In December 2001, the General Assembly of the United Nations adopted a resolution to establish an ad-hoc committee to consider elaborating on an international convention to oppose reproductive cloning of human beings. The committee convened for its first meeting in February 2002. During the exchange of views between government representatives, there was general agreement that the reproductive cloning of human beings should be prohibited by an international ban. However, cloning for the purpose of medical research and experimentation—that is, therapeutic cloning—also raised concerns. Several delegations suggested that the convention should be comprehensive and include a ban on all human embryonic cloning.

Concern about cloning has already found expression in international human rights instruments. The Universal Declaration on the Human Genome and Human Rights, 1997 (UDHGHR) recognizes that genetics research could have vast potential for improving the health of humankind, but it also emphasizes the need to fully respect human dignity, freedom, and human rights. Article 11 states: “Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted.”


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A ban on cloning constrains two important liberties—freedom of reproduction and freedom of science. The essence of liberty is that it may not be constrained except to protect the liberty of another person or a strong public interest. Proposed justifications to prohibit reproductive cloning are based primarily on concern for human dignity and the moral status of the human embryo. This commentary suggests that there are other concerns about therapeutic cloning that justify restrictions on research, including in the private sector. These concerns relate to the protection of egg donors as subjects of research and to the human right of universal access to potential health benefits. The argument is that therapeutic cloning raises issues of global justice that, if not addressed through regulation, might pose a threat to human integrity.

Liberty and Morality

The apparent international consensus against reproductive cloning reflects a popular sentiment that deeply opposes human cloning. Literary classics feed our fascination with and fears of tampering with human nature and the consequences of playing god. Will we lose control and create a monster—a *golem* or a Frankenstein that destroys its inventor?5

Objections to cloning are often connected with objections to all research in human embryos (including surplus in vitro fertilized eggs) because of concern for the moral status of the embryo. Some even consider that the human embryo should be protected by human rights. However, in liberal jurisprudence, it is only after human beings are born that they are covered by these rights and obligations. Moreover, enforcing morality by law is unacceptable in liberal theory. In the 1960s, this was the subject of the well-known Hart-Devlin debate about crimes of prostitution and homosexuality.6 The accepted conclusion was that the moral belief or repugnance of “the man on the Clapham omnibus” is not sufficient to outlaw conduct engaged in by consenting adults. In other words, the right to privacy includes a right to moral integrity even if most others disapprove. Liberty
not only constrains the power of government, but it also limits the moral tyranny of the majority.

**Freedom of Reproduction**

A prohibition on cloning interferes with the right to reproductive privacy and autonomy. The Universal Declaration on Human Rights (UDHR) guarantees the right to found a family and protects the family as a sphere of privacy.

The right to decide freely and responsibly on the number of and spacing between children is also recognized in the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW). Many of the arguments against cloning are reminiscent of those raised 30 years ago against test-tube babies. Concern with playing god was a prominent theme, and alas we are still afflicted with the shortcomings of being mere humans. Other concerns, such as the welfare of the child, remain valid but are not unique to cloning and are largely assuaged when there are adults who will assume the moral and legal responsibilities of parenthood. In what way is cloning different from other methods of medically assisted reproduction? Why should cloning in particular be ruled out as a method of infertility treatment?

**Freedom of Science**

The UDHR includes the right to share in scientific advancement. Under the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR), states undertake to respect “the freedom indispensable for scientific research.” Major advances in science have historically been unforeseen and surprising: We look for one thing and find by chance something else far more significant. The moral status of the embryo is a cultural issue on which even religions may differ and is therefore not sufficient justification to ban cloning.

**Human Dignity**

Some argue that cloning is contrary to human dignity. But what do we mean by this? Cloned individuals would be like identical twins. They would be no less human, since
they would be born of woman and man and “endowed with reason and conscience.” If “all human beings are born free and equal in dignity,” cloned individuals, in themselves, would not be an affront to human dignity. A foundation of human rights is the prohibition of any form of discrimination against persons because of circumstances of birth or genetic heritage. It should be crystal clear that any child born as a result of cloning—whether legal or illegal—is entitled to recognition as a human being and to enjoy all human rights without discrimination.

