

# The Israeli Approach to Cloning and Embryonic Research

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## *Chapter A – The Israeli Prohibition of Genetic Intervention Law*

### Legislative History

In February 1997, an unprecedented scientific storm was caused by the announcement of the birth of a small cloned sheep. Dolly – as she quickly became known – forced legislators, legal experts and scientists around the world to confront the possibility of cloning as a technique for creating human beings. The issue caused lively debates in Israel as well, and in March 1997, no fewer than three bills<sup>1</sup> were submitted to the Knesset<sup>2</sup>. One aimed at actually prohibiting the cloning of human beings and even animals, and the others intended to supervise experimentation in order to prevent medical experiments that aim to clone human genetic traits. Only the first of these bills became law, but in a form very different from the original proposal.

The legislative process in Israel provides that a member of Knesset who wishes to promote a bill must submit it to the Knesset so that other members can consider it before the vote at the preliminary reading. After it is approved in this reading the bill is brought before one of the committees of the Knesset to prepare it for the first reading. After the bill passes the first reading it is returned to the Knesset committee to prepare it for the second and third readings. Only after being approved in this final vote, is it promulgated as a law.

### Preliminary Bill

The preliminary bill submitted to the Knesset was extremely broad and sought to forbid any medical experiment related to the replication of genetic traits in human beings and not intended to heal or prevent disease<sup>3</sup>. The explanatory note to the bill expressed the fear that "... genetic engineering could remove the spirit, uniqueness, character and distinctiveness of the individual ... it represents a serious danger to the human race. Humanity must defend itself from the possibility

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<sup>1</sup> The Genetic Experiments (prohibition of cloning) Bill, 5757–1997 (no. p/1245); The Supervision of Medical Experiments on Human Beings Bill, 1557–1997 (no. p/1309); The Prohibition of Experiments of Cloning Human Beings, 5757–1997 (no. p/1379).

<sup>2</sup> The Knesset is the Israeli house of legislators.

<sup>3</sup> Bill no. P/1245, which was the only one of the three that has actually become law.

of minting and replicating people, since such activity would endanger moral and ethical values of human foundation.” The government, which at first objected to the spirit of the preliminary bill, eventually agreed to the legislative process being undertaken with coordination and cooperation of the relevant governmental ministries. Therefore, the bill passed the preliminary reading and was transferred to the Knesset’s Special Committee for Scientific and Technological Research and Development (hereinafter: the “Scientific Committee”) in preparation for the first reading. During the course of debates in the Knesset plenum, the member of the Knesset who initiated the bill announced his intention to find a way of regulating the issue so it would not harm research and it would permit research intended to benefit humanity.<sup>4</sup>

The bill covered very fundamental questions involving morality, research, science and society. Hence, numerous discussions were held in the Scientific Committee of the Knesset. Scientists, researchers, physicians, philosophers, rabbinical experts and legal experts were invited to express their opinions on the issue. Most of the researchers and physicians who took part in the discussions argued with ardour against legislative intervention in research that is promoting science. They stated that “what society needs to do today ... is not to prepare a broad, global prohibition on research for scientists, but to set out moral guidelines and limitations on the rules of the game for the coming millennium. ... We do not know how things will appear in another fifty years. Science will keep moving forward, that is its nature. Any answer to the question is an opening to another question, and so on *ad infinitum*. Therefore ... politicians must not, and cannot forbid science from advancing; and it would be better for all concerned: for science, politics and religion, if we work together – to coordinate and to cooperate with one another, whilst society prepares the guidelines for the researchers.”<sup>5</sup>

One of the participants claimed that we are afraid of wrongful use of cloning technology, because “... Nazism and the Holocaust are a substantial part of our fear of cloning. The Nazis sought the improvement of the Aryan race. They destroyed not only people from other nations, but also Germans whom they thought to be defective. They destroyed Germans with Down Syndrome and invalids. We can imagine what Hitler would have done had today’s genetic engineering been available to him. This is the scenario that we fear. It is not surprising that Germany, of all of the nations in the West, is the one to impose the harshest prohibitions on itself regarding genetic engineering.”<sup>6</sup>

Whilst these discussions regarding cloning were taking place in the Knesset, a special meeting of the Scientific Committee was held at the offices of the Chief Rabbis of Israel. At this meeting, Knesset members sought the *Halachic*<sup>7</sup> opinion

<sup>4</sup> *Divrei Ha’Knesset*, 5758 (1998) 14 January 1998.

<sup>5</sup> Protocol of the meeting of the Scientific Committee, 31 March 1997.

<sup>6</sup> Avinoam Reches, *ibid*.

