Chapter Fifteen

Stem-Cell Research Utilizing Embryonic Tissue Should Be Conducted

Jane Maienschein

Moral claims against human-embryonic stem-cell research are based in a priori claims that include and often start from mistaken assumptions about the natural world. They amount, in effect, to deriving an *is* from an *ought*. The result is bad moral arguments, and also bad policy. This chapter looks at what stem cells are, what stem-cell research is, what embryonic stem cells are, why researchers want to do embryonic-stem-cell research, what leads opponents to their poorly informed moral positions, and then why such research should be at least allowed and even why it should be actually conducted.

Introduction

Centuries of moral philosophers, starting most notably with David Hume (1711–1776) in his work, *A Treatise of Human Nature* (Hume, 1739–1740/1975), have worried about the relationship between what is the case and what we think ought to be the case. The question has been whether it is possible to derive an *ought* from an *is*, and the answer has typically been *no*. Or at the least, it is accepted that what exists in the world is not sufficient to tell us about what is morally good (Falk, 1976). Attempting to do so has been labeled the *naturalistic fallacy* (initially by philosopher G. E Moore). And rejection of this fallacy has led generations of moral theorists to assume that scientific knowledge of the empirical world will not allow us to derive moral claims. A mistake in reasoning occurs also when one reasons from claims regarding what ought to be the case to claims regarding what is the case.

I argue that in fact there are cases of moral decision-making in which misunderstanding of the actual natural world leads to moral errors of this latter sort. This is the case with human-embryonic stem-cell research. Here, most of the moral claims against engaging in this research are based in strong a priori moral claims that include and perhaps begin from mistaken assumptions about the natural world. Starting with claims linked to bad science (or pseudo-science or nonscientific claims about nature), the result is bad arguments and, to the extent that these moral arguments influence political decisions, bad policies. This has surely happened with human-embryonic stem-cell research.

Let us look at what stem cells are, what stem-cell research is, what embryonic stem cells are, why

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researchers want to do embryonic stem-cell research in particular, what opponents seem to be thinking that leads them to their poorly informed moral positions, and then at arguments for why such research should be at least allowed and even why it should be actually conducted.

What Are Stem Cells?

The term *stem cell* goes back to the late nineteenth century embryological work of researchers when it was used to refer to those cells that are not yet differentiated into the diverse types of cells that come later (Maienschein, 2003). Stem cells have the capacity to self-replicate and also to give rise to cells that do become differentiated. Some stem cells are called *unipotent*, which means that they can become just one kind of differentiated cell; for example a neural stem cell can become only a nerve cell. At least this is the case under anything like normal conditions; we do not know about all the possible experimental conditions that might allow different results. *Multipotent* stem cells are just like they sound, so that they have the capacity to self-replicate like all stem cells do and also can become differentiated as at least two different kinds of cells. This is true of hematopoietic stem cells, for example. These are found in the bone marrow and have the capacity to self-replicate and also to become any of several different kinds of cells in the body. *Pluripotent* stem cells have the capacity to self-replicate and can become differentiated as any kind of cell. Embryonic stem cells are pluripotent, and researchers are now able to induce pluripotency in adult somatic stem cells, too. As far as we know, nearly all stem cells that we can actually find in the body are these kinds of stem cells: uni, multi, or pluripotent stem cells (see the NIH website or any number of textbooks on stem-cell research for definitions and distinctions).

The nature of uni- and multipotent stem cells had already been well established in humans since the 1950s when researchers discovered that hematopoietic stem cells in the bone marrow could produce blood cells after the marrow was transplanted from a donor to a patient. Early cases, in France through the research of Jean Dausset (1958) and then elsewhere, showed that bone-marrow transplants could help leukemia patients or patients who had been exposed to excessive radiation or for a few other conditions. This led to the study of what it was that allowed those particular cells to become blood cells, and it raised questions about how much transplantation of other cells might be possible and to what effect.

As often with human experimentation, unless there is a desperate immediate medical need, we do research in other animals before experimenting with humans. Researchers therefore learned a lot about mice, and how and why the bone marrow has special capacities that other tissues and cells do not have. They also learned much about cell culture from cancer cells, including the famous HeLa cells that proved easy to reproduce and very powerful for a wide variety of research questions. Hannah Landecker (2007) has written an important study of such cells and their history, and Rebecca Skloot (2010) provides a wonderful story about the original donor, Henrietta Lacks.