The preamble to the European Protocol explains that “the instrumentalisation of human beings through the deliberate creation of genetically identical individuals is contrary to human dignity.” What jars our moral sensibility is the intention to treat a human being as a means to others’ ends. This concern makes sense in the context of an Orwellian “brave new world” where a government or corporate body, intent on political or economic gain, mass-produces genetically designed lines of individuals. But it is difficult to find anything wrong with using cloning to help adults fulfill their wish to parent and nurture a child.

Another argument, however, is that cloning tampers with a fundamental feature of what it means to be human. Until now, human reproduction has been the unpredictable result of the random recombination of two genomes—sperm and egg. In contrast, a single genome determines the characteristics of a cloned person. There is concern for the psychological implications. Cloning might impair a child’s ability to have a personal identity or “the right to a free future.” This, it is claimed, is an existential interest that is fundamental to human nature as we know it now.

Although our moral intuition about human dignity is difficult to rationalize, the liberty interests are also rather weak. The expected benefits of reproductive cloning, if any exist at all, are to solve the rare cases of infertility and genetic disease that cannot be treated by such safe and proven options as gamete donation and prenatal diagnosis. And cloning cannot be considered a priority for women’s reproductive health, considering the global agenda of maternal mortality, sexually transmitted diseases, violence against women, and the like.
Rights of Research Participants

In contrast to reproductive cloning, research into therapeutic cloning holds great promise of health benefits. Here, aside from general objections to embryonic research, there are concerns about the rights of research participants. Medical research may be carried out only within the legal protections guaranteed to the individual human subjects, primarily the right to consent freely to participate in medical research. Considerations related to the well-being of participants constrain the goals and methods of scientific research. Medical research using human subjects may be conducted only if its objectives and potential benefits outweigh the inherent risks and burdens to the participants.

According to this standard, research in reproductive cloning should not be allowed. A recent U.S. report concluded that, from the data on animal cloning, reproductive cloning procedures are unsafe and likely to fail. Most animal cloning attempts (as many as 90%) are unsuccessful. Many of the clones die during gestation, even at late stages, and newborns often die or are abnormal. The procedures used and the oversized fetuses that they produce put carrying mothers at risk. Such risks clearly outweigh the supposed benefits of reproductive choice and the right to infertility treatment.

However, further research into cloning for therapeutic purposes is expected to produce major public health benefits. Cloning techniques are already being used (on DNA and cells) to manufacture vaccines, pharmaceuticals, and diagnostic products. In the future, best-case scenarios envision available lines of cloned stem cells with properties that could regenerate tissues and organs for transplantation.

Protecting Egg Donors

To clarify the limits between reproductive and therapeutic cloning, it might be a criminal offence to implant a cloned embryo in a woman's womb. Eggs, however, are the raw material for all cloning research, and though therapeutic cloning does not involve implantation (and subsequent risks of gestation and birth), it does put substantial burdens on egg donors. Women undergo rigorous hormonal treatment to produce a large number of eggs in a given cycle. The
risk of ovarian hyperstimulation can be life threatening in extreme cases. In addition, egg retrieval is an intrusive procedure that can be painful enough to require anesthesia.

Women donors need to be guaranteed the finest medical care during the donation procedure and treatment of any adverse outcomes. Researchers should provide coverage for all health costs. The nature of the medical procedure and the research project, including ethical considerations, must be explained to candidates in plain language so they can give informed consent. For consent to be free and voluntary, prospective participants should be informed of the shortage of eggs for infertility treatment and be given the option to donate eggs to women undergoing in-vitro fertilization (IVF) as an alternative to cloning research.

**Commodification and Exploitation**

One might ask why a woman would consent to undergo the risks and discomforts of egg donation. The international norm is that the human body and its parts shall not, as such, give rise to financial gain. But in other medical and pharmaceutical research, payment often induces healthy people to volunteer. Sperm donors are paid, so why would paying egg donors for their services be unreasonable? Concern for the commodification of eggs need not be an issue. Eggs as such cannot be traded because they cannot, so far, be preserved (only fertilized eggs can be frozen). But there might be concern about the exploitation of women.

High costs of eggs from healthy volunteers could be reduced by recourse to women from countries with lower income levels. Since eggs cannot be preserved, the women themselves would need to travel to places that have safe medical and research facilities. There is already evidence of medical enterprises that support the transportation of women from poor countries across national borders to private facilities where they provide eggs for infertile women. Practices such as these should be followed closely in case they develop into a form of trafficking in women.

