REVIEW ARTICLE

In vitro fertilization and stem cell harvesting from human embryos

The law and practice in the United States

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KEY WORDS

embryo-destructive research, induced pluripotent stem cells, in vitro fertilization, somatic nuclear transfer (cloning), supernumerary embryos

ABSTRACT

The challenges before science and medicine are these: science must explore the natural world as thoroughly as possible, while still honoring, protecting, serving and preserving the subject of its investigations, and the human beings for whom it is a tool; medicine must confront disease and disability as effectively as possible, while also honoring, protecting, and preserving those beings for whom it serves – all of those beings, not just some, or even most, at the potential expense of others. These goals are challenged by embryo-destructive human embryonic stem cell research.

The human embryo is a human being as clearly defined by embryology, and as such should be protected by the codes governing human subject research. However, because of the "potential" benefits offered by pluripotent stem cells, coupled with abortion politics and a very poorly regulated infertility industry, United States governmental advisory commissions and the scientific, medical, and political communities have attempted to define away the humanity of the human embryo, with a few notable exceptions.

Because infertility treatments in the United States are poorly regulated, there are large numbers of supernumerary embryos in cryopreservation. However, only a tiny portion of these will ever be potentially available for research, and thus are not a realistic source of the cells necessary to provide treatments to the millions who might benefit from proposed stem cell based therapies. Cloning will not be the answer either, given the millions of women who must be exploited to provide sufficient numbers of eggs to generate the cloned cell lines. Moreover, the disposition decisions parents must make for their extra embryos are often agonizing, and not uncommonly change.

The use of supernumerary embryos as a source for human embryonic stem cells is unethical, will never be a sufficient source for the medical treatments expected from stem cell research, and is often a source of great distress for the conceiving parents. The United States experience is not a positive model for other countries to emulate.

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Introduction One of the great challenges of science is to explore the natural world as thoroughly as possible, while still honoring, protecting, serving, and preserving the subject of its investigations, and the beings for whom it is a tool. One of the great challenges of medicine is to confront disease and disability as effectively as possible, while also honoring, protecting, and preserving those beings for whom it serves – all of those beings, not just some, or even most, at the potential expense of others. In most things, and on most days, it is possible to accomplish these ends without controversy or conflict. The area of human embryonic stem cell research, however, is one in which these ends are placed in stark conflict, challenging our understanding of the goals and limits of science and medicine, and our understanding of our identities as human beings and human persons.

In the United States, where embryonic stem cells were discovered a little over a decade ago (1998), the public debate of these issues has been intense, the source of great political wrestling and posturing, with the result of there evolving a collection of disparate approaches legislatively at the state and federal level. The discussion and pursuit of human embryonic stem cell research, and stem cell research more broadly, has demonstrated some of the finest and the worst of the American and international scientific and political communities. This discussion has been a social scientist's bonanza, reflecting the degree to which rhetorical hyperbole, euphemism, and deliberately dehumanizing language will be shamelessly used to commodify human beings for their exploitation by others. And it is a clear demonstration of how a thoughtlessly unregulated medical technology, in vitro fertilization (IVF), and its analogs, such as intracytoplasmic spermatic injection, can encourage bad science and bad policy.

In the course of this brief review and analysis, this paper will: 1) review the development of United States federal and state policy on embryonic stem cell research, 2) examine the possible use of leftover embryos from IVF as a source of embryonic stem cells, 3) briefly illustrate why somatic nuclear transfer will never be a practical source of stem cells for reputed therapeutic purposes, 4) reflect on the problems of unregulated reproductive technologies, and 5) comment on the state's proper role in protecting human dignity and regulating science.

The history of embryonic stem cell regulation in the United States In 1978, Louise Brown, the first child to reach term after being conceived by IVF, was born. The use of IVF to address problems of infertility quickly increased. On March 28, 1984, Zoe Leyland became the first child to be born from a frozen human embryo not implanted at the time of fresh IVF. One of the many ethical and social challenges created by IVF involves the disposition of embryos conceived by IVF who are not implanted immediately. In order to minimize the number of stimulation cycles, all retrieved oocytes (eggs) are fertilized if possible, and those embryos not implanted are usually cryopreserved for possible future implantation. Consequently, many couples are left with a number of frozen embryos (sometimes as many as 20 or more) after a cycle of IVF. Some couples will implant some or all of their embryos as they complete their families, but there are also many who will not implant all of the embryos they and their physicians have conceived. Options for the disposition of these "frozen unchosen" have included destruction by discarding, donating to another family (the process of embryo adoption), or donation for research. This dilemma existed even before the discovery in 1998 of embryonic stem cells, and researchers in infertility and other areas were quite interested in using these smallest of human beings for research purposes.