<sup>7</sup> *Halacha* is the set of rules outlining religious Jewish law. In the process of legislation in the Knesset the position of *Halacha* is sought regarding legislative proposals, which can influence the wording and content of the provisions of the law finally promulgated.

on the question of cloning. The Rabbis made it clear that their view does not object to genetic treatment or genetic science; however, limitations and boundaries are necessary since the selectivity, which could be a consequence of cloning, could bring about a disaster: “referring to super-humans versus sub-humans, who should be annihilated, reminds us of those darkest days in human history. Therefore, every society, and especially the Jewish people who have experienced so much suffering, has to be aware of the dangers involved.”<sup>8</sup> The Chief Rabbis emphasized that from the *Halachic* point of view there is an obligation to do the utmost to heal human beings. The pursuit of cloning, despite the healing and benefit that could be derived from it by humanity, seems to us today to be a portent for disaster and might bring about serious *Halachic*, ethical and human consequences.

After lengthy debate both within and outside the Knesset among scientists, researchers, legal experts and legislators, a new form of the bill was drafted under the name of A bill for the Prevention of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells), 5758–1998.<sup>9</sup>

The purpose of the wording of the draft was to carefully avoid having the law become a stumbling block to the advancement of research in Israel, an argument raised at the beginning of the legislative process.

## The Provisions of the Law

### *The Purpose of the Law*

The Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells) Law 5759–1999 came into force on January 7, 1999<sup>10</sup> (hereinafter: the “Prohibition of Genetic Intervention Law”). The purpose-clause states that:

“The purpose of this Law is to determine a prescribed period of five years during which no kind of genetic intervention shall be performed on human beings in order to examine the moral, legal, social and scientific aspects of such kinds of intervention and the implications of such intervention on human dignity.”

Due to the fact that science tends to advance faster than law and the legislator, the Knesset thought it proper for the law to remain in force for a period of only five years. This was meant to prevent the Israeli legislative code from including an archaic law that might no longer be relevant in the near future. Thus, the Prevention of Genetic Intervention Law is in fact a “temporary order”. The period of five years was set in accordance with the recommendations of a report submitted

<sup>8</sup> Ibid. (note 5).

<sup>9</sup> Bill no. 2741, 5758 (1998) 20 July 1998, 482. The Bill passed the first reading in the Knesset on 2 November 1998, and the second and third readings on 29 December 1998.

<sup>10</sup> The Book of Laws 1697, 5759, 7 January 1999, 47.

to the President of the USA by the National Bioethics Advisory Commission on "Human Cloning". The report recommended, *inter alia*, the declaration of a moratorium on the transfer of federal funds for research in cloning and a review of the issue at the end of three to five years in order to examine whether there is still a need for the prohibition. The report emphasized the importance of further public deliberation on the subject.

The purpose-clause also states that during this period a thorough examination of the moral, legal, social and scientific aspects of those acts of intervention and their consequences on human dignity will be made. This wording stating the necessity for examination of the consequences of cloning on human dignity, rather than stating categorically that such an act is in contravention of human dignity, was consciously selected. That was in order to avoid the wording used in the Universal Declaration on the Human Genome and Human Rights, made by UNESCO in November 1997, which stated that cloning is a practice that contravenes human dignity.<sup>11</sup> The Israeli legislator did not want to determine categorically, at this stage that it does.

The requirement of using a time-frame for the prohibition in order to examine the consequences of genetic intervention is expressed in section 4 of the law, which states that the Advisory Committee<sup>12</sup> is to pursue developments in medicine, science and biotechnology in the area of genetic experiments on human beings. The Advisory Committee is to submit a report to the Minister of Health once a year advising the Minister on the matters set out in the law and making recommendations regarding the force of the prohibitions set out in the law. The first report required by the law will soon be submitted.

#### *Prohibited Genetic Intervention*

Section 3 of the law defines prohibited genetic intervention. The law states that during the term of its validity "no person shall perform any act of intervention in the cells of any person for one of the following purposes", setting out two types of prohibited activity. The first of these is "human cloning", defined in the definitions section of the law as "the creation of a complete human being, chromosomally and genetically absolutely identical to another person or fetus, living or dead". The second act prohibited by the law is "causing the creation of a person by use of reproductive cells that have undergone a permanent intentional genetic modification (Germ Line Gene Therapy)".

The definition of the term "human cloning" was chosen intentionally and contrasts with various bills proposed around the world that set out an express prohi-

<sup>11</sup> Universal Declaration on the Human Genome and Human Rights, United Nations Educational, Scientific and Cultural Organisation, Paris, 11 November 1997. Note that the Israeli representative expressed objection to the wording of the declaration that stated that cloning was a practice that contravened human dignity, a view which was shared by representatives of other countries as well.

