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### The ABCs of Global Governance of Embryonic Stem Cell Research: Arbitrage, Bioethics and Cloning

George J. Annas

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# THE ABCS OF GLOBAL GOVERNANCE OF EMBRYONIC STEM CELL RESEARCH: ARBITRAGE, BIOETHICS AND CLONING

GEORGE J. ANNAS\*

Thank you for that introduction, which reminds me that I used to do regulatory work for the Commonwealth of Massachusetts, primarily as a member of the Board of Registration in Medicine, and we had real regulations, real law, that could be enforced. What I am going to talk about today is not “fake law,” but a kind of law that is often seen as more like ethics—international law. There is really no such thing as global bioethics governance, but I would like to think that someday it will be a part of international law. Certainly, if we are going to pursue embryonic stem cell research and human cloning, there should be global governance of it.

The birth of Dolly the sheep ushered in an international debate about whether we should clone humans and about whether we needed some form of global bioethics governance. The core bioethics question, of course, is not *can* we clone humans, but *should* we clone humans? Not *can* we do embryonic stem cell research, but *should* we do embryonic stem cell research? And, if we should, how should we do it? One of the most salient features of science in general is that it is inherently international because if you can do something in the United States, it is likely you can do it in at least a dozen other countries in the world that have similar scientific expertise and scientific facilities. So, it is not surprising that a year after scientists in Massachusetts announced (prematurely) that they had produced the first cloned human embryo, Korean scientists announced that they had in fact created the first stem cell from a cloned human embryo.<sup>1</sup>

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1. Woo Suk Hwang et al., *Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived from a Cloned Blastocyst*, 303 SCI. MAG. 1669 (Mar. 12, 2004); see also Claudia Dreifus, *2 Friends, 242 Eggs and a Breakthrough*, N.Y. TIMES, Feb. 17, 2004,

Unlike the American team, the Koreans were actually able to make stem cells from their cloned human embryo. When the Korean government said, shortly after the announcement, that it was going to forbid the scientists from pursuing their research, the scientists said they were going to move; that they would take their research to Singapore or England, or maybe even to China.<sup>2</sup> That is an example of what can be termed *ethical arbitrage*—going to another jurisdiction because it has looser ethical rules that permit you to do your research. The question that has been on the minds of most people involved in human embryo research is whether it is possible to have international regulation, or whether scientists will always be able to engage in ethical arbitrage. Is it misguided for us to try to develop international treaties or international protocols, or global standards or guidelines, because unless all scientifically advanced countries adopt them scientists would always be able to get around them by moving?

My short answer to that is that I think the effort to move toward global governance is worthwhile. One of the reasons I think so is because the Korean scientists, two weeks after they said they were going to leave Korea, changed their minds and said they would stay in Korea and would not restart their research until the Korean government gave them permission. They said that they think it is essential to do this research under strict ethical guidelines, and they would wait for their government to develop ethical guidelines to proceed.<sup>3</sup> I think most, if not all, responsible researchers feel essentially the same way, and would welcome global standards to guide their work.<sup>4</sup>

There are some researchers, of course, who are not ethically responsible. We have three would-be international outlaws who have said repeatedly that they are willing to engage in human cloning to make a baby: Panos Zavos, Severino Antinori, and Brigitte Boisselier.<sup>5</sup> They each

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at F1.

2. Dreifus, *supra* note 1.
3. Anthony Faiola, *Dr. Clone: Creating Life or Trying to Save It?*, WASH. POST, Feb. 29, 2004, at A1. See generally Rosario M. Isasi & George J. Annas, *Arbitrage, Bioethics, and Cloning: The ABCs of Gestating a United Nations Cloning Convention*, 35 CASE W. RES. J. OF INT'L L. 397 (2003); see also Dennis Normile & Charles C. Mann, *Asia Jockeys for Stem Cell Lead*, 307 SCI. MAG. 660, 663 (Feb. 4, 2005).
4. The Korean Bioethics Association, to follow up on Judy Norsigian's luncheon speech, has said they want to know where this group of researchers got their human eggs, how they got them, how they got informed consent, and what their relationship was with the eggs. So far, these researchers have refused to tell them, and that is a big issue—Judy Norsigian is right about that—where you get the human eggs to do research is a big issue. Judy Norsigian, *Stem Cell Research and Embryo Cloning: Involving Laypersons in the Public Debates*, 39 NEW ENG. L. REV. 527 (2005).
5. See, e.g., Robyn Riley, *Frankenstein Unleashed*, SUNDAY HERALD SUN (Melbourne,