Soon after Louise Brown's birth, the then United States Department of Health, Education and Welfare (HEW) convened an Ethics Advisory Board to study IVF and embryo transfer, which issued its report on May 4, 1979. This panel concluded that research involving research in IVF was "ethically defensible but still legitimately controverted."[1] They stated, "the human embryo is entitled to profound respect; but this respect does not necessarily encompass the full legal and moral rights attributed to persons," a fairly predictable, though practically meaningless, conclusion in the post-*Roe v Wade* climate in the United States. With Orwellian linguistic finesse, the Board claimed to have profound respect (to allay the concerns of the pro-life members of the political spectrum), while permitting the deliberate pursuit of a research strategy that necessarily entails the creation and destruction of embryonic human beings.

The HEW statement is an excellent example of the impact of post-*Roe v Wade* abortion politics on the relative lack of meaningful regulation of assisted reproduction, and subsequently on embryo-destructive embryonic stem cell research policy. "Choice," or so-called reproductive freedom, as opposed to reproductive responsibility, has dominated the discussion of anything related to reproduction, rather than consideration of the true nature of the human embryo as a human being. The American Society of Reproductive Medicine, the largest professional organization for practitioners of assisted reproduction in the United States, an organization that has long denied that the embryo is a human being, has consequently done little to appropriately regulate the number of embryos conceived by IVF techniques, focusing rather on achieving successful pregnancy as its major concern. Anything that acknowledges the true nature of the embryonic human being has been vigorously opposed by pro-abortion politicians and organizations. For example, during the debate over Proposition 71, the legislation that authorized the State of California to fund embryo-destructive research independent of federal regulations, the National Abortion Rights Action League and Planned Parenthood, two organizations whose only interest in embryo stem cell research is to ensure that the embryo is treated like a thing, not a human being, were strong supporters of the proposition. Abortion politics has led the United States government to deny settled embryology and established codes regulating human subjects research.

Human subject research in the United States is governed by the Federal Common Rule which defines "human subject" as a "living individual about whom an investigator (whether professional or a student) conducting research obtains: 1) data through intervention or interaction with the individual, or 2) identifiable private information."[2] Further, the Belmont Commission, which defined the ethical principles underlying the conduct of human subjects research, declared that human

subject research should be guided by the principles of beneficence (the obligation to do good) and nonmaleficence (the obligation to avoid harm) to the subject.[3] It is, therefore, important to understand whether or not the human embryo is a "human subject."

Embryology clearly answers this question. As we all learned in medical school, each of us as a human being began at fertilization. Langman's textbook states, "The development of a human being begins with fertilization, a process by which the spermatozoon from the male and the oocyte from the female unite to give rise to a new organism, the zygote."[4] Moore and Presaud are even more definitive: "…Union of these gametes during fertilization produces a zygote or fertilized ovum which is the primordium or *beginning of a new human being* [emphasis in the original text]. Human development begins at fertilization… This highly specialized, totipotent cell marked the beginning of each of us as a unique individual."[5]

Thus there is little scientific question or doubt as to the nature of the human embryo as a unique human being. But the political and pragmatic desire to dehumanize and functionalize the embryo has led the United States courts, legislatures and executive branches, and many of its citizens, to deny this reality. In contrast, pro-life individuals, organizations, and politicians have endeavored to protect the youngest of human beings as much as possible. The result of the ongoing argument between the two positions has left a patchwork of contradictory regulations.

In 1995, the National Institutes of Health (NIH) Human Embryo Research Panel's final report stated both that 1) embryos should not be created specifically for research purposes, but 2) supernumerary embryos from IVF could be used for research purposes.[6] Later that year the United States Congress passed, with President Clinton's signature, the Dickey Amendment prohibiting the use of any federal funds provided to the Department of Health and Human Services (replacing the health-related functions of the old HEW) for research that resulted in the destruction of human embryos, regardless of the source of the embryos.[7] It is important to note that the ground-breaking research of Dr. James Thompson in 1998, which discovered embryonic stem cells, was, therefore, funded by private sources, rather than government grants, because of the Dickey Amendment.