Commercial factors are increasingly evident in medical practice and research. Private institutions often tout new reproductive procedures as innovative therapy, rather than
experimentation. Entrepreneurs introduce new technologies (for example, sex selection) that professional organizations disapprove of. Some individuals willingly pay large sums of money for reproductive procedures (including cloning, apparently) that have not been tested scientifically for safety and efficacy. Conversely, subjects who participate in pharmaceutical studies are not expected to pay for trial treatments.

Global Health

According to a recent WHO report, it is difficult to determine how much genuine progress genomic research is making and to predict when results will become relevant to clinical practice. Much interest, however, has been generated about how stem cells might be cultured to differentiate into tissues and organs in treating various disorders.

A major challenge is to overcome immune rejection of the products of cell lines. One solution to this problem could be to use adult stem cells from the prospective recipient. This would provide high-cost “autistic” therapy for particular individuals. Research, however, might take a different direction if the goal is to establish public depositories (similar to blood banks) for biological materials. In this case, there might be waiting lists similar to those for organ transplantation, and potential recipients would have to be matched for compatibility.

The UDHGHR states that the objective of genetic research is “to improve the health of individuals and humankind as a whole.” Health disparities between haves and have-nots are already evident globally, and the fear is that benefits from the genomic revolution will exacerbate inequities of health care between developing and developed countries. One major concern is that genetic medicine and pharmaceutics will be a high-tech product that is beyond the reach of public health systems. In developed countries, health economies are already facing dilemmas of priorities because of their inability to provide universal access to costly medical and pharmaceutical technologies. It is unlikely that any country with a public health system will be able to bear the costs of providing all possible genetic health serv-
ices to the general population. Certainly there are serious considerations of equitable access worldwide.

Even the costs of research are prohibitive to most public economies because of the sophisticated infrastructures, as well as the organizational and research capacity, that bioinformatic technology requires. Public-private collaborations have become the norm. Doctors in university hospitals conduct studies for pharmaceutical companies, and academic researchers depend on resources from private funds. Governments are signing agreements with private corporations because they do not have the technological capacity to undertake national genomic projects on their own.24

Although the public sector initially conducted much of the genomics research, private-company spending is now substantially higher than that by governments and nonprofits. In 2000, worldwide public funding of genomic research amounted to more than 800 million U.S. dollars. Estimates put private funding at possibly twice that amount.25 Research priorities in the private sector are driven by profit and biased toward the needs of individuals who can afford expensive technologies. The private sector does not invest in research aimed at diseases found predominantly in developing countries because the populations of those countries do not have purchasing power. To ensure high returns on investments, research focuses on curing diseases and health problems that are most prevalent in developed countries.26 Thus the needs of the “paying consumer” seem to determine the current global research agenda, rather than the general health needs of the world population.

**Intellectual Property**

Intellectual property law substantially influences the market. Patent owners can use licensing privileges to restrict access to findings that could be used in further research and development. For the life of the patent, owners enjoy a marketing monopoly and can control pricing of therapeutic products. Similar to funding for research, intellectual property is concentrated in the private sector of developed economies.

There is significant debate about the justifications for
patenting genes. A WHO report stated that the current situation regarding the patenting of discoveries from genomics is “little less than chaotic.”27 Interestingly enough, the 1994 Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement allowed the exclusion of diagnostic, therapeutic, and surgical methods from patentability.28 A major question is whether a similar public-domain policy should be established for genetic medicine, rather than the pharmaceutical model of corporate intellectual property rights.

**Human Integrity**

The emerging worst-case scenario forebodes a world inhabited by two distinct human species: Some will have access to advanced genetic and other health services and will live disease free for a currently unthinkable number of years, while others will suffer illness and disease and have a life expectancy similar to those who lived 100 years ago.

What’s more, some claim that cloning is a component of a eugenic ideology and that cloning techniques are the technical platform for a larger agenda that will permit inheritable genetic modification and genetic enhancement. “New” humans with enhanced inheritable characteristics (the “GenRich”) would dominate the lesser and inferior form of natural humans, as we know ourselves today.29

If cloning could create a genetic schism within the human species, it could pose a serious threat to the integrity of humankind. To preempt this concern, it might be necessary to constrain and regulate market forces to guarantee that people and populations throughout the world have equitable access to the benefits of genetic medicine. Restrictions on freedom of enterprise and contract could be justified by considerations of human rights and social justice.

