



The Ban on Genetic Interfering Act, 2009

An informative position paper

Presented to the Science and Technology Committee

by

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1. Introduction

At present, the Israeli parliament's Science and Technology Committee is assembled in order to discuss a proposal for the renewal of the *Ban on Genetic interfering Act (1999)* for another five years moratorium.

Today, after two five-year moratorium periods, we plead the following:

- A. The legislature should turn the above act into a permanent one that completely and clearly bans human cloning.
- B. The legislature should explicitly define the allowed and forbidden aspects of genetic interfering in gametes and in experimental cloning processes.
- C. The legislature should formulate effective regulatory mechanisms for these topics.

The above demands are consistent with legal norms in countries that had taken legal action concerning cloning and genetic topics, and with relevant international conventions that Israel had signed. This document lays down the processes that led to the forming of a temporary act; the latest scientific developments in the field of cloning as well as scientific and ethical-social reasons for the demand to turn the above bill into permanent one.

The *Ban on Genetic interfering Act (1999)* was intended to prevent the abuse of new genetic technology¹. The act determined a **five-year period**,² during which different genetic interfering procedures will not be allowed to be performed on humans, in an attempt to examine the moral, legal, social and scientific aspects of these procedures and their effects on human dignity.³

Due to the complexity of this issue, two bodies were established in order to advise and report to the government on different aspects of genetic interfering and cloning. Helsinki high committee was asked to deal mainly with the scientific aspects, alongside the legal and social aspects of genetic interfering, to examine different aspects of scientific developments in these areas and to report their findings to the government. The national council of bioethics, on the other hand, was asked to examine the ethical dilemmas these issues raise and to inform the public about topics dealt with at the committee meetings. These two bodies were set to be independent, pluralistic as well as multi-disciplinary and asked to deliver annual reports. By establishing these two bodies, the legislature wished to allow comprehensive public discussion regarding different aspects of scientific developments during the moratorium it had set, so that a decision would be eventually made regarding turning the act into a permanent one that balances between scientific needs and social values. Since it was first proposed a second moratorium was set in 2004 which is about to expire in the upcoming days.

After the two moratoriums had been given, it is possible to state that the ten years that had passed since the first temporary legislation in 1999 did not facilitate even a limited public debate concerning the relevant issues. Due to the absence of a wide and diverse public debate it is not possible today, following two moratoriums, to determine the position of Israeli society regarding these issues. Furthermore, it can be said that Israeli society is not sufficiently aware of scientific developments and its influence on it.

¹ Attorney Gali Ben-Or, Genetic Cloning and Artificial Fertilizing Technologies- Arrangement in Israel and around the world:

<http://www.medethics.org.il/articles/ASSIA/ASSIA61-62/ASSIA61-62.02.asp>

² Highlighting the above sentence does not appear in the original text.

³ Act of Genetic Interfering, Human Cloning and Genetic Change in Gametes, 1999, p.4

2. The first moratorium extension – parliament discussions regarding the Ban on Genetic Interfering Act, 2004

At the end of 2003, towards the end of the first moratorium, six discussions of the Science and Technology Committee took place in order to determine whether to prolong the temporary act validity or to turn it into a permanent act. The legislators who attended the discussions, Chairwoman Meli Polishook and PM Ofir Pines, held the opinion that the moratorium should be abolished because of the fact that human cloning is immoral, regardless of scientific developments and because this message should be clearly introduced to the public.⁴

Representative of The Commission of Future Generations, Nira Lamay, emphasized the Israeli commitment to international agreements that ban human cloning.⁵

Prof. Hagit Messer-Yaron advocated the idea that permanent banning of human cloning does not harm scientific progress, but rather states a moral standing the legislators should adopt. Representing a unique voice among fellow scientists, Prof. Messer-Yaron stated that the debate about cloning is a moral one and does not harm scientific progress. In comparison to other scientists she stated that the legal authority and the public should supervise over science and research.

In opposition to this viewpoint, Rabbi-Dr. Yigal Shafran stated in the name of some of the medical and scientific community that withdrawing the moratorium and turning the act into a permanent one will harm scientists' prestige among the public, force them to bypass the law and harm fertility fostering.⁶ Other scientists claimed that withdrawing the moratorium will harm the scientific practice autonomy and could harm important scientific progress. These claims oppose the fact that in all western countries scientists act within the legal framework containing a permanent act.

In spite of the fact that only one interest group asked for the moratorium to be prolonged, while other public representatives asked for its termination, the act that bans cloning (2004) and prolongs the moratorium for five additional years, was legislated. Many committee members who were not present during the discussions voted in favor of the act, and according to Chairwoman Polishook their voting reflects the massive pressure applied by various interest groups within the scientific community.⁷

3. Latest scientific developments in the field of cloning

In the last few years, scientific research of cloning shows major developments in three close fields: cloning and fetal stem cells, developments in the human genome area and the forming of chimera.⁸

Developments in the field of cloning and fetal stem cells

The most important discovery of the last year is the one that proved that fetal stem cells can be produced from adult cells, without the usage of egg-cells.⁹

⁴ Science and Technology Committee of the Israeli Parliament, 12.01.2004.