President Clinton's National Bioethics Advisory Commission (NBAC) conducted an extensive review of the ethical concerns raised by human embryonic stem cell research, and published their results in September 1999. NBAC concluded, "…the derivation of stem cells from embryos remaining following infertility treatments is justifiable only if no less morally problematic alternatives are available for advancing the research… The claim that there are alternatives to using stem cells derived from embryos is not, at the present time, supported scientifically. We recognize, however, that this is a matter that must be revisited continually as science advances."[8] Though beyond the scope of this paper, and a subject that will be covered in more detail in other papers in this symposium, the science did advance rapidly. During the past decade, the therapeutic use of adult stem cells (ASC) in a number of conditions, beyond the use of hematopoietic stem cells in the bone marrow and peripheral stem cell transplantation, from end-stage heart disease to repairing injured spinal cords, has been quite remarkable. In 2007, induced pluripotent stem cells (iPSCs) were created and found to possess many of the desired characteristics of embryonic stem cells without the need to destroy embryos. Unfortunately, these findings, which should eliminate the perceived need to destroy embryos to obtain human embryonic stem cells, has not decreased the demand for embryo-destructive research from many quarters, including the scientific and the pro-abortion communities.

Paralleling the developments in ASC and iPSC research was the reality that supernumerary embryos could be given to other infertile couples, called embryo adoption, leading to successful pregnancies and delivery of healthy infants. This demonstrated that there was a life-protecting and affirming alternative to destruction by research or discard of "left-over" embryonic human beings. Embryo adoption, however, despite strong promotion during the administration of President George W. Bush, has remained a fairly rare route of embryo disposition.

Early in his presidency, George W. Bush confronted the challenge of embryo-destructive research. On August 10, 2001, President Bush, in an address to the nation declared that he would allow federal funding for research on the presently existing cell lines derived from human embryos (that is, those cell lines produced before August 9, 2001), "where the decision on life and death has already been made," but forbade the use of federal funds for any research that would involve the killing of additional embryos. "This allows us to explore the promise and potential of stem cell research," he stated, "without crossing a fundamental moral line by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life."[9] Mr. Bush believed that approximately 60 cell lines derived from human embryos existed at that time. In time, it became more evident that only about 20 of these cell lines were usable. Throughout the rest of his presidency, Mr. Bush supported the use of significant funding for adult stem cell research (including the Stem Cell Therapeutic and Research Act of 2005 which provided $265 million for ASC research, in addition to the NIH allocation that year of $607 million for stem cells research, including $39 million for embryonic stem cell research). He issued Executive Order 13435 on June 20, 2007, expanding funding of research involving alternative methods for producing pluripotent stem cells, such as

iPSCs, and for harvesting embryonic stem cells without embryo destruction, such as single blastomere extraction as is performed in preimplantation genetic diagnosis.[10] Despite the clear fact that President Bush strongly supported stem cell research, aside from embryo-destructive research, he was, and continues to be, accused of imposing a ban on stem cell research in the United States. The "ban" was a fiction promoted by pro-abortion and other political opponents. The reality is that stem cell research advanced significantly during the Bush administration, particularly in the only ways that will have practical meaning for developing patient-oriented therapies.

Some members of the scientific community, pro-abortion forces, and opponents of the Republican Party in general claimed that the Bush restrictions on embryo-destructive research were the equivalent of a "war on science," and contrary to the needs of millions of patients who would benefit from embryonic stem cell based therapies (which to this day remains more of a theoretical speculation rather than anything demonstrated, contrary to the benefits already produced by ASC therapies). The resultant coalition of interest groups convinced the state legislatures in 10 states (California, Connecticut, Illinois, Iowa, Maryland, Massachusetts, Missouri, New Jersey, New York, and Wisconsin) to provide state based funding for embryo-destructive research.[11] Practical patient treatment outcomes of this research are still pending.