**Human Rights**

The ICESCR recognizes the human right “of everyone” to the enjoyment of the highest attainable standard of health.30 It also recognizes the cultural right “to enjoy the benefits of scientific progress and its applications.”31 Health
is a human right, not a commodity or a privilege. Human rights are universal. This means providing equal access to affordable health services at a comparable level throughout the world.

The human right to have access to and to enjoy the health benefits of genetic research raises difficult dilemmas of distributive justice because of the high costs of the technology. However, all undertakings of states under the ICESCR are qualified by “maximum available resources.” Problems of prioritizing the just allocation of limited resources are intrinsic to social rights, and particularly to health care. New medical technologies increase efficacy in terms of individual outcomes but also increase dramatically the costs of care. The costs of health care are potentially beyond the reach of the resources available to any given society.

Compared with other priorities in health care, reproductive cloning seems to be a waste of money. But therapeutic cloning research might produce great benefits, depending on its objectives and products. A rights-based approach justifies constraints made on the private market in setting priorities for both research and service development, in an effort to enhance public health and promote global justice.

Justice

A common understanding is that liberty is the underlying principle of civil and political rights. At the same time, justice is seen as the underlying principle of economic, social, and cultural rights, such as the right to share in the health benefits of cloning research. Justice acts like a constraint on the market, just as liberty acts like a constraint on the state. Private transactions between individuals and corporations have broad implications for the health and lives of many others. The principle of justice trumps considerations of economic utility, much as liberty trumps the power of the state to violate civil and political rights.

In liberal philosophy, John Rawls’s theory of justice presents a unifying ethical concept for social rights that complements John Stuart Mill’s concept of liberty. Rawls’s concern is with fairness in the distribution of two kinds of “public goods”: fundamental freedoms and wealth and social status.
The principle of equality applies in a strict, formal sense to individual freedoms, and exceptions are allowed only to protect the liberty of the other. But for wealth and social status, Rawls adopts a “difference principle,” which amounts to the notion of “substantive equality” in feminist legal theory and is often referred to as “equity” in health-policy literature.35

According to the difference principle, social inequalities must be considered in the distribution of resources, so that the position of the least advantaged is maximized. Norman Daniels suggested that health inequalities should also be considered and that ill health itself engenders various forms of disadvantage.36 The principle of justice is thus a strategy for arranging social or economic advantage to the greatest benefit of the least advantaged. This amounts to the notion of solidarity.

Rawls's theory also implies procedural fairness, or due process, in determining the principles for the just allocation of resources. Fairness requires transparency and accountability in making decisions, as well as public participation. Procedural fairness is of central importance when facing dilemmas of health-care priorities, because there is often no substantively right answer.

**Equity**

Who stands to benefit from cloning research? The European Convention refers to the duty of parties to provide “equitable access to health care of appropriate quality.”37 The UDHGHR declares that “benefits from advances in biology, genetics and medicine . . . shall be made available to all.”38 The setting of research agendas is usually a matter of scientific freedom, but if objectives of global health seem unachievable through the market, then considerations of equity come to bear on priorities in allocating resources. To reduce health disparities, an affirmative-action policy could direct public funding for research so as to prioritize the needs of vulnerable groups.39 However, some research cannot be undertaken without private funding. Priorities could also be set for public-private collaboration in genetic research.

Equity in the sharing of benefits should also be
addressed. For example, profit-making entities could be required to earmark a percentage of annual net profit for public health purposes. Where the results of research are still remote and uncertain, issues of affordability and accessibility need to be discussed with participating individuals and publicly debated.\textsuperscript{40}

**Solidarity**

Social rights discourse takes into account the needs of disadvantaged groups, both locally and globally. The General Comment of the ICESCR Committee on the right to health, states that a primary core obligation of governments is, \textit{“to ensure the right of access to health facilities, goods and services \ldots , especially for vulnerable and marginalised groups.”}\textsuperscript{41} In the context of cloning, the vulnerable are the poor, who constitute the majority of the world's population and who will probably be unable to afford the health benefits of genetic research.