Then, starting in the 1950s biologist Leroy Stevens was at the Jackson Laboratories in Maine studying early developmental stages in mouse cells (Lewis, 2000). He discovered a particular strain of mouse—number 129—that developed differently from normal. Inside the testes in many individuals within this lineage, there emerged a mess of hair, teeth, and other cells that obviously should not normally arise in testes. Stevens (1970a, 1970b) set out to understand why this strain behaved this way, and in 1970 he reported that what he named "pluripotent stem cells" from the blastocyst stage did not differentiate as they normally would in mice from strain 129. Instead, they settled in the testes and gave rise to these out-of-place types of cells.

What Are Embryonic Stem Cells?

Other researchers realized the importance of Stevens's work. By 1981, two groups—Martin J. Evans and Martin H. Kaufman (1981) in Cambridge and Gail Martin (1981) at the University of California San Francisco—had succeeded in isolating and culturing pluripotent cells directly from early embryos. Finally, in 1998, James Thomson and John Gearhart (Thomson

et al., 1998) demonstrated the same ability to culture pluripotent stem cell lines in humans. This step is important because these pluripotent stem cells come from embryos, and unlike the uni- or multipotent cells found in the bone marrow, for example, these embryonic pluripotent cells are not yet differentiated at all. They are not totipotent, meaning that they do not have the ability to become the whole body with all its different types. Rather, they have "plural" rather than "total" potential and are therefore pluripotent.

Pluripotent stem cells may also exist in the developing or adult body, but not in large numbers and not in a way that can be isolated and studied. At this time, the only known significant source of many pluripotent stem cells is in the embryo. Experimental approaches have produced induced pluripotent stem cells (or iPS, which involves intervening by adding specific genes that can cause some adult cells to redifferentiate into cells that have some but not all of the capabilities of embryonic stem cells). The full capacities of these iPS cells remain unknown, and the cells do not seem to act *exactly* as embryonic pluripotent stem cells do (see recent discussions in response to 2012 Nobel Prize award to Shinya Yamanaka for stem-cell research).

Where do these stem cells come from? What happens in normal development is that the egg cell is fertilized by a sperm cell, and in those cases where the fertilization is successful (which is a relatively small percentage in humans) the cells begin to divide. The fertilized egg, which is one cell, divides into two, then into four, then into eight cells. These eight cells are actually all totipotent, and if they are separated from each other, they can often develop independently. We know this because of studies in mice as well as the fact that humans can give rise to multiple identical twins, triplets, up to octuplets. Since the cells up to the eight-cell stage in humans are totipotent, each can give rise to a whole new organism. Normally, however, the dividing cells will be held together to make up one individual.

After the eight-cell stage, the cells begin to divide at different rates and to divide many times. The cluster of cells goes through a stage called a *morula*, which looks like a blackberry with cells sticking out all around. Then, at typically day 3–5 and no later than day 14 after fertilization in humans, the blastocyst is formed. At this stage, there is a single layer of cells around the perimeter, and these will give rise to the placenta later if development progresses (which it often does not). Inside most of the space is a large cavity, yet there is also a cluster of cells that make up what is called the *inner cell mass*. These cells are completely undifferentiated but have lost their totipotency. They are now pluripotent stem cells. And they are called embryonic stem cells because they come from the embryo.

Normally, then, these embryonic pluripotent stem cells are neatly packed away inside the blastocyst, protected by the surrounding layer of cells that will eventually make contact with the woman's uterine wall. This blastocyst will in cases of normal development become implanted in the woman's uterus, and the two will begin to grow together. The blastocyst must be implanted or frozen by no later than 14 days (and often earlier), or it will stop cell division and die. Only a relatively small percentage of blastocysts actually become implanted and develop normally and fully to full term birth; there are many obstacles along the way.

At implantation, the embryo begins to exchange nutrients and eventually waste products with the woman host. Judging from what we know about mouse blastocysts, cells very quickly lose their pluripotency and their ability to self-replicate. They are no longer embryonic stem cells and instead become differentiated cells with increasingly determined roles.

Embryonic Stem-Cell Research

Because stem cells are self-replicating, they can be cultured in glass dishes to produce more and more of themselves. The number of cell division, or cell cycles, may be limited biologically, though that is not clearly established. At any rate, the cells can divide many times and provide a sustainable research material.