As one of his first acts as President, Barack Obama issued Executive Order 13505 on March 9, 2009, repealing the Bush restrictions on embryo-destructive stem cell research.[12] Yet on March 11, 2009, Mr. Obama signed the Omnibus Appropriations Act of 2009, which continued to include the Dickey Amendment prohibiting federal funding for embryo-destructive research. The net result was that more cell lines were available to study using federal funds (cell lines created using private funding), but the prohibition against use of federal funds for the creation of new cell lines via embryo destruction remained.

Practical realities regarding the limited value of using supernumerary embryos for research and therapeutic purposes Given the continued restrictions against creating embryos specifically for research purposes, the embryos used for the creation of new stem cell lines must come from supernumerary embryos left over from IVF treatments. Despite all the claims of possible cures of hundreds of diseases for millions of patients from the use of embryonic stem cells, a practical question arises: will the use of supernumerary embryos left over from IVF adequately supply the needs of the research community and proposed therapeutic interventions? The answer is a resounding, NO. In 2002, the Society for Assisted Reproductive Technology and the RAND Corporation performed a survey of the 430 assisted reproductive technology practices in the United States. They determined that 396,526 embryos were in cryostorage as of April 11, 2002. Of these, 88.2% were still intended to be used for family completion by the conceiving parents. Of the remaining 47,200, 9225 were intended to be donated for embryo adoption, 8840 were to be discarded, 18,000 were in limbo due to divorce, lost contact with the parents, etc., 752 would be destroyed in quality assurance projects, and only 11,283 were designated for research. Some of these embryos designated for research would be used for IVF research, not embryonic stem cell research. Assuming, however, that 11,000 would be available for stem cell research, only 65% would survive the freeze-thaw process, leaving 7,334. Of these, only 25% (1834) would likely survive to the blastocyst stage. Estimating a 7.5% to 27% success rate for developing a viable cell line, it was concluded that only about 275 cell lines could be derived from the close to 400,000 embryos then available.[13] Given the immunological issues involved with cell therapies, this is a paltry number of cell lines, vastly below the numbers required to produce usable therapies for millions of patients.

A more recent survey (2007) of only 9 fertility centers throughout the United States revealed that ~20% of parents with cryopreserved embryos were likely to donate unused embryos to research, but that was for all types of research, not just embryo stem cell research.[14,15] Even if all of this 20% of 1020 families donated their embryos to stem cell research it would still not generate sufficient cell lines for any practical therapeutic purposes. Hug[16] reviewed 67 publications from different countries and revealed a wide variance in the percentage of parents who have or would donate their embryos for stem cell research, from 27% in Australia, to 92% in Sweden.

Would somatic nuclear transfer (cloning) produce sufficient numbers of useable embryos from which to develop therapeutic cell lines? The only possible way to generate sufficient numbers of immunologically acceptable embryonic stem cell lines for widespread therapeutic use would be through somatic nuclear transfer, or cloning, which, appropriately, is banned in many countries and the European Union. Even if such bans were not in place, cloning itself will never prove sufficient for the need either. Let us look at one example to prove this claim. Diabetes mellitus is one of the diseases thought to be amendable to regenerative cellular replacement therapy. Diabetic patient representative organizations have been some of the most vocal in demanding expansion of embryo-destructive research. There are 17 million diabetics in the United States. How many eggs will be required to produce regenerative cellular therapies by cloning techniques to treat this number of patients? Assuming a collection of on average 10 eggs per donor, a very generous 20% cloning success rate to the blastocyst stage, and an equally generous 10% efficiency of harvesting these blastocysts to produce embryonic stem cell

cultures, it would require a minimum of 850 million eggs and 85 million women to produce the cell lines to treat those afflicted with just one disease. Given that there are only 55 million women of child-bearing age in the United States, it is clear that cloning cannot produce the number of cell lines required.

The reality is that the only practical way to produce sufficient stem cells for therapeutic purposes is through the use of autologous ASC or iPSCs. Embryonic stem cells are not needed, nor will ever be practical, for the development of treatments for the millions of patients who might benefit from cellular therapies. It is illogical and immoral to pursue an unethical line of research that cannot in the most optimistic estimates produce the desired end.

