Testimony of

Dr. Leon Kass

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Mr. Chairman and Members of the Committee. My name is Leon R. Kass. I am the Hertog Fellow in Social Thought at the American Enterprise Institute and the Addie Clark Harding Professor (on leave) in the Committee on Social Thought and the College at the University of Chicago. I am grateful to you, Senator Hatch, for the invitation to present some of my thoughts on human cloning, a topic on which I have been thinking and writing for thirty-five years. I speak today in my own name, and not on behalf of, or as chairman of, the President's Council on Bioethics, though I shall have occasion to refer briefly to the Council's report, Human Cloning and Human Dignity.

Mr. Chairman, I share your view that human cloning is immoral, as I also share your wish to advance ethical approaches to regenerative medicine. Human cloning constitutes unethical experimentation on the cloned-child-to-be. It confounds his genetic and social identity; it would threaten his sense of individuality. It represents a giant step toward turning procreation into manufacture. And it is a despotic attempt of parents to select and control the genetic make-up of their children. For all these reasons, I conclude that human cloning threatens the dignity of human procreation, giving one generation unprecedented control over the next, and marking a major step toward a eugenic world in which children would become objects of manipulation and products of will. Human cloning should be banned.

The question is how best to do it, effectively and ethically, with as little interference as possible to potentially beneficial biomedical research. With all due respect, I regret to say that the approach proposed in S. 303, "The Human Cloning Ban and Stem Cell Research Protection Act of 2003," will not, in my opinion, do the job we want done. It offers an ineffective, and even counterproductive, means of preventing the cloning of children. It is ethically problematic. It offers inadequate regulatory safeguards. And, in truth, it is unnecessary for advancing the mainstream of stem cell research, both embryonic and adult, about which the bill is, in fact, largely silent. Before backing up these claims, I need to speak first about the matter of terminology. For the ethical discussion we need to have is obscured by the confusing and misleading language of bill S. 303.

Whether undertaken for the ultimate purpose of producing children or for the purpose of extracting stem cells for research, the deed of nuclear transplantation is itself an act of cloning (it is the deed that produces the genetic replica), and its product is in both cases identical: a cloned human embryo. This is the view of both the earlier National Bioethics Advisory Commission and the current President's Council on Bioethics--including those members who favor cloning-for-biomedical-research--which unanimously adopted this terminology as accurate and fair. When identical cloned embryos are grown to the blastocyst stage, their different fates depend solely on the purposes of the human users: baby-making or research. The National Academy of Science report on Scientific and Medical Aspects of Human Reproductive Cloning (January 2002) also shares this opinion. S. 303's term "unfertilized blastocyst" is confusing and has no scientific currency or basis; and its definition as "intact cellular structure" hides the fact that this "structure" is a self-developing, embryonic, human organism. We should, of course, listen to

scientific or ethical arguments about why it would be important or permissible to create such cloned human blastocysts solely for research. But if we are to do so forthrightly, we should not hide from ourselves or others what we are doing. And we should not try to win the argument by definitional sleight of hand.

Here then are my reasons for believing that a ban that tried to block cloning-to-produce children while permitting cloning-for-biomedical research is a bad idea and for supporting a comprehensive ban on all human cloning.

1. Ineffective and counterproductive. If we want to prevent the development of anthrax bombs, we do best to block the production of anthrax spores, not just their transfer to a weapons delivery system. Similarly, if we mean to be fully serious about stopping the cloning of human children, we should try to stop the process before it starts, at the creation of the embryonic human clones, not merely rely on efforts to prevent their transfer to women for delivery. For a law (such as S. 303) that tried to prevent cloning babies by banning only implantation of cloned embryos would be ineffective and unenforceable. It would be difficult to know when the law had been violated; it would be impossible to enforce it once it had. Further, by endorsing cloning-for-research, such a law would in fact increase the likelihood of cloning-to-produce-children, by perfecting the procedure to practice it.

a. Permitting cloning for research will lead to improvement of cloning technique and increased success at getting cloned human embryos to the blastocyst stage, in the process making the whole practice safer. Once embryo-cloning techniques are thus perfected, people interested in cloning babies will be better able to succeed.

b. Once cloned embryos are produced and available in commercial laboratories, it will be very difficult to control what is done with them. As with the left-over embryos in the IVF clinics, cloned embryos produced for one purpose (research) could easily be used for another purpose (producing children).

c. Produced under conditions of industrial secrecy, they could be bought and sold without anyone's knowledge. Only under strict and transparent regulatory system of licensing, inventory, and reporting arrangements (not now included in S. 303) would we even have a guess as to the number and disposition of the cloned embryos produced.

d. Once available to medical practitioners of assisted reproduction, cloned embryos could be transferred to a woman's uterus without anyone's knowledge, protected by doctor-patient privacy and confidentiality.

e. Illicit "cloning pregnancies" would be impossible to detect.

f. Even if detected, there would be no enforceable legal remedy; the state could not and would not compel the abortion of the clone.