<sup>12</sup> The Supreme Helsinki Committee appointed pursuant to the National Health (Medical Experiments on Humans) Regulations, 5741-1980 Regulation code 4189, 5741 (11 December 1980), 292.

bition of particular techniques.<sup>13</sup> The Prohibition of Genetic Intervention Law intends to set up a wider definition prohibiting any human cloning technique, irrespective of the specific scientific technique used. That is to say that what is important is not the way in which cloning is achieved, but the very fact of cloning. The purpose was to prevent a situation in which a new technique might bypass the prohibition that the law seeks to prescribe. Apart from the prohibition on cloning, the law also sets out a prohibition on germ line gene therapy, that is, the use of altered reproductive cells that could influence coming generations. This prohibition was added to the law, after one of the participants in the drafting session pointed out the following problem: The Law seeks, on the one hand, to prohibit human cloning, although cloning in general is an extremely inefficient technique that has not been used in respect to human beings, while on the other hand, the law does not prohibit the possibility of creating human beings using cells that have undergone genetic manipulation, although this technique is in the advanced stages of research and could influence the genetic structure of coming generations.<sup>14</sup>

To enable the law to advance at the same rate as scientific developments and not prevent them, a unique mechanism was set up in section 5 of the law, empowering the Minister of Health to make regulations permitting certain types of genetic intervention even though they were originally prohibited. Here too, the legislature sought to prevent Israel from lagging too far behind other enlightened countries because of this law, and to enable acts that are considered desirable and acceptable in other parts of the world to be performed in Israel as well. The Minister may permit such acts after consulting with the Advisory Committee, and he may set out conditions for the grant of such permits. The law provides that an act permitted under this section requires the receipt of a permit in advance. Criminal penalties of two-years' imprisonment have been set for breach of provisions of the law.

It should be emphasized that the main purpose of the Prohibition of Genetic Intervention Law is declaratory. Neither the Member of Knesset who initiated the law nor the Knesset intended to promulgate a law that would be used daily. As declared by scientists before the Knesset, there are no experiments taking place in Israel aimed at cloning human beings. The main intention of the law was to declare that at this stage, prior to examining fully all moral, legal, social and scientific aspects, the cloning technique does not seem to the Israeli legislature to be a proper and desirable method of bringing children into the world. The purpose of the law was to declare, both inwardly and outwardly, that Israel is one of those countries that has prohibited cloning.

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<sup>13</sup> Most of the bills specify the technique used to create Dolly – somatic cell nuclear transfer.

<sup>14</sup> This prohibition is inspired by the Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine on the Prohibition of Cloning Human Beings, 12 January 1998. It is also influenced by the provisions of the first clause of the UNESCO declaration (see note 11 above), which stated that genetic material is the heritage of humanity.

As can be seen from the above survey, the Prohibition of Genetic Intervention Law contains no provisions outlawing embryonic research. Rather the law aimed at prohibiting any act of genetic intervention intended to clone a human being. Therefore, acts of genetic intervention for purposes of experimenting or tissue cloning should not be prohibited by the law. For instance, research on creating organs or tissue for transplants, or research on medical or nutritional applications that makes use of cloning technology, will not be prohibited. A liberal interpretation of the provisions of the law could enable the undertaking of preliminary research regarding cloning, so long as the purpose is not the creation of a whole human being.

### *Chapter B – Embryonic Research in Israel*

#### Legislation

Embryonic research is a very sensitive topic. It is research involving cells that have the potential to become a whole person. Scientists, ethicists and religious leaders refer to these cells with almost holy reverence. But the more genetic and medical research develop, the more we discover what an enormous amount of knowledge can be derived from experimentation on these embryonic cells. The aim of the research is to advance our understanding of the early development of embryos, their differentiation mechanism and mitosis. This information will enable us to create many tools and solutions for various issues in the fields of medicine and health. Such understanding could assist in healing cancer or in promoting the use of embryonic stem cells for certain purposes such as creating tissue or organs. A mature human being has stem cells in the brain, liver, muscles and bone marrow, but the number of such cells in those tissues is limited, and therefore it is difficult to locate them. On the other hand, embryonic stem cells are noted for their number and versatility.

In many countries around the world, the entire issue of research, and embryonic research in particular, is subject to laws, regulations and ethical rules. In Israel there are at present only the regulations regarding experiments on human beings.<sup>15</sup> The Experiments on Human Beings Regulations adopted the Helsinki Declaration of 1964, as amended in Tokyo in 1975. They make no special reference to embryonic research. The Regulations set out procedures for the grant of a permit to perform experiments on human beings in accordance with the provisions of the Helsinki Declaration.