The unspoken costs of in vitro fertilization There is another aspect of this story that must also be examined: the burdens of IVF practices that produce supernumerary embryos. When patients begin their IVF courses in the United States they may be asked to provide an advance directive detailing disposition instructions for left-over embryos should something happen to the conceiving parents, or contact between the parents and the practice be lost. Other parents confront the disposition question after they have completed their families, and some parents, though filling out a disposition form at the beginning of the course, change their minds.

Hug,[16] in her systematic review of literature found that the majority of parents struggle significantly with the disposition decision. Some reported that it was the most difficult decision of their lives. Hammerberg et al.[17] found that 25% of parents described the decision-making process as "very distressing." De Lacy et al.[18] reported patients describing the decision as "anguished" or "agonizing," and many wished they had never had to make the decision. Some of the patients indicated they would rather leave their embryos cryopreserved indefinitely, even though this would result in the eventual death due to deterioration, rather than make a decision. Many parents delay the decision until forced because they wish to avoid the responsibility of deciding to destroy their embryos, either directly or via research. Nachtigall et al.[19] reported that after 4.2 years of cryopreservation, 72% of parents had not reached a disposition decision. Similarly, McMahon et al.[20] found that 70% of Australian women with supernumerary embryos were unable to come to a decision 5 years after completing their families by IVF. Cattoli et al.[21] reported that 25.1% of Italian patients allowed their embryos to be destroyed without making a definitive decision.

As mentioned, many programs in the United States attempt to minimize the struggles with decision-making or indecision by asking patients to prepare an advance directive delineating disposition choices before beginning the IVF process. This proactive step, however, has not resolved the issue as significant numbers of patients change their minds over the course of treatment. Examining the changes in disposition decisions in one practice in Chicago, Illinois, Klock et al.[21] reported substantial variance in choices from pretreatment baseline to those made after or during the IVF course, with only 29% of families adhering to their initial choices. Of those who initially opted to dispose of their remaining embryos, 59% later chose to use or donate their embryos to other couples. Of those who initially wished to donate unused embryos to others, 82% changed their minds. And of those who had indicated a desire to donate their unused embryos to research, 87% later chose to implant them themselves or dispose. Further complicating this information is the fact that these numbers reflect only 57% of the families with cryopreserved embryos in the practice because the others families could not be located to interview.[21] All of this information underscores the challenges and hazards of making any presumption about the availability and appropriateness of using supernumerary embryos.

In a series of interviews, Nachtigall et al.[19] uncovered substantial reasons for the difficulties parents encounter when confronted with the disposition question. While patients are initially reassured that they may have large numbers of embryos with which to become pregnant, once their families are completed they often enter a phase of avoidance of the question of disposition. This is because the parents frequently have complex conceptualizations of their embryos. Many considered their embryos living beings with the capacity to experience discomfort and suffering. Others considered their embryos "virtual children that had interests that needed to be considered and protected". Some incorporated the embryos into their family structure, "referring to them as siblings of their living children". The thought of donating the embryos to another couple was often uncomfortable for some as in these patients minds this amounted to abandonment, or relinquishing control of their children to others. Viewing pictures of their embryos instilled strong feelings of attachment for some parents.[17] In essence, for many patients considering the thought of disposal, donation for research, or donation to another couple of their supernumerary embryos produced the same degree of distress that might accompany similar thoughts of disposition of older, postnatal children. Therefore, policy makers when considering approval of and guidelines for IVF, and the use of supernumerary embryos that might be created by IVF technologies, should factor in the substantial emotional and social costs of these technologies, in additional to the medical risks, financial costs, and overall ethical questions regarding the nature of the human embryo.

The dangers of unregulated reproductive technologies In many ways, reproductive technologies are unregulated, or at best loosely regulated, in

the United States. In 2002, the President's Council on Bioethics issued their report, Reproduction and Responsibility: Regulating New Biotechnologies, in which the Council concluded, among other concerns: 1) there is no uniform, comprehensive, and enforceable system of data collection, monitoring, or oversight for biotechnologies affecting human reproduction in the United States, 2) there is minimal direct governmental regulation of the practice of assisted reproduction, and 3) while there is some degree of professional self-regulation, compliance with recommended practice guidelines are entirely voluntary.[22] While standard practice has slowly evolved to a general recommendation of implanting only 2, or at most 3, embryos per transfer (to minimize the risk of multiple pregnancies), there is no restriction on the number of embryos conceived, which necessarily results in the conception of significant numbers of supernumerary embryos. A discussion of alternative approaches to IVF which avoid the creation of excess embryos is beyond the scope of this paper, but these options do exist. The United States experience is not a positive example for the regulation of reproductive technologies that 1) recognizes and protects the humanity of the embryo, and 2) takes into appropriate consideration the significant existential/emotional burdens that parents encounter regarding the disposition of supernumerary embryos.