2. Ethically problematic. Allowing cloned embryos to be produced for biomedical research and/or stem cell extraction is morally highly problematic. It crosses several important moral boundaries, accelerating our slide down a slippery slope (or, more accurately, jumping us off an ethical cliff) into a dehumanizing world of genetic control of offspring and the routine use of nascent human life as a mere natural resource. In contrast, a ban on all human cloning is morally unproblematic.

a. The merely partial cloning ban proposed by S. 303 crosses a major moral boundary by endorsing the deliberate production of early human embryos for the sole purpose of research and exploitation, and requiring their necessary destruction. (This goes beyond the use of the spare

embryos in the IVF clinics, each one of which was created solely for reproductive use but is now no longer needed and will likely die anyhow. Only yesterday, in the stem cell debate of 2001, many proponents of embryonic stem cell research, including some who are today sponsors of S. 303, made clear public statements opposing on moral grounds the creation of embryos specifically for research. Today they would cross that line without blinking. The slippery slope seems to be very steep.)

b. Cloned human embryos would be the first human embryos whose genetic makeup would be determined not by the chance union of egg and sperm but by deliberate human selection and design. When research cloning is seen in the context of growing powers of genetic screening and genetic manipulation of nascent human life, it becomes clear that saying 'yes' to creating cloned embryos, even for research, means saying 'yes,' at least in principle, to an ever-expanding genetic mastery of one generation over the next.

c. Use of cloned embryos in research, once allowed, will be impossible to limit. Arguments now used to justify creating cloned embryos to produce stem cells also justify growing embryos beyond the blastocyst stage. Today the demand is for stem cells; tomorrow it will be for embryonic and fetal organs. Experiments with cloned cow embryos implanted in a cow's uterus (Advanced Cell Technologies) already suggest that there may be greater therapeutic potential using differentiated tissues (e.g., kidney primordia) harvested from early fetuses than using undifferentiated stem cells taken from the 5-6 day old blastocyst stage. Should this prove correct, there will be great pressure to grow cloned human blastocysts to later stages, past 14 days--either in the uteruses (or other body cavities) of suitably prepared animal or human hosts or (eventually) using artificial placenta-like structures in the laboratory--in order to obtain the more useful tissues.

d. Combined with a legal prohibition on the implantation of cloned embryos (for the purpose of baby-making), permission to clone embryos for research creates a class of human embryos that it would be a federal felony not to destroy. Such a law obliges the state to enforce the destruction of nascent life, a troubling novelty.

e. In addition to the harm done to embryos, there is moral harm done to a society that comes to accept as normal the routinized production and use of early human life as a natural resource for our own benefit: we risk becoming desensitized, indifferent, callous; we lose our awe and respect for the mystery and wonder of emerging new human life.

3. Inadequate regulation. Given the unique status and dangers related to the creation of cloned embryos, the limited regulatory provisions of S. 303 give too little oversight. They fall far short even of the regulatory recommendations of those members of the President's Council on Bioethics who were in favor of cloning-for-biomedical research.

a. They do not clearly apply to privately funded research.

b. They do not provide mechanisms for keeping track of all cloned embryos produced in laboratories, nor do they establish standards or guidelines for the handling and use of cloned human embryos.

c. They are silent on whether cloned human embryos can be patented.

d. They are silent on putting human nuclei into animal eggs. (The definitions of "oocyte" and "nuclear transplantation" offered in the bill do not specify that the egg be a human egg.)

e. The prohibition on "valuable consideration" for egg donation is effectively undermined by permitting compensation for time, costs, and inconvenience, absent declaring who gets to define those things, or how much is too much to charge. As written, the loophole swallows the rule and

egg-selling is allowed to continue (as it does today in obtaining "donor" eggs for assisted reproduction).
f. By applying only existing human subject protection regulations to research cloning, S. 303 protects egg and somatic cell donors, but says nothing about the treatment of the cloned embryo once it is created.