⁵ Science and Technology Committee, of the Israeli Parliament, 06.01.2004

⁶ *ibid.*, 12.11.2003

⁷ *ibid.*, 31.12.2003

⁸ SA Newman: Averting the Clone Age: Prospects and Perils of Human Developmental manipulation in: Journal of Contemporary Health Law and Policy, 2002

<http://scholar.google.co.il/scholar?q=info:aNtp0BLh8tYJ:scholar.google.com/&output=viewport&pg=1&hl=iw>

In 2006, scientists discovered that they can make adult cells undergo a developmental withdrawal into IPS (Induced Pluripotent Stem) that look similar to fetal stem cells. In July 2009, two articles were published in *Cell Stem* and *Cell Nature* scientific journals, describing breakthroughs in the field of fetal stem cells and demonstrating that IPS cells and fetal stem cells are identical.

Two different groups of scientists, from Beijing and Shanghai, succeeded in generating fetal stem cells from adult cells of mice skin, and to grow from these cells adult mice that are identical to the genetic profile of the original skin cells. Once again these results prove that egg-cells are not needed for producing fetal stem cells.

On the one hand, these results allow medical researchers to easily produce tissues for transplanting procedures. On the other hand, they raise substantial concerns that human cloning is becoming relatively simple, and thus very tempting.

Developments in researching the human genome

In May 2006 the project of mapping the human genome was completed. **This achievement has supplied researchers with tools that can be used in healing methods based on genetic interfering.**

Developments in researching the field of chimera

Chimera is formed by combining human and animal cells. In order to bypass the substantial shortage of human egg-cells, scientists transplant nuclei of human cells into animal egg-cells hoping to produce tissues suitable for transplanting in human beings.¹⁰

Two research methods, explored worldwide, were derived from this technology. In the first one, chimerical cloning technology is used for growing partially human, hybrid fetus until the fourteenth day. From this fetus fetal stem cells are produced, thus obtaining tissues for transplanting nerve cells, skin cells, etc. But this is not enough. In order to produce whole organs, not just tissues, it is necessary to grow the fetus to a developed stage at which its organs can be harvested. Thus the second method: planning the engineering of hybrid creatures, partially human, grown to the advanced stages as a source of human organs.

Difficulties facing scientific developments

Today, after three decades of cloning efforts, it is clear that a vast amount of work is still needed. Only a small part of the experiments reached the phase of transplanting a clone into the womb of the animal experimented on. Furthermore, only in a small percentage of those cases involving a transplant, a healthy animal was born, and almost in all cases the born cloned animal suffered from many anomalies, most of which were not expected. For instance, it is very widespread, and so far unexplained, that the fetus grows in an unproportional way that makes it inevitable to kill the animal carrying the fetus. There were also cases in which animals were born with enlarged organs, or were born healthy but underwent an accelerated aging process or suffered a sudden, unexplained death. In most cases, it was reported that there were chromosomal breakings, genetic deformations and mutations.¹¹

⁹ Rob Stein Mice studies may ease need for stem cells from embryos, *The Washington Post*,
Posted: 07/24/2009 01:00:00 AM MDT

¹⁰ Helsinki Committee Report, 2008, Part 2,
SA Newman, "Averting the Clone Age: Prospects and Perils of Human Developmental manipulation,"
Journal of Contemporary Health Law and Policy, 2002

¹¹ On anomalies in the placenta and other biological mechanisms in cloned animals:

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Progress in researching the human genome raised hopes that it will be possible to produce cloned fetuses, genetically engineered in a way that rules out genetic weaknesses inherited from the fetus' parents. Besides the ethical problems in producing improved babies, which will be discussed later, there are difficulties in scientific developments in the field of genetic cloning, due to the fact that manipulating the genes is not the only factor determining the final outcome of the human being or animal conceived via cloning. The cloning process itself produces genetic changes. In order for the cloning process to succeed, the somatic cell (i.e. the transplanted cell) must restart itself, thus to undergo changes that will eventually cause genetic changes¹².

The chimera process presents greater problems because animal egg-cells that undergo genetic manipulation in order to produce a fetus from them are exposed to numerous genetic damages due to which many chimerical creatures (and the females carrying them) die during the process. In addition, cloning includes transferring the nucleus only, while the cellular material surrounding it originates from the host creature. Until today, the influence of the mitochondria of the host on the genetic profile of the cloned fetus is not fully understood. Thus, cloning stem cells by producing chimeras and transplanting them in an ill person may cause many unpredictable genetic problems.¹³

Following the latest breakthroughs, alongside the many problems discovered in the process of cloning and genetic interfering, many members of the scientific community began to demand the government to legislate an act that bans human cloning, to enhance regulation on the whole cloning process, to determine clear rules regarding what is approved and banned in manipulating human fetuses and to declare a firm objection to human cloning and to mixing human and animal cells.

