuclear transfer from mature B and T donor cells, *Nature* 415 (2001), 1035-8, 967-9. Faithful

expression of imprinted genes is reported for cloned mice, *Science* 295 (2002), 297. However cloned animals still seem to die early, *NS* (16 Feb. 2002), 14.

Transgenic mouse models include: Huntington's disease mice models have better outcome with transglutaminase inhibitor cystamine, *NatMed.* 8 (2002), 143-8; a mouse model with learning deficits, *Nature* 415 (2002), 526-30. Oestrogen protects FKBP 12.6 null mice from cardiac hypertrophy, *Nature* 416 (2002), 334-7. Purkinje cell degeneration is caused by mutations in axotomy-induced gene, *Nna 1*, *Science* 295 (2002), 1904-6. Colorectal cancer is caused in mice deficient for mucin *Muc2*, *Science* 295 (2002), 1726-9. In general on understanding knockout mice, *Nature* 415 (2002), 8-9.

### Designer Molecules

A method to turn chicken feathers into high grade animal feed has been found, *AgraFood Biotech* 72 (15 Jan. 2001), 20. Spider silk has been manufactured by rDNA technology, Lazaris, A. et al. "Spider silk fibers spun from soluble recombinant silk produced in mammalian cells", *Science* 295 (2002), 472-6, 421-2. A new plastic that can mend itself has been made, *NS* (9 March. 2002), 21.

Microbial production of vitamin B12 is reviewed in *Appl. Microbiol. Biotechnol.* 58 (2002), 275-85.

### Biotechnology & the Public

The European Commission has called for more social issues to be considered in biotechnology, in their document, Life Sciences and biotechnology – A strategy for Europe, COM (2002) 27 final of 23 January, 2002. A series of 10 papers on bioethics, biotechnology and the public from Europe is published in *Notizie di Politeia* XVII, N.63 (2001), 3-116. Educating the public about bioethics and science is discussed in *Science and Engineering Ethics* 8 (2002), 43-58. Bioethics and the media is discussed in *HCR* 32 (Jan. 2002), 32-9.

A discussion of bioethics and dilemmas faced by a company is in the 2001 Annual report of Novo Nordisk, Reporting on the Triple Bottom Line 2001, *Dealing with Dilemmas*, 67pp. The third volume of a major series is Sasson, Albert. *Biotechnologies in developing countries: present and future. Volume 3: Regional and subregional co-operation, and joint ventures* (UNESCO Publishing, 2000, 1103pp. )

### Regulation & Field Trials of GMOs

Methods to delete foreign DNA after transfer have been developed, *Environmental Health Perspectives* 110 (2002), A88-91. Flaws in a paper on gene transfer frequency have been alleged, *Nature* 415 (2002), 948. The issue of boundaries on the spread of genes and the integrity of organisms is *Ram's Horn* 199 (2002), 1-2.

India has approved GM Bt cotton for 3 years of commercial trials. On the farm impact of Bt cotton in South Africa, *Biotechnology and Development Monitor* 48 (Dec. 2001), 15-21. On the risks of Bt maize in Kenya, *Biotechnology and Development Monitor* 48 (Dec. 2001), 6-9. The NAS Panel has suggested tighter monitoring of GM releases, *Nature* 415 (2002), 948; *Science* 295 (2002), 1619-20. The UN is attempting to boost biosafety in developing countries, *Nature* 415 (2002), 353.

The WHO has put off the destruction of **smallpox** virus in case it is needed for future vaccine research, *Science* 295 (2002), 598-9; *BMJ* 324 (2002), 69. Also on the reasons to delay destruction, *SA* (March 2002), 12-3; *NS* (26 Jan. 2002),

3, 12; *Nature* 415 (2002), 356. Several papers on biowarfare are in *GeneWatch* 15 (March 2002), 3-11; *Science* 295 (2002), 44, 1464, 1467-8; *NatMed.* 8 (2002), 6. On the **anthrax** outbreak and investigation, *NS* (9 Feb. 2002), 8-10; (2 March 2002), 11; *Nature* 415 (2002), 719-20; *Science* 295 (2002), 43, 1425, 1447, 1861. The genomics of anthrax is discussed in *Nature* 415 (2002), 373-4, 396-402; *Science* 295 (2002), 1442. Better vaccines are sought, *Nature* 416 (2002), 116; *Science* 295 (2002), 427-8; *SA* (March 2002), 36-45. Access to agents and risk is discussed in *Nature* 415 (2002), 364.