**Due Process**

Both the UDHGHR and the European Convention require all research, including that initiated by profit-making funders, to undergo scientific and ethical review for the protection of participants.\textsuperscript{42,43} But once a study has been approved, researchers have no reporting duties. Governments are not vested with powers to monitor ongoing research; to require periodic reporting on progress, outcomes or applications; or to receive on-demand information about specific transactions. As a result, private-sector research is neither transparent nor publicly accountable.

The European Convention mandates public discussion of fundamental questions raised by biomedicine.\textsuperscript{44} Public involvement in policymaking is also mentioned in the ICESCR General Comment on the right to health. A core and nonderogable obligation of States parties is to adopt a national public health strategy that addresses the health concerns of the whole population and that is devised and periodically reviewed, using a participatory and transparent process.\textsuperscript{45} The General Comment also refers to \textit{“the right of individuals and groups to participate in decision-
making processes, which may affect their development.”

Human cloning raises many serious concerns that call for broad public debate.

Conclusion

The debate on human cloning has focused mainly on reproductive cloning. The moral intuition—that it should not be allowed—has been framed in terms of human dignity. But, aside from the moral debate on whether the embryo is a human being, arguments about human dignity do not hold up well under rational reflection. Additionally, liberty interests involving freedom of reproduction and of science, which require a strong public interest to justify any limitation, must be considered. Nevertheless, reproductive cloning research is currently unsafe, and even if animal cloning is perfected, the physical dangers and psychological risks of human experimentation might be prohibitive. Moreover, the interest in reproductive freedom is weak, and the potential health benefits are marginal. In the balance, a prohibition of reproductive cloning seems justified.

On the other hand, research into therapeutic cloning is expected to lead to significant health products. In this context, the concern is about the exploitation of women as egg donors and the need to protect women participating in research from violation of their human rights and dignity. Much of the research is, however, being conducted in the private sector, where ethical review mechanisms and standards are not uniform and may result in “forum shopping” for convenience. In addition, private corporations are not publicly accountable or transparent. They report to their shareholders and to a stock exchange if publicly traded. But these are reports on profits and losses and not on ethics and human rights. Governments are not vested with powers of surveillance to observe and monitor private-sector activities.

Priorities in privately funded research are motivated by profit and not by the quest for pure knowledge or for promoting public health. Intellectual-property law guarantees returns on investment by giving pricing control to patent holders. It is likely that if the private business sector is left alone, global health disparities would exacerbate rather than
diminish. Hence, priorities in research and service development call for extensive public debate.

The key question is, who stands to benefit from research? If we put cloning in the context of the interplay of public and private actors and the enormous finances involved globally in genomic research, it appears that we are facing a major issue of global health and justice. There is a universal human right to access and enjoy the health benefits of genetic research. The goal of genetic research is to relieve suffering and improve health, and the challenge is to guarantee people throughout the world equitable access to the health services that can do so.

References

7. Universal Declaration of Human Rights (UDHR), Articles 12, 16(1).
9. See note 7, Article 27(1).
10. International Covenant on Economic, Social and Cultural Rights (ICESCR), Article 15.3.
11. See note 7, Article 1.
12. See note 7, Article 1.
14. See note 4, Preamble.
15. International Covenant on Civil and Political Rights (ICCPR), Article 7: “No one shall be subjected without his free consent to medical or scientific experimentation.”
16. Universal Declaration on the Human Genome and Human Rights [UDHGHR], Article 10.
17. World Medical Association Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects (October 2000), Paras. 5, 16-18.
21. See note 20, p. 121.
22. See note 16, Article 12[b].
23. See note 20, p. 123.
27. See note 20, p. 136.
30. See note 10, Article 12.
31. See note 10, Article 15.1[b].
32. See note 10, Article 2.1.
34. J. S. Mill, On Liberty [London: Longman, Roberts and Green, 1869].
35. See note 33, p. 302.
36. N. Daniels, Just Health Care [Cambridge: Cambridge University Press, 1985].
37. See note 33.
38. See note 16, Article 12[a].
40. Ethics Committee, Human Genome Organization [HUGO], Statement on Benefit-Sharing [April 2000].
42. See note 16, Article 5 [d].
43. See note 19, Article 16 [iii].
44. See note 19, Article 28.
45. See note 41.
46. See note 45, Para. 54.