Specific provisions regarding reproductive cells may be found in the National Health (In Vitro Fertilization) Regulations, 5747–1987 (hereinafter: the “IVF Reg-

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<sup>15</sup> (Note 12). Note that the Experiments on Humans Regulations use the term “medical experiment” (defined in clause 1 of the Regulations), whilst the Helsinki Declaration, to which the Regulations refer, uses the term “bio-medical research”, which is a broader term.

ulations").<sup>16</sup> Clause 3 of the IVF Regulations provides that an ovum may be extracted "only for the purpose of IVF and its implantation after fertilization." That is, an ovum may not be extracted for the purpose of research. Note that these regulations do not contain any express provisions regarding research.

#### Recommendations for the Amendment of Legislation

The issue of research on embryos was dealt with in Israel by the Public and Professional Committee appointed by the Minister of Justice and the Minister of Health, in June 1991, in order to examine all aspects of the question of extra-corporal insemination, including the question of surrogacy agreements. The Committee's report was published in July 1994 (hereinafter: the "Aloni Committee Report").<sup>17</sup>

The Aloni Committee recommended that decisions regarding the use of frozen embryos – donations to other patients or to medical research – should be made by the patients themselves for the custody period set out in the Regulations, that is, by the couple from whom the reproductive cells used in making the embryos were extracted.<sup>18</sup> As far as embryonic research is concerned, the Committee recommended setting a limitation in the law of 14 days to enable such research, as is done in many countries. At the end of this period, the Committee recommended destroying the embryos and prohibiting any other use of them.

In respect of other norms implemented in other countries, such as the prohibition of creating embryos for research, the provision of a permit for use of surplus embryos that will not otherwise be used, or limitations on research on embryos, the Committee preferred not to take a stance. These matters were left to the discretion of the Supreme Committee – the Helsinki Committee, which is authorized under the Experiments on Human Beings Regulations to allow genetic experiments in human beings and experiments relating to non-natural fertilization of women.<sup>19</sup>

The Aloni Committee's conclusions were submitted to the Minister of Health and the Minister of Justice. To date, however, they have not been fully turned into legislation either in respect of IVF in general or in respect of embryonic research, that is apart from the question of surrogacy agreements.<sup>20</sup>

The Israeli Ministry of Health is preparing a Scientific Research on Human Beings Bill that is to be submitted to the Knesset in the coming months. However, at present, the bill does not contain any special provisions regarding embryonic research.<sup>21</sup>

<sup>16</sup> Regulation Code 5035, 5747, 11 June 1987, 978.

<sup>17</sup> Report of the Public-Professional Committee to Examine the Issue of Extra-Corporal Insemination, headed by the Emeritus Judge Shaul Aloni (Jerusalem, 5754–1994), Ministry of Justice.

<sup>18</sup> Aloni Committee Report, 34, para. 6.6.

<sup>19</sup> *Ibid.*, 52, para. 8.7.

<sup>20</sup> The Surrogacy Agreements (Approval of Agreement and Status of Newborn Child) Law, 5756–1996, which came into force on 17 March 1996, adopted some of the recommendations of the Aloni Committee Report regarding surrogacy agreements.

<sup>21</sup> Scientific Research on Human Beings Law Memorandum, 5758–1998 (Ministry of Health).

### Conclusion

As described above, there are no specific rules in Israel either as statutory law or in the form of regulations regarding embryonic research. This causes some scientists to stay away from embryonic research, as they understand that Israeli law prohibits such research completely, whilst others are apparently involved in some research, although only partially. This matter should not, as a matter of principle, be left open to the interpretation of scientists, however ethical and careful they may be. The lack of rules causes some researchers to feel that the prohibition is more far-reaching than it actually is, and they do not submit applications that might be approved in accordance with common practices around the world. There is no doubt that this lack of clear and definitive rules on such a sensitive issue is extremely undesirable.

The State of Israel should examine carefully the rules existing in other parts of the world regarding embryonic research<sup>22</sup>. This examination process should clarify which rules are required and are appropriate for inclusion in the Israeli code of statutes. In this way, scientists will not be required to guess whether they are in compliance with the rules, since the rules will be clear and self-explanatory. Because all such rules will be explicitly enumerated, their breach will be considered a criminal offense. Protection of embryos is the moral obligation of every advanced society. Such embryos could be our key to a better, healthier and more advanced future and we must ensure that we will attain this future while securing and respecting the basic human genetic heritage contained within these precious cells.

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<sup>22</sup> Apparently these rules can change dramatically with regard to the change that might happen in the United Kingdom, see Rachel Sylvester, Ban on Human Spare Parts Cloning Research to be Lifted Electronic Telegraph, April 3, 2000 ([www.telegraph.co.uk](http://www.telegraph.co.uk)).