### Vaccines & Diseases

A review of the biosocial program at TDR in WHO is in *TDR News* 66 (Oct. 2001), 5-8. Antimicrobial peptides of multicellular organisms are reviewed in *Nature* 415 (2002), 389-95.

### AIDS & Sexually Transmitted Diseases

A report from the French national bioethics committee on the ethics of assisted reproduction for those at risk of HIV transmission is in *Les Cahiers* 30 (Jan. 2002). 5-12.

### Microbes & Pollution Remedies

A discussion of biotechnology in the mining industry is *Australasian Biotechnology* 11 (Dec. 2001), 30-1. A fish that glows after being exposed to toxins like PCBs has been used to detect pollution in the USA, *NS* (12 Jan. 2002), 36-7.

### Environmental Issues

A new volume of papers from a 2000 bioethics conference in India is Gabriel, M, Joshua, K., Azariah, J. *Current Issues in Bioethics and Environment* (Madras Christian College, 2001, 291pp.). A report is Pollard, SJ. et al. "Current directions in the practice of environmental **risk** assessment in the UK", *EST* 36 (2002), 530-8. Life cycle assessment and the precautionary principle are reviewed in *EST* 36 (2002), 71-5A. **Poverty** and the environment are discussed in *Environment* 44 (Jan 2002), 9-18. In general on the damage to people our damage to the environment makes, *SA* (Feb. 2002), 72-9.

The persistence of **DDT** is discussed in *Environmental Health Perspectives* 110 (2002), 125-8. On the consequences to health of mercury spills, *Environmental Health Perspectives* 110 (2002), 129-32. A survey of the persistence of pharmaceuticals in US stream water is *EST* 36 (2002), 1202-11. The USA and Vietnam are to study the impact of Agent Orange, *Nature* 416 (2002), 252.

A call for life cycle preferences to be balanced with consumption and health is made in *J. Health Economics* 21 (2002), 161-6. On the issue of **sustainability**, *EST* 36 (2002), 523-9; *Agricultural Economics* 26 (2001), 227-36; *Ecological Economics* 40 (2002), 13-22.

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Europe has been accused of plundering the **fish** stocks from poor nations, *NS* (12 Jan. 2002), 15. Chinese statistics are questioned on fish catches in *Newsweek* (21 Jan. 2002), 42-3; and on fishery management, *Science* 295 (2002), 1235-6. A

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A book review on Hulme, D. & Murphee, M., eds., *African Wildlife and Livelihoods: The Promise and Performance of Community Conservation* (Heinemann, 2001, 344pp.) is in *Nature* 415 (2002), 591-2. Protests in the USA have failed to block a mountain lion survey, *Nature* 416 (2002), 5. There have been claims of misconduct in endangered species issues in the USA, *Science* 295 (2002), 250-1.

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## Safety of Recombinant DNA Products

A method to treat rheumatoid arthritis with TNF alpha blockage has been reported, *BMJ* 324 (2002), 312-3. A discussion of the potential of producing human monoclonal antibodies in yeast is *BioCentury* (19 Feb. 2002), A6-7. A discussion of antiplatelet drugs is in *BMJ* 324 (2002), 59-60. TPA is discussed in *NatMed.* 8 (2002), 5; and a wire grappling hook to remove clots is also being developed, *NS* (16 March 2002), 20. A discussion of molecules being tested in pancreatic cancer is *Canadian Biotech. News* (11 Feb. 2002), 7.

## Food safety

Draft guidelines on assessment of food safety produced from biotechnology have reached step 8 in the Codex Alimentarius process after the March meeting of the Task Force on Novel Foods Produced by Biotechnology in Japan

(see Codex web site). A public survey from Ghana on attitudes towards consuming fungal and mycotoxin contaminated dried cassava products found 59% would still consume mouldy cassava products, *Int. J. Food Science and Technology* 36 (2001), 1-10.

Croatia is drafting laws to ban GM food import, *AgraFood Biotech* 73 (29 Jan. 2001), 17. Italy may have zero tolerance for GM components, *AgraFood Biotech* 73 (29 Jan. 2001), 5. GM bacteria to help clean teeth are suggested in *NS* (23 Feb. 2002), 10.

