

International Governance of Human Cloning

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Overview

- ✧ Reasons for exploring the issue
- ✧ Critical analysis of international legal governance
- ✧ Impact of recent scientific developments and legal or social changes
- ✧ Exploration of possible future governance mechanisms

Reasons for UNESCO Re-exploring Human Cloning Governance

- Recent change to US policy creating regulatory opportunity
- Consensus creating regulatory opportunity
- Concern about rogue scientist(s)
- Technological developments exposing inconsistencies, imprecision and lack of enforcement power
- Unresolved concern about long term impact on human gene pool/global public health/ethics in science
- Vulnerability of (infertile or DNA-donating) people in developing nations that lack relevant legislative prohibition
- Religious or scientific lobbying to clarify issue

General background on present international legal governance of human cloning

Putative international legal norms:

1) 'Reproductive cloning of human beings' is prohibited (as it is) (if it is) 'contrary to human dignity'

2) 'States and competent international organizations are invited to co-operate in identifying such practices

UNESCO Universal Declaration on the Human Genome and Human Rights (11 Nov 1997) endorsed by UN General Assembly Resolution 53/152 9 Dec 1998.

3) 'All forms of human cloning' are prohibited 'inasmuch as they are incompatible with human dignity and the protection of human life'

United Nations Declaration on Cloning (8 March 2005).

4) 'Any intervention seeking to create a human being genetically identical to another human being, whether living or dead is prohibited'



General background on present international legal governance of human cloning

Putative international legal norms:

5) 'Foster continued and informed debate and take appropriate steps, including legal and juridical measures, to prohibit cloning for the purpose of replicating human individuals.

World Health Organization. Resolution WHA51.10 (16 May 1998) Also WHA50.37

6) National legislation and guidelines (set out in Annex to IBC Report) prohibit human cloning, human reproductive cloning, human cloning for reproductive purposes

Other Relevant International Norms and Regulatory Options

Article 16 – UDBHR

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Ius Cogens

Common Heritage of Humanity

Technology transfer norms in TRIPS and UDBHR

Precautionary principle

MDGs, social responsibility principle and global public goods theory

Constitutional rights or prohibitions

Informal Moratoriums or Industry self regulation

Market forces

Regulatory Pyramid

- ✧ **Apex:** Constitutional rights; trade agreements; UN conventions, statutory (legislative) rights and prohibitions, common law (judicial) rights and prohibitions
- ✧ **Middle:** UN Declarations; expert guidelines; institutional and professional codes of conduct; R&D funding; corporate self regulation; moral and ethical principles
- ✧ **Base:** individual and social virtues and conscience-respect for equality, justice, scientific integrity, public good, human dignity

Sources of International Law

Statute of the International Court of Justice

Article 38 (3) *The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply:*

- a. international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;*
- b. international custom, as evidence of a general practice accepted as law;*
- c. the general principles of law recognized by civilized nations;*
- d. subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law;*

Critical Analysis of International Legal Governance on Cloning-I

- ❑ Norms a mixture of moral, ethical, domestic law and international 'soft' law
- ❑ Norms are mutually inconsistent
- ❑ Norms are vague and inaccurate
- ❑ Norms do not constitute international legal obligations enforceable either by states or individuals but may evolve into such
- ❑ Norms may have unintended consequences of either inhibiting socially valuable medical research or encouraging prohibited practices for profit.

Critical Analysis of International Legal Governance on Cloning-II

- ❑ Cloning as producing identical human beings is scientifically impossible.
- ❑ Term 'clone' is scientifically and etymologically misleading but is embedded in international and national governance
- ❑ Cloning as producing immunologically compatible DNA, cells and tissue will reduce disease and suffering
- ❑ Attempted reproductive cloning has serious health risks for both women and foetuses and would likely produce professional misconduct and malpractice proceedings in every jurisdiction

Impact of Recent Scientific Developments

Cloning by SCNT has allowed

- propagation and expansion of gametes from prized livestock and transgenic modification of large animals.