Concluding comments The 20th century was the bloodiest in human history. It witnessed great advancements in medicine, science, and technology, but on occasion these advancements were achieved with significant consequences and great tragedy due to the commodification and denigration of members of the human family.[23] Arising out of the ashes of this grim history have been codes regulating human subjects research, including the Nuremberg Code, the Belmont Report in the United States, and the more recent European Union Convention on Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine. It is therefore disturbing that arguments offered in the current debate about embryo-destructive stem cell research used to justify the sacrifice and destruction of supernumerary embryos employ the same rationale as those used by German physicians in their defense during the Nuremberg trials. The following key points of comparison have been gleaned from a more complete enumeration by Michael Grodin.[24]

First, "[r]esearch is necessary in times of war and national emergency. Military and civilian survival may depend on the scientific and medical knowledge derived from human experimentation. Extreme circumstance demand extreme action."[24] We are faced by a crisis of phenomenal proportions as millions are afflicted with diabetes, Parkinson's disease, cancer, traumatic neurological injury, heart disease, and the whole host of clinical problems ostensibly remediable by stem cell-based therapies. Indeed, the rhetoric of war is so prominent in the human embryonic stem cell discussion that some researchers have claimed that "the suffering of millions will be on the hands of those who do not permit and support this research."[25]

Second, "[t]he prisoner utilized for human experimentation were already condemned to death."[24] Geneticist Jerome Lejeune has called these "leftover' frozen embryos prisoners of 'the concentration can'."26 In this case, it is not prison camp physicians who have made the disposition decision, but parents and their reproductive physicians.

Third, "[e]xperimental subjects were selected by the military leaders of the prisoners themselves. An individual physician thus could not be held responsible for the selections."[24] Similarly, the NBAC argued that the supernumerary embryos have been rejected by their parents and, thus, that the research community bears no responsibility for their deaths[8] (ignoring the clear fact that the research community solicits these embryos from IVF facilities, and happily accepts these still living embryonic human beings in order to deliberately kill them with full moral autonomy).

Fourth, "[s]ometimes it is necessary to tolerate a lesser evil, the killing of some, to achieve a greater good, the saving of many."[24] The American bioethicist, Arthur Caplan, has referred to human embryo-destructive research as simply a matter of "small sacrifices".[27]

Finally, "[w]ithout human experimentation, there would be no way to advance the progress of science and medicine."[24] While this statement is true at face value, codes, guidelines, and regulations have been developed specifically for the purpose of bridling research enthusiasm with ethical principles in order that science remains the tool and servant of human beings, rather than human beings being the tools and servants of science.

The Nuremberg tribunal, guided by the fundamental principle that human beings are never to be treated as means to an end, but must always be the ends in themselves, rejected these arguments. Yet just a few decades later, scientists and politicians using utilitarian and pragmatic reasoning, are once again endorsing the commodification and destruction of members of the human family. The author is not equating stem cell researchers with Nazi physicians nor embryo-destructive research with the Holocaust. It is assumed that human embryonic stem cell researchers are not pursuing a racist eugenic policy and are genuinely working to produce treatments that will benefit patients. The focus of this argument is solely concerned with human subject abuses, and the rhetorical pathways used to promote or defend those abuses. The historical record is clear that the logic and reasoning used to justify the destruction of supernumerary embryos for research purposes is identical to that used historically to justify the destruction of other members

of the human family in the name of research. This should give us pause.

We are therefore left with several critical questions regarding IVF and embryo-destructive research:

1 While infertility is a common and emotionally painful condition, should not the technologies developed to address the problem be regulated to prevent the creation of more embryos than can be used?