have said at least three times, and one of them has said it as many as fourteen times, that they have succeeded in cloning a human baby. The truth of the matter is that all they have cloned so far are press conferences. Nonetheless, their proclamations have impressed upon people that without some global regulation there is nothing to prevent fringe scientists or true believers like this group from doing whatever they want to do with cloning technology.<sup>6</sup>

Where do you go if you want to set up international standards for research involving stem cells, whether they are from leftover or spare embryos and IVF clinics, or from somatic nuclear cell transfer? The answer is the United Nations, and in about ten minutes—the timing could not be better—about five minutes from now, literally, the Sixth Committee at the United Nations, the drafting committee for treaties, is scheduled to vote on the latest proposal by the United States to have a cloning treaty.<sup>7</sup> Since 2001, the U.S. proposal has consistently sought to outlaw both cloning embryos for stem cell research, and cloning embryos to make a baby—to outlaw all forms of human cloning. And the United States has gotten about sixty countries to agree to its position. Since the United Nations almost always acts on consensus, some compromise is likely. One most likely is a new proposal by Italy not to draft a treaty at all, but instead to draft a “declaration on human life” saying that there should be no cloning to create human life, and leaving it to individual countries to decide whether cloning to make an embryo for stem cells is permissible versus cloning for

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Austl.), Oct. 19, 2003, at 14. Zavos claims to have a “secret team” helping him at a laboratory in the Middle East. In 2002, Severino Antinori, Panos Zavos, and Brigitte Boisselier all separately announced that they had successfully cloned a human being, or were just about to do so. None of these announcements turned out to be true. Nonetheless, the international press still gives some credence to the serial announcements of these “mad scientists” who have so far only succeeded in cloning press conferences. *Id.* Antinori claims that at least three babies had been born from cloned embryos in reproduction experiments he had collaborated on. *Italian Doctor Says Three Cloned Babies Born*, REUTERS, May 5, 2004, available at <http://cmbi.bjmu.edu.cn/news/0405/15.htm>.

6. There has become a renewed interest in not just international ethical guidelines for research, but the whole international research agenda itself. There is better recognition that it is intolerable that ninety percent of research funds to do global research go into diseases that only ten percent of the people in the world have. This gross inequity means that not only do we need new ethics, but we also need new research priorities. See, e.g., David B. Resnik, *The Distribution of Biomedical Research Resources and International Justice*, 4 DEVELOPING WORLD BIOETHICS 42-57 (2004).
7. The Sixth Committee is the U.N.’s legal committee, which has been working on the cloning treaty. For information on the Sixth Committee, see generally <http://www.un.org/law/cloning> (last visited Feb. 24, 2005).

implantation to make a baby.<sup>8</sup> I think that is a terrible development. It is, of

8. The resolution to draft a treaty was replaced with Italy's draft resolution for a "declaration" on November 19, 2004. U.N. GAOR 6th Comm., 59th Sess., Agenda Item 150, U.N. Doc. A/C.6/59/L.26 (Jan. 14, 2005). The Declaration, with some modifications, was formally adopted by the UN General Assembly on March 6, 2005 by a vote of 84 to 34 with 37 abstentions. The most populous countries in the world, India and China, voted against the declaration, as did many countries now doing embryonic stem cell research, including England and, of course, So. Korea. Thus the declaration cannot be said to represent a global consensus, and will likely have little impact on research practices. The final text reads:

United Nations Declaration on Human Cloning

*The General Assembly,*

*Guided* by the purposes and principles of the Charter of the United Nations,

*Recalling* the Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organization on 11 November 1997, and in particular article 11 thereof, which states that practices which are contrary to human dignity, such as the reproductive cloning of human beings, shall not be permitted,

*Recalling also* its resolution 53/152 of December 1998, by which it endorsed the Universal Declaration on the Human Genome and Human Rights,

*Aware* of the ethical concerns that certain applications of rapidly developing life science may raise with regard to human dignity, human rights and the fundamental freedoms of individuals,

*Reaffirming* that the applications of life science should seek to offer relief from suffering and improve the health of individuals and humankind as a whole,

*Emphasizing* that the promotion of scientific and technical progress in life science should be sought in a manner that safeguards respect for human rights and the benefit of all,

*Mindful* of the serious medical, physical, psychological and social dangers that human cloning may imply for the individuals involved, and also conscious of the need to ensure that human cloning does not give rise to the exploitation of women,

*Convinced* of the urgency of preventing the potential dangers of human cloning to human dignity,

*Solemnly declares* the following:

(a) Member States are called upon to adopt all measures necessary to protect adequately human life in the application of life sciences;

(b) Member States are called upon to prohibit all forms of human cloning as they are incompatible with human dignity and the protections of human life;

(c) Member States are further called upon to adopt the

course, no international law at all, although it is an “ethical” declaration. It seems to me that the United States has frustrated the opportunity to have an international treaty, and I think that we should attempt to have an actual treaty on reproductive cloning (making a baby), which every country in the world agrees should be outlawed. A treaty on both reproductive and research cloning is impossible because only about half the countries in the world agree both should be outlawed.

We should also look at drafting a broader treaty that outlaws what I used to call (and I will take responsibility for that) *species altering procedures*—procedures that change the definition of what it means to be human. Any time you want to alter the definition of what it means to be human, you should have a species-wide discussion. We do not know how to take a worldwide vote yet, but at least a global discussion is warranted. The category of scientific experiments that we should be concerned about is *species endangering procedures*; we need a treaty outlawing species endangering procedures—procedures that threaten the very existence of the human species.<sup>9</sup> Some, but probably not all, species altering procedures

measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity;

(d) Member States are called upon to take measures to prevent the exploitation of women in the application of life sciences;

(e) Member States are also called upon to adopt and implement without delay national legislation to bring into effect paragraphs (a) to (d);

(f) Member States are further called upon, in their financing of medical research, including of life sciences, to take into account the pressing global issues such as HIV/AIDS, tuberculosis and malaria, which affect in particular the developing countries.

*Id.*

9. We can take some actions on a national level, but we also need international rules about the new science, including not only cloning and genetic engineering, but also human-machine cyborgs, xenografts, and brain alterations. These could all fit into a *new category* of “crimes against humanity” in the strict sense, actions that threaten the integrity of the human species itself. This is not to say that changing the nature of humanity is always criminal, only that no individual scientist (or corporation or country) has the social or moral warrant to endanger humanity, including altering humans in ways that might endanger the species. Performing species-endangering experiments in the absence of social warrant, democratically developed, can properly be considered a terrorist act. Xenografts, for example, carry the risk of releasing a new, lethal virus upon humanity. No individual scientist or corporation has the moral warrant to risk this. Altering the human species in a way that predictably endangers it should require a worldwide discussion and debate, followed by a vote in an institution representative of the world’s population, the United Nations being the only such

would fall into this category. Now, that sounds a little grand, and cloning per se would not fit into the species-endangering category—but cloning's next step, inheritable genetic alterations, would. Cloning, for all its novelty and weirdness is not that important in itself. I say that as someone who opposes cloning to make a baby and has for years. Cloning is much more important as a gateway to other procedures, especially germline or inheritable genetic alterations, which would be used to try to make not an identical baby, not to make someone just like yourself, but to try to make a "better baby."