## Disease Risks & Drugs

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Chaperone overload might contribute to multifactorial diseases, *TIG* 17 (Dec. 2001), 701-4. Large differences in **asthma** prevalence can occur without large differences in **atopy** frequency, as shown in a UK, Albania comparison, *Lancet* 358 (2001), 1426-7. Also on asthma, *Lancet* 359 (2001), 599-600. Questions of how to distinguish good and bad responders to drugs are discussed in *F&S* 76 (2001), 1185-90.

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The International Space Station will not allow **alcoholics**, *Nature* 415 (2002), 568. The link between alcohol and breast cancer is discussed in *JAMA* 286 (2001), 2143-51. Suicide is one of the major risks of alcoholism, *BMJ* 323 (2001), 817-8.

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## Patenting & Business

There have been rising concerns over public access to the rice genome sequence, *Nature* 416 (2002), 111-2. A campaign has started on an end to all gene patents, *NS* (9 Feb. 2002), 15. The question of whether there is a unique status of human DNA to prevent patenting is discussed in *KIEJ* 11 (2001), 359-86. IPRs are also discussed in *Asian Biotechnology & Development Review* (Feb. 2002), 51-62. Some UK medical doctors have claimed a patent to hemochromatosis held by

Biorad is hindering diagnostic tests, *Nature* 415 (2002), 577-9; *Guardian* (7 Feb. 2002). On bioprospecting, *Nature* 416 (2002), 15.

The crisis in lack of profits for pharmaceutical companies is discussed in *BME* 174 (2002), 1. A discussion of Monsanto and its green image is in *Biotechnology and Development Monitor* 48 (Dec. 2001), 13-4. Also on company images, *Splice* 8 (Jan. 2002), 4-6, 10-11.

### Birth Control

Medicalization of menopause is discussed in *Int. J. Health Services* 31 (2001), 769-92; *NS* (16 March 2002), 38-41. On the future of sex, *Nature* 415 (2002), 963. Reproductive health education in China is discussed in *Health & Place* 7 (2001), 261-71.

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### Embryo Status

The question of privacy, abortion and resources is discussed in *Developing Word Bioethics* 1 (2001), 70+. Two papers on abortion are in *AIBA Newslink* 5 (Feb. 2002), 1-3. Information on a claimed safe herbal method to naturally induce miscarriage is available on <[www.geocities.com/naturalmiscarriage/](http://www.geocities.com/naturalmiscarriage/)>

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### Fetal Environment & Neonates

A paper discussing the role of nurses in preventing cot death is *Nursing Ethics* 9 (2002), 137-54. The question of whether home births are safe is discussed in *CMAJ* 166 (2002), 315-23, 335-6. The ethical issue of alienation from labour is discussed in *Bioethics* 15 (2001), 206+.

Discussion of the **ethics** of using antipsychotic drugs for challenging behaviour in learning disability is *JME* 27 (2001), 338-43. The epidemiology of **ADHD** is reviewed in *Can. J. Psychiatry* 46 (2001), 931-40. Infants can even pick up language in their sleep, *NS* (9 Feb. 2002), 13. The question of whether IQ scores should change is discussed in *NS* (2 March 2002), 3. Relationship between birth weight and IQ is discussed in *BMJ* 323 (2001), 1426-7. Ways to teach reading are discussed in *SA* (Jan 2002), 70-7. On the neurobiology of

child abuse, *SA* (March 2002), 54-61. Imitation in preverbal infants is discussed in *Nature* 415 (2002), 755.

### Genetic Disease Markers

Four papers on various aspects of Alzheimer's disease are in *Pathways* 3 (Jan. 2002), 4-23.

### Genetic Screening Methodology

SNP typing by real-time PCR is discussed in *PharmaGenomics* 2 (Jan. 2002), 48-55.

### DNA Fingerprinting & Privacy

Reports on **genetic discrimination** include, Wong, JC. & Lieh-Mak, F. "Genetic discrimination and mental illness: a case report", *JME* 27 (2001), 393-7; *GeneWatch* 15 (Jan. 2002), 3-4. A book review of Wailoo, K., *Dying in the City of the Blues: Sickle Cell Anemia and the Politics of Race and Health* is *Nature* 415 (2002), 477-8. The use of the physician as a gate keeper for the criminal justice system regarding use of genetic information is discussed in *JLME* 30 (2002), 88-94. Old fashioned fingerprinting may not hold up to Supreme Court evidence standards in the USA, *Science* 295 (2002), 418. However a Y chromosome can be a marker for rape, *NS* (2 March 2002), 12.