2 Must we always pursue a technological solution to a problem? There are millions of orphans in the world today, who need loving families. When faced with infertility, a couple must ask themselves, "Are we called to procreate, or are we called to parent?" If the later, adoption is an outstanding solution that avoids the problems and complexities associated with IVF.

3 As a society, are we willing to devalue and commodify the youngest members of our human family, acknowledged by science/embryology as human beings?

4 Are we willing to violate the principles of human subject protections derived out of previous tragedies of human denigration and commodification?

5 Are we willing to allow a tool, science, to negate the principles of human dignity, and become our master rather than our servant?

6 In a deliberative democracy, should the state remove basic human protections from a group on the basis of majority opinion or utilitarian calculus, or should the default always be to err on the side of the broadest protection for all members of our species?

The European Union Convention declares, "The interests and welfare of the human being shall prevail over the sole interest of society and science."[28] These are words of great wisdom learned from the fiery trials and abuses that mark the history of the 20th century. May such wisdom guide the physicians, citizens, and leaders of Poland as that noble country weighs the questions of assisted reproductive technologies and stem cell research.

Note Dr. Hook's comments are solely his own, and do not necessarily reflect the views of the Mayo Clinic and Foundation, and the position of the *Polish Archives of Internal Medicine*.

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ARTYKUŁ POGLĄDOWY

Zapłodnienie *in vitro* i pozyskiwanie komórek macierzystych z ludzkich embrionów

Prawo i praktyka w Stanach Zjednoczonych

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Mayo Clinic, Rochester, Minnesota, Stany Zjednoczone

SŁOWA KLUCZOWE

badania, w których niszczy się zarodki, indukowane pluripotentne komórki macierzyste, transfer jądra komórki somatycznej (klonowanie), zarodki nadliczbowe, zapłodnienie *in vitro*

STRESZCZENIE

Przed nauką i medycyną stoją ogromne wyzwania. Nauka musi możliwie najdokładniej badać świat przyrody, jednocześnie szanując i chroniąc przedmiot swoich badań oraz człowieka, w którego rękach jest narzędziem. Medycyna musi jak najskuteczniej walczyć z chorobami i niepełnosprawnością, jednocześnie szanując i chroniąc istoty, którym służy – wszystkie, a nie tylko wybrane (nawet jeśli jest to większość), dla których poświęciłaby inne. Zagrożeniem dla tych celów są badania nad ludzkimi zarodkowymi komórkami macierzystymi.

W embriologii zarodek ludzki jest definiowany w sposób jednoznaczny jako istota ludzka, dlatego powinien podlegać tym samym prawom, które regulują badania z udziałem ludzi. Potencjalne korzyści płynące z wykorzystania pluripotentnych komórek macierzystych, polityka na rzecz aborcji oraz brak unormowań dotyczących zapłodnienia *in vitro* przyczyniły się jednak do tego, że w środowiskach naukowych, medycznych i politycznych w Stanach Zjednoczonych próbuje się wykluczyć pojęcie człowieczeństwa z definicji embrionu ludzkiego.

Leczenie niepłodności jest źle uregulowane prawnie w Stanach Zjednoczonych, czego wynikiem jest zbyt duża liczba zamrożonych embrionów. Tylko nieliczne z nich będą kiedykolwiek wykorzystane w badaniach, jest więc mało prawdopodobne, że staną się źródłem komórek macierzystych potrzebnych do leczenia milionów ludzi, którym taka forma terapii mogłaby pomóc. Klonowanie również nie rozwiązuje problemu, ponieważ liczba kobiet niezbędna do tego, by pozyskać komórki jajowe potrzebne do wyprowadzenia sklonowanych linii komórkowych, oscyluje w granicach milionów. Co więcej, decyzje, jakie rodzice muszą podjąć w związku z losem zamrożonych embrionów, są wyjątkowo trudne; nierzadko też zmieniają oni zdanie.

Wykorzystanie nadliczbowych embrionów do pozyskania zarodkowych komórek macierzystych jest nieetyczne, nigdy nie będzie wystarczającym źródłem komórek potrzebnych do celów terapeutycznych i często staje się źródłem cierpienia rodziców, którzy zdecydowali się na zapłodnienie *in vitro*. Stany Zjednoczone nie stworzyły więc pozytywnego wzorca do naśladowania dla innych krajów.

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