A thought experiment suggested by a *Wired* magazine cover picturing a human with wings gives you some idea of what is involved. What would you do with a baby who had wings? Is it a better baby? Is it an "enhanced" human? Would the obstetrician amputate the wings immediately after birth? Would this child end up in a side-show, or would the child be viewed as a superior human? You can decide that yourself. The general program to make better humans, superior humans, obviously got a deservedly bad reputation with the Nazis. We are not Nazis, but all eugenics programs are dangerous because we do not know what a better baby is, or what a better human would be like.

What we do know is that whenever we radically change the perception we have of other human beings, we change our relationship to them, and this can permit us to do terrible things to them. The Japanese in World War II, for example, dehumanized both Chinese and American POWs. And we dehumanized the Japanese after Pearl Harbor. As Paul Fussell writes, "Among the Allies, the Japanese were also known as jackals or monkeys, or subhumans, the term also used by the Germans for Russians, Poles, and Slavs during the war and amply justifying their vivisection."<sup>10</sup> Ultimately, Paul Fussell concludes that our dehumanization of Japanese was the prelude to Hiroshima and Nagasaki. And, as many of us followed the fight against Fallujah last week, we could not help but notice that some of the U.S. soldiers were referring to the insurgents there as "rats." You do have to dehumanize people before you can kill them. It seems to me that the prospect of creating two separate species or sub-species of humans in the future: the "enhanced" (or we may see them as deformed), and us, the "regulars," will lead almost inevitably (but even if it is a one percent probability, that is high enough) to genocidal action of one

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entity today. It should also require a deep and wide-ranging discussion of our future and what kind of people we want to be, what kind of world we want to live in, and how we can protect universal human rights based on human dignity and democratic principles. See generally GEORGE J. ANNAS, *AMERICAN BIOETHICS: CROSSING HUMAN RIGHTS AND HEALTH LAW BOUNDARIES* (Oxford Univ. Press 2005).

10. PAUL FUSSELL, *WARTIME* 117 (Oxford Univ. Press 1989).



group against the other group. Either we (the regulars) will feel threatened by the new arrivals, and try to kill them preemptively before they kill us, or vice versa—they will see us as suitable for enslavement and for their own amusement, and treat us as subhuman. That prospect is a real enough reason, it seems to me, to outlaw human cloning to make babies, and its next step, germline genetic alteration.<sup>11</sup>

One alternative to global regulation is the market—this is the way we control things now, or do not control things. We say we have no world government, but we do have a World Trade Organization, and we do have very strict rules on world trade and intellectual property. We do not have many rules on research. Whether that is in gathering human eggs for embryo research or for doing research generally, we have a tendency to believe that research is good and the market will ultimately produce good results even if we do need some small-scale regulation along the way. In regard to research cloning, it is one thing to extract eggs from women so that they or other women can have babies, but it is quite another thing to extract eggs from women simply to do research. We rely heavily on local Institutional Review Boards (IRBs) to regulate research today. We set up a group of what is essentially other researchers and ask whether this other group of researchers is doing a good job, and mostly they say, “Yes, they are and should proceed.” Whatever you think of IRBs, the system is not adequate to protect either research subjects or society. In stem cell research these issues have come to a head in the United States because of what has been called the “great stem cell war”—the August 9, 2001 position of the President that no National Institutes of Health (NIH) funding should be given to embryonic stem cell research for stem cell lines not in existence on August 9, 2001, to avoid creating embryos to use instrumentally by

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11. The core argument is that cloning will inevitably lead us down a slippery slope to attempts to modify the somatic cell nucleus to create not genetic duplicates of existing people, but “better” children. This attempt will either succeed or fail. If it fails, that is the end of it. If it succeeds, however, something like the scenario envisioned by Silver and others, such as Nancy Kress, will unfold: a new species or subspecies of humans will emerge. The new species, or “posthumans,” will likely view the old “normal” humans as inferior, even savages, and fit for slavery or slaughter. The normals, on the other hand, may see the posthumans as a threat, and if they can, engage in a preemptive strike by killing the posthumans before they themselves are killed or enslaved by them. It is the predictable potential for genocide, which I have termed “genetic genocide,” that makes species-altering experiments potential weapons of mass destruction, and makes the unaccountable genetic engineer a potential bioterrorist. This is why cloning and genetic modification is of species-wide concern and why an international treaty to address this species-endangering activity is called for. Such a treaty is necessary because existing laws on cloning and germline genetic alterations, even though often well-intentioned, have serious limitations. ANNAS, *supra* note 9, at 51.