4. Unnecessary for Promoting Regenerative Medicine Research. The benefits of embryonic stem cell research (in both knowledge and potential therapy) do not necessarily require the creation of cloned embryos (or stem cells from cloned embryos). The putative benefits of cloning research are at best speculative, and it is unlikely to be the solution for the immune rejection problem. In contrast, a narrowly constructed yet complete ban on all human cloning would not interfere with stem cell research, adult or embryonic (using cells derived from non-cloned embryos).
a. The highly touted concept of "therapeutic cloning"--individualized, custom-made, rejection-proof cells derived from stem cells extracted from one's own embryonic clone--is not likely to succeed as an effective or practical form of regenerative medicine. Its alleged promise is vastly overrated, not to say spurious.
(1) Cells derived in this way may not be rejection-proof. They will contain (antigenically significant) mitochondrial DNA, originating in the egg that received the somatic cell nucleus. They will therefore NOT be fully genetically identical to the patient donor of the nucleus. This non-identity could cause immune rejection of cells reintroduced into the donor as potential therapy. There is virtually no animal evidence of any sort indicating that stem cells taken from cloned animals will not be rejected or, for that matter, that they will be therapeutically effective in treating diseases (in animals). (A recent MIT study, published on-line in Cell and touted as the first success in therapeutic cloning, reports that the tailor-made stem cells were in fact attacked as foreign by the host that had supplied the somatic cell nucleus to produce the cloned embryo.)
(2) Stem cells derived from cloned embryos may be abnormal. Reprogramming of somatic nuclei introduced into oocytes is extremely difficult to achieve, and it generally results in numerous errors of gene expression. Such epigenetic "errors" could render stem cells derived from cloned embryos abnormal and hazardous for therapeutic use.
(3) "Therapeutic cloning" is impractical. It will require thousands of human eggs, a prohibitively costly business, especially at the beginning, as the success rate in getting clones to the blastocyst stage is very low. Also, therapy using individualized stem cells, produced in the laboratory via embryo cloning, would need to be scrutinized by the FDA, patient by patient, to make sure that nothing hazardous had been introduced in the process. (From the commercial point of view, far better to engineer rejection-proof stem cells that could be universally used with every patient; only one FDA approval would be needed). The verdict that "individualized therapeutic cloning" cannot be done on a large scale and is not commercially viable is the near unanimous judgment of the leading biotech companies; at a biotech conference last year on stem cell research NONE of the companies expressed any interest in pursuing somatic cell nuclear transfer as the means of overcoming the immune rejection problem.
b. There are other routes to solving the immune-rejection problem. Scientists are pursuing ways to engineer embryonic stem cells to make them rejection-proof in ALL recipients. Many new kinds of multipotent cells (found in the bone marrow, blood, fat, etc., of adults) have been transformed into nerve cells, bone cells, heart muscle cells, etc. If reintroduced into the patient from whose body they were first taken, these cells and tissues would not be rejected because they would contain only the patient's own DNA.

c. Cloning is not essential for basic research on selected diseases. If taken from patients with certain inherited diseases (e.g., juvenile diabetes), the multipotent adult precursor cells could be used to study the embryological development that leads to the diseases. It is not true that embryo cloning is the only way to obtain a library of stem cells that would permit such investigations.
d. Neither is it true that cloning of human embryos provides the only route to study the process of reprogramming of a specialized nucleus back to the unspecialized and totipotent state. Such studies can be carried out using somatic cell nuclear transfer in animals, with animal oocytes and animal donor somatic nuclei. They have yet to be done.

In sum: Even if no single argument above is by itself decisive, their cumulative weight leads me to support a comprehensive ban on all human cloning, including the cloning of embryos for research. Such a ban is prudent, moral, and virtually cost-free. It is the only real ban on human cloning. In contrast, a ban only on implanting cloned embryos is imprudent and morally dubious, and would likely yield little benefit that cannot be obtained by other (morally unproblematic) means. Purporting to be a ban on reproductive cloning, it would in fact increase the chances that cloned human beings would be born, and sooner rather than later.

Opposition to human cloning-to-produce-children in America is overwhelming: the vast majority of our fellow citizens, including most scientists, would like to see it banned. Nearly every member of Congress has condemned it. Yet despite this near-unanimity, and despite the fact that bans on all human cloning are being enacted in many nations around the world, we have so far failed to give national public force to the people's strong ethical verdict. The failure of the last Congress to enact a ban on human cloning casts grave doubt on our ability to govern the unethical uses of biotechnology, even when it threatens things we hold dear. If Congress fails again to act this time around, human cloning will happen here, and we will have acquiesced in its arrival. It is my profound hope that Congress will rise to the occasion, and strike a blow in defense of human dignity.