4. Scientific reasons for permanent banning of human cloning and limiting genetic interfering

Arnold DR, Fortier AL, Lefebvre R, Miglino MA, Pfarrer C, Smith LC., "Placental insufficiencies in cloned animals - a workshop report. " Placenta. 2008 Mar;29 Suppl

A:S108-10. Epub 2008 Feb 20.

On cloning influences on anomalies creation during the process of genome consolidation:

Senda S, Wakayama T, Arai Y, Yamazaki Y, Ohgane J, Tanaka S, Hattori N, Yanagimachi R, Shiota K. DNA methylation errors in cloned mice disappear with advancement of aging. Cloning Stem Cells. 2007

Fall;9(3):293-302.

On anomalies in the size of cloned fetuses:

Inui A. Obesity--a chronic health problem in cloned mice? Trends Pharmacol Sci. 2003 Feb;24(2):77-80

12 This process necessitates change in epigenetic components that compose the chromosomes (methyl groups, arranging the proteins and the RNA molecules that are attached to the DNA etc..) Effect of Epigenetic Modifications of Donor Somatic Cells on the Subsequent Chromatin Remodeling of Cloned Bovine Embryos.

A. M. Giraldo, D. A. Hylan, C. B. Ballard, M. N. Purpera, T. D. Vaught, J. W. Lynn, R. A. Godke, and K. R. Bondioli (2008) *Biol Reprod* **78**, 832-840

¹³ On the influence of the mitochondria, see research proposition of Douglas Wallace: The Dangers of Mitochondrial DNA Heteroplasmy in Stem Cells Created by Therapeutic Cloning http://www.cirm.ca.gov/ReviewReports_RC1-00353-1

Among scientists' arguments, based on scientific considerations only, the following two are most prominent:

A. Cloning primates in general and humans in particular is less understood and more complicated than other creatures. Therefore, all cases of human cloning could end up in the death of the mother carrying the cloned fetus. Furthermore, high incidents of mutant newborns are expected, including cases in which the fetus could have medical problems that do not appear until after birth. In short, danger for both mother and baby is high and the procedure must not be approved.

B. Similar to our inability to predict many anomalies and genetic deformations that appear in cloned animals, we cannot predict those that might appear in humans, especially deformations in the human brain. In fact, manipulations performed on the human genome may bring us to a point at which it is not certain whether all newborns can be given the same biological definition, because we may encounter taxonomic differences unknown to us.

5. Ethical reasons for permanent banning of human cloning and limiting genetic interfering

A. Due to the fact the human cloning is a process in which many failures are bound to happen, the dangers that will face the mother, fetuses and newborns at the various stages of the process represent a moral barrier for human cloning.

B. Because of the high chances of changes in the cognitive and morphological structures of cloned persons, there will be a disintegration of common basic human features that will represent a moral barrier for human cloning.

C. Hybrid creatures produced via human cells cloning into animal egg-cell will have an uncertain legal status, and the only role they will have is to be a source from which organs will be harvested. Therefore, it will be unethical to produce them in the first place.

D. Even if we assume that the cloning process will be flawless, using cloning techniques for genetic improving of humans will generate a situation in which some human beings will be regarded as genetically superior as opposed to others, thus irreversibly harming an important principal of western democracy which states that all human beings are born equal and considered legally equal throughout their lives. As mentioned above, the difference between human beings and industrial-medicals product could become dangerously blurred.

6. Political and regulative reasons for permanent banning of human cloning and limiting genetic interfering

A. A decision of renewing the moratorium will weaken the validity of the message against human cloning, and will furthermore weaken the legal authority in its efforts to demand a firm regulative system whose duty, among others, is to ban human cloning or other usage of human gametes. Avoiding these hazards can be reached when the act is permanent and the social message within it is clear.

B. Since signing the act in 1999 until the debate about prolonging the moratorium at the beginning of 2004, three electoral campaigns took place for

the Knesset (The Israeli Parliament).¹⁴ This rapid change of government induces a state of temporariness among Knesset members and instability in the process of laying a firm policy. Changing the government means replacing the various committees' members, and delays in issues discussed. In the case of such a complex issue, applying a temporary act forces the political system to reconsider all the legal, political, moral and scientific aspects of developments in the field of cloning, as the political members of the committee are the least involved in the topics discussed. Allowing enough time for a thorough debate will enable the committee members to become sufficiently experts in the field, and allow making a permanent act that is not dependent on various political changes.

In light of the ethical, scientific and political-regulative considerations, we ask the Knesset members, yet again, to legalize a permanent act that bans genetic interfering, while specifying exactly what is allowed and banned in the realm of genetic interfering, and setting a firm regulation system, as is done in all modern countries today.

14 The dates of elections in Israel between 1999 and 2004 are: 1999, 2001, 2003