destroying them to create stem cell lines. This is at odds with the position of most scientists that federal funding is essential, and that the cut-off date of August 9, 2001 does not make any ethical sense. It may make political sense, but it makes no ethical sense.<sup>12</sup>

The public response to this federal policy, and I think a direct response to the Bush policy, is Proposition 71, which passed in California overwhelmingly, and does a number of things. The first, and weirdest thing it does, is create a constitutional right to create and work with pluripotent stem cells derived from surplus embryos from IVF clinics, as well as embryos created by somatic cell nuclear transfer (i.e., cloned human embryos). It does not permit, and you tell me why, researchers to make embryos in the laboratory with a human egg and human sperm.<sup>13</sup> There

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12. George J. Annas & Sherman Elias, *Politics, Morals and Embryos*, 431 NATURE 19 (Sept. 2004).
  13. Proposition 71, Stem Cell Research Funding, Bonds (California 2004). The constitutional amendment portion of the initiative reads:

Article XXXV is added to the California Constitution to read:

Section 1. There is hereby established the California Institute for Regenerative Medicine.

Section 2. The Institute shall have the following purposes:

(a) To make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and/or medical procedures that will result in, as speedily as possible, the cure for, and/or substantial mitigation of, major diseases, injuries, and orphan diseases.

(b) To support all stages of the process of developing cures, from laboratory research through successful clinical trials.

(c) To establish the appropriate regulatory standards and oversight bodies for research and facilities development.

Section 3. No funds authorized for, or made available to, the institute shall be used for research involving human reproductive cloning.

Section 4. Funds authorized for, or made available to, the Institute shall be continuously appropriated without regard to fiscal year, be available and used only for the purposes provided in this article, and shall not be subject to appropriation or transfer by the Legislature or the Governor for any other purpose.

Section 5. There is hereby established a right to conduct stem cell research which includes research involving adult stem cells, cord blood stem cells, pluripotent stem cells, and/or progenitor cells. Pluripotent stem cells are cells that are capable of self-renewal, and have broad potential to differentiate into multiple adult cell types. Pluripotent stem cells may be derived from somatic cell nuclear transfer or from surplus products of in vitro fertilization treatments when such products are donated under appropriate informed consent

had to be some reason for that. Proposition 71 allocates \$3 billion to establish a new stem cell research institute to promote and fund stem cell research in California. So, most embryonic stem cell research in the United States will take place in California for the foreseeable future, although other states are considering smaller stem cell initiatives. Harvard, for example, is setting up a \$125 million stem cell lab in Massachusetts, but it simply cannot compete with California at this level of funding.<sup>14</sup> Some researchers who want to spend full time on human stem cell research may move to California. This gives California an opportunity to set the standards for ethical oversight for this research, and if California does it right, these could become national standards.

Even international stem cell organizations favor standards so that they can say that they are following recognized ethical standards.<sup>15</sup> Where would one get these standards? I have argued before, and I will argue again, that you cannot derive them from bioethics. Bioethics is much too narrow in its agenda; in fact, in the United States, bioethics has narrowed to embryonic stem cell research and cloning for the last couple years. The President's Bioethics Council is obsessed with stem cells. Its entire reason to exist is to come up with an ethical rationale for Bush's limitation on funding to human stem cell lines created before his August 9, 2001 speech, and it has not been able to do that.<sup>16</sup> So, bioethics, at least as reflected by the current administration, does not work here.

In the international arena, since World War II, the language of human rights has developed to the point where it is the right language to use. And,

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procedures. Progenitor cells are multipotent or precursor cells that are partially differentiated, but retain the ability to divide and give rise to differentiated cells.