- genetically identical mouse clones from a variety of differentiated cell types

- *Eggan, K. et al. Mice cloned from olfactory sensory neurons. Nature 2004; 428: 44-49.*

- *Wakayama, T et al Full- term development of mice from enucleated oocytes injected with cumulus cell nuclei. Nature 1998; 394: 369-374.*

But genetically tailored human embryonic stem (hES) cell lines not developed.



Eggan K. Dolly Legacy: Human Nuclear Transplantation and Better Medicines for Our

Children. Cloning and Stem Cells. 2007; 9(1) DOI: 10.1089/clo.2006.0013.

iPS cells and Human Cloning

□ Transient over-expression of transcription factors can reprogram differentiated cells into induced pluripotent stem (iPS) cells that resemble embryonic stem (ES) cells.

Zhou, H. et al. Generation of induced pluripotent stem cells using recombinant proteins. Cell Stem Cell 4, 381-384 (2009).

□ The most stringent test of pluripotency in iPS cells is generating full-term or adult mice in tetraploid complementation assays.

□ In 2009-fertile adult mice were derived entirely from iPS cells generated by inducible genetic reprogramming of mouse embryonic fibroblasts.

Boland MJ et al Adult mice generated from induced pluripotent stem cells Nature 2009; 461 (3 September) doi:10.1038/nature08310



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Xiao-yang Zhao iPS cells produce viable mice through tetraploid complementation.

Human Cloning and Oocyte Donation

- ❑ iPS cells placed in an oocyte to develop cloned human cells or produce immunologically compatible organs.
- ❑ Most oocytes acquired from those left over after ART
- ❑ But oocyte freezing is becoming a practical reality
- ❑ Thus, plentiful high-quality oocytes may soon exist in excess of clinical need.

Harrison, K. et al. April 02, 2007. "Oocyte cryopreservation as an adjunct to the assisted reproductive technologies". The Medical Journal of Australia 186 (7): 379

Impact of Recent Scientific Developments

- ❑ iPS cells and oocyte freezing may allow therapeutic cloning of cells and human reproductive cloning without the initial use of embryonic cells
- ❑ Norms prohibiting human reproductive cloning chiefly on basis of infringement of moral status of embryo (via broad human dignity standard) becoming outdated

Causes of Governance Complexity

- Extended spatial and temporal scales of cloning
- Ecological limits-human cloning and the population problem
- Irreversible or cumulative inputs once a single cloned person reproduces naturally
- Pervasive risk and uncertainty of cloned DNA in human gene pool
- Important medical research not traded/valued
- New ethical/legal/human rights dilemmas-respect for human dignity of cloned person
- Policy arising ad hoc from knowledge silos
- Corporate greed hindering public good policy/convention



Future Governance Options-I

UNU-IAS report

- ❑ International Bioethics Committee of UNESCO (IBC) promotes issues concerning reproductive and research cloning.
- ❑ Sixth committee of the UN General Assembly takes up the issue of customary international law on cloning.
- ❑ UNESCO informally promotes dissemination, discussion and debate on cloning issues at the international level.

Future Governance Options-II

UNESCO *Declaration on the Governance of Human Cloning*

- Clarifying the terminology
- Clarifying specific prohibition on reproductive cloning for purposes of national legislation and bioethical guidelines
- Highlighting related issues of public and private goods in medical research
- Highlighting relevant moral issues including vulnerability of embryo/fetus/child
- Highlighting bioethical and human rights responsibilities of states, corporations and medical researchers

Future Governance Options-III

UNESCO *Convention on Governance of Human Cloning*

- Permits embargo on research co-operation
- Prohibits trade in cloned embryos but not cloned tissue or cells
- Permits trade cross-retaliation with offending state/corporation/institution
- Permits *International Court of Justice* to hear disputes between states-ie: France/Germany v rogue state
- Makes human reproductive cloning a crime justiciable before *International Criminal Court*
- Require ratifying states to impose criminal sanctions under domestic law
- Allow legal guardian of cloned human to appeal to UN human rights committee if domestic remedies non-existent or inadequate

Future Governance Options-IV

International governance of human cloning as part of broader text:

❑ **UNESCO *Universal Declaration on the Public Good in Healthcare*** -code of conduct for managers of healthcare systems, not just professionals

❑ **UNESCO *Universal Declaration on the Public Good in Medical Research*** -code of conduct for scientists