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The Danish Council of Ethics has published a report, *Genetic Investigation of healthy Subjects. Report on Presymptomatic Testing*, 83pp. (2002) with their 2000 Annual report. Copies are available free. A call to allow testing in children unless clear harm will be caused is Robertson, S. & Savulescu, J. "Is there a case in favour of predictive genetic testing in young children?", *Bioethics* 15 (2001), 26-49. On the disclosure of genetic risk, *Bioethics* 15 (2001), 231-7.

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A 60 page report in French from a symposium on what is **normal** appears in *Les Cahiers* 30 (Jan. 2002). A paper criticising the views of some bioethicists on disabled persons is Munzarova, M. "Towards the abolition of man: The voice of disabled persons cannot be avoided", *BME* 174 (2002), 13-21. Disability is discussed in *JME* 27 (2001), 361-2. Innateness is discussed in *Nature* 415 (2002), 739. A book review of *The Impact of the Gene* is *NatGen* 30 (2002), 137. On the increase in IQ, *NS* (2 March 2002), 24-7.

A paper on how to apologise for the past and **Nazi Science** is *Science and Engineering Ethics* 8 (2002), 31-42. A new book on genocide is Power, Samantha, *A Problem from Hell: America and the Age of Genocide* (Basic Books, 610pp.). A discussion of genetics in **Iceland** is *GeneWatch* 15 (Jan. 2002), 6-10.

### Gene Therapy

Results of a UK survey of 100 patients with cancer found limited knowledge about genes, Holm, S. & Jayson, G. "What

do patients, their relatives and medical staff know about gene therapy?", *BME* 173 (2001), 13-9. A discussion of enhancement and social justice is Savulescu, J. "Procreative beneficence: Why we should select the best children", *Bioethics* 15 (2001), 413-26; 16 (2002), 72-83.

The future of the RAC is discussed in *NatMed.* 7 (2001), 983. The gene therapy death in Pennsylvania is discussed in *Science* 295 (2002), 604-5. A report of a "cyborg" family in the USA, is *Time* (11 March 2002), 42-3.

A general review on gene therapy is in *Medicine* 81 (2002), 69-82. Efficient recombination has been induced in mouse ES cells, *NatGen* 30 (2002), 66-72. The question of germline stem cells for males is reviewed in *NatGen* 30 (2002), 133-4.

### Human Genome Project (HGP)

A discussion of HGP is *NatGen* 30 (2002), 125. The genome of *Schizosaccharomyces pombe* is published in *Nature* 415 (2002), 871-80, 845-8. The genome of plant pathogen of *Ralstonia solanacearum* is in *Nature* 415 (2002), 497-50. A review of proteomics is in *SA* (Jan 2002), 27-41.

### General Medical Ethics

Medical education in **Albania**, and in general is discussed in *Croatian Med. J* 43 (2002), 45-53. Students opinion on the disclosure of true diagnosis in **Croatia** is reported in *Croatian Med. J* 43 (2002), 75-9.

A series of 7 papers on negotiating consensus in bioethics is in *CQHE* 11 (2002), 7-67. A new book based on a Ph.D thesis is Salvi, Maurizio. *Rationalising Individuality. The notion of individuality in biology, philosophy, (bio)ethics.* 300pp. Please contact the author (Maurizio.Salvi@cec.eu.int).

### Law & Medical Ethics

Results of a survey of US hospital ethics committees on their successes and failures are in *CQHE* 11 (2002), 87-93. Pediatric research regulations in the USA, and the John Hopkins case, are examined in *JLME* 30 (2002), 38-57. The US NBAC has been replaced with the President's Council on Bioethics. Dr. Leon Kass of the University of Chicago chairs the Council. The Council is charged with keeping the President informed of new developments in the bioethics arena and to provide a forum for discussion and evaluation of those issues. It is interesting that in the USA the National Bioethics Committee changes with the political party.