Section 6. Notwithstanding any other provision of this Constitution or any law, the institute, which is established in state government, may utilize state issued tax-exempt and taxable bonds to fund its operations, medical and scientific research, including therapy development through clinical trials, and facilities.

Section 7. Notwithstanding any other provision of this Constitution, including Article VII, or any law, the institute and its employees are exempt from civil service.

CAL. CONST., art. XXXV (as amended 2004).

14. There is also a move to amend Massachusetts law on fetal research to make the state more research-friendly for cloning embryos. MASS. GEN. LAWS ch. 112, § 12J (2002).
15. England, which has the most comprehensive set of regulations on embryo research, is now poised to take the international lead in cloning research for stem cells. Associated Press, *Britain Grants "Dolly" Scientist Cloning License*, N.Y. TIMES, Feb. 9, 2005, at A8.
16. Address to the Nation on Stem Cell Research, 2 PUB. PAPERS 953 (Aug. 9, 2001), available at <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html>.

I would argue, we have to adopt a universal human rights framework if we are going to regulate embryonic stem cell research reasonably at all. The human rights framework evolves from Nuremberg. It takes us back to Nazis again, not what the Nazis did, but what the Allies did in trying the Nazis and setting up basic rules based on human rights. The War Crimes Trial at Nuremberg, the International Military Tribunal, established the Nuremberg principles: There are such things as war crimes and crimes against humanity; people can be found guilty as individuals for committing them, and saying "I have just followed the orders" is no defense.<sup>17</sup> More important for our discussion is the Doctor's Trial, where U.S. judges held the Nazi doctors accountable for what the Nazis called human experimentation in the concentration camps, but General Telford Taylor, the chief prosecutor, called these practices simply "murder and torture."<sup>18</sup> The judges promulgated the Nuremberg Code, which is a set of basic rules for human experimentation—informed consent being the most important one. We think that we have nothing in common with the Nazis, and I would like to think we do not either, but we can learn from this experience. As my colleague Jay Katz said, we have not learned the lessons of Nuremberg yet. We have not learned how to respect human dignity and to protect human subjects, especially children, in medical research.<sup>19</sup>

So the central question is, can we have global human rights standards that matter? I think we can, but it is going to be very difficult, especially with the United States so far refusing to endorse any international standard outside of world trade and intellectual property. The United States will not even endorse the International Criminal Court, although it is best described as a "Permanent Nuremberg Tribunal," which was fundamentally a U.S. creation. This is unconscionable and unsustainable, as is the U.S. rejection of the Geneva Conventions in the war on terror, which led directly to our use of torture, which is against all that our country has stood for since World War II, and is a war crime.

In conclusion and summary, we have a lot going on in science, we have some going on in bioethics, but most of the action worldwide is in human rights. The task is not to define human rights (we have done that in the Universal Declaration of Human Rights and the two treaties), but to devise a way to enforce human rights that goes beyond naming and shaming, beyond publicity, and holds individuals and private corporations,

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17. See generally Charter of the International Military Tribunal, Aug. 8, 1945, 59 Stat. 1544, 82 U.N.T.S. 279.

18. See THE NAZI DOCTORS AND THE NUREMBERG CODE 95-96 (George J. Annas & Michael A. Grodin, eds., Oxford Univ. Press 1992).

19. See, e.g., JAY KATZ, EXPERIMENTATION WITH HUMAN BEINGS (Russell Sage Found. 1972).

as well as governments, accountable for human rights violations. The fastest growing type of organization is not corporations (amazingly), not even biotech corporations, but nongovernmental organizations (NGOs). Nongovernmental organizations are absolutely necessary for world governance, even though they have no authority other than their own *moral* authority. They can help us identify issues crucial to the survival of humanity, not of embryos, but humans—the risks to children, the risks to humanity, and the risks of the weird view that immortality is a reasonable goal for medicine. Human rights can also help us re-focus our entire research agenda, not on trying to do more and more things for fewer and fewer rich people, but on trying to confront the actual problems that real people have around the world. Thank you very much.

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