### Scientific Ethics

A series of papers on the theme of the ethics of bioethics is in *Law and Bioethics Report* 1 (Dec. 2001), 2-10. Peer review is discussed in *Science and Engineering Ethics* 8 (2002), 99-112.

### Euthanasia & Terminal Care

Assisted suicide is discussed in *JLME* 30 (2002), 6-37. Virtue ethics and euthanasia is discussed in *NZ Bioethics J.* 3 (Jan. 2002), 18-27. Euthanasia in the Netherlands is discussed in *JLME* 30 (2002), 95-104. An English translation of the Belgium euthanasia bill is in *BME* 174 (2002), 9-11. A review of problems nurses encounter in caring for the terminally ill is *Nursing Ethics* 9 (2002), 155-78.

### Organ Transplants & Brain Death

Several papers on organ transplants and donor shortages are in *CQHE* 11 (2002), 68-75. Parental consent to the use of children's dead bodies is discussed in *KIEJ* 11 (2001), 337-58.

### Health Costs

The ethics of health care rationing are discussed in *JLME* 30 (2002), 82-7. A Jewish and Catholic approach to rationing is discussed in *KIEJ* 11 (2001), 317-36.

### Internet Journals

Elsagen project: Ethical, Legal and Social Aspects of Genetic Databases <<http://www.elsagen.net>>

Prepared by Darryl Macer

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HGP and ethics, HIV

### Conferences

*Grief Across Life Span*, 13-15 May, 2002, King's College, London, Ontario, Canada. Email: [deathed@uwo.ca](mailto:deathed@uwo.ca)

*Ethics of Research with Humans: Past, Present and Future*, 17-21 June, 2002, University of Washington School of Medicine, USA. Email: [mbarnard@u.washington.edu](mailto:mbarnard@u.washington.edu)

*Third International Conference of Bioethics*, 24-29 June, 2002, National Central University, Taiwan. Contact: Prof. Shui Chuen Lee, Director, Graduate Institute of Philosophy, National Central University, Chungli, Taiwan, R.O.C. Email: [shuiclee@cc.ncu.edu.tw](mailto:shuiclee@cc.ncu.edu.tw)

*Summer Seminar in Health Care Ethics*, 5-9 August, 2002, University of Washington School of Medicine, USA. Email: [mbarnard@u.washington.edu](mailto:mbarnard@u.washington.edu)

*21st World Congress of Philosophy*, 10-17 August, 2002, Istanbul, Turkey. See [www.fisp.org.tr](http://www.fisp.org.tr).

*16th International Congress of the European Society for the Philosophy of Medicine and Healthcare, European Philosophy of Healthcare and Bioethics*, 21-24 August, 2002, Malta. Contact: Henk ten Have, Email: [h.tenhaven@efg.kun.nl](mailto:h.tenhaven@efg.kun.nl).

*The 3<sup>rd</sup> International DNA Sampling Conference*, 5-8 Sept. 2002, Montreal, Canada. Website <http://www.humgen.umontreal.ca>

*Between Technology and Humanity: The impact of new technologies on Health Care Ethics*, 18-19 Oct. 2002, Brussels, Belgium. Email: [congress.info@palcobru.be](mailto:congress.info@palcobru.be).

*Sixth World Congress of Bioethics: Bioethics, Power and Injustice*, 30 Oct. – 3 Nov., 2002, Brasilia, Brazil. Info and submission: [www.bioethicscongress.org.br](http://www.bioethicscongress.org.br). Abstracts are invited for papers on the Congress theme and on any other topic in bioethics. Abstracts may be submitted through the Congress website. The deadline for abstracts is 31st May 2002.

*IVth Asian Conference of Bioethics: Asian Bioethics in the 21st Century*, 22-26 Nov. 2002, Seoul National University, Seoul, Korea.

Contact: Dr. KOO Young-Mo, Email: [ethics65@netsgo.com](mailto:ethics65@netsgo.com); Prof. SONG Sang Yong, Email: [songsy63@hotmail.com](mailto:songsy63@hotmail.com).

*Second International Conference on Human Rights. Theoretical Foundations of Human Rights*, 17-18 May, 2003, Qom, Iran. Secretariat: Mofid University, Sadooq Ave., Qom, Iran. Email: [TFHR@mofidu.ac.ir](mailto:TFHR@mofidu.ac.ir).

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