Because stem cells are not yet differentiated, a great many researchers working hard in numerous labs have figured out many of the conditions that will cause those cells to become particular differentiated cell types in the body. Because the cells are shaped by what they eat, it is possible to culture them with different food, that is to use a different culture medium, and they will differentiate in different ways. Culturing

with a certain medium will lead to differentiation as, say, heart muscle cells, nerve cells, pancreatic islet cells, or any other cell type.

This means that researchers can largely control the kinds of cells that they can produce in culture. They can then study the factors involved in different cases: which genes are expressed in producing a heart muscle instead of a nerve, for example? Which environmental and genetic factors lead each nerve cell to differentiate in particular specialized ways? Researchers have learned a tremendous amount about the factors involved in many steps of development as a result of embryonic stem-cell research.

This has led to the hope that we can build on the scientific knowledge about developmental biology to understand what differentiates a stem cell in a particular way, and with that knowledge also understand what differentiates other cells. From the beginning, researchers and the public have eagerly hoped to produce particular kinds of cells with defined clinical applications. The bigger challenge is to understand what causes cells, once differentiated, to stay differentiated. Clinical successes will depend on being able to cultivate, say, a heart muscle cell in culture and then have it stay a heart muscle cell when transplanted to a patient's heart. This is very challenging, and every responsible party agrees that we should not try the experiment clinically until we understand the underlying science much better (see nih.gov for the latest on clinical trials and results).

Much of the work until recently has taken place in mouse cells, which are very instructive because they are parallel to human cells in many ways. But if we are going to confirm the knowledge about development in humans and then apply it in clinical treatments, which so many patients hope happens soon enough for them, researchers must also study human-embryonic stem cells. Fortunately, federal funding in the US and elsewhere, along with state support and philanthropic and industrial funding, has allowed research to progress. And progress it has, leading to increased knowledge and even the first applications in the US for approval to carry out a clinical trial.

The California biotech company, Geron, received approval for the first clinical trial using human-embryonic stem cells in early 2009. This approval came from the US Federal Drug Administration (FDA), which has come to have jurisdiction over medical procedures since the passage of the Pure Food and Drug Act in 1906. For various reasons, Geron did not proceed immediately but pulled back from the trial. In August 2010, they were again awarded approval to proceed and report that they are doing so; but in 2011, due to financial problems, they dropped their entire program devoted to human-embryonic stem-cell research (Frantz, 2012). Other trials have begun or are being planned, and the US National Institutes of Health (NIH, nih.gov) and FDA (fda.gov) websites both provide updates on research and requests for clinical trials, respectively.

One challenge for clinical trials comes from outside science, because of the unstable political and economic environment in the United States. This makes investors nervous, for example, and it makes young researchers nervous about entering a field that is periodically under attack. That concern was very clear after the Federal District Court ruling on August 23, 2010 in Washington, DC, when Judge Royce Lamberth ruled that federal funding cannot be allowed to support human-embryonic stem-cell research on the grounds that it violates the intentions of the Dickey–Wicker Amendment (LC, 1995–1996; CR, 2010; Lamberth, 2010). The ruling had the effect of putting an immediate stop to federal funding of human-embryonic stem-cell research and was considered "shocking" by most researchers and congressional supporters, who vowed to work to gain explicit legislative support for the research. However, on July 27, 2011, due to a lift of Lamberth's injunction by the DC Court of Appeals on April 29, 2011, Lamberth actually reversed his ruling and dismissed the case entirely.

The problem in the US is that Congress has not yet passed clear legislation regulating or endorsing stem-cell research. Instead, we have legislative regulation of human-subjects research (HHS, 2009). And we have the Dickey–Wicker Amendment that was passed to restrict federal funding for embryo research, plus a series of presidential executive orders. Beyond that, we are left with a patchwork of state decisions, judicial decisions that some consider "legislating from the bench," and presidential orders (Matthews & Rowland, 2011).

President Bill Clinton issued an order that human-embryonic stem-cell research could be carried out,

with federal funding through the NIH. President George W. Bush ordered that it could continue with federal funding on only those lines of cells that had already existed before he began his address on August 9, 2001. Then, President Barack Obama's executive order in 2009 allowed federal funding of the research once the NIH had adopted ethical and procedural guidelines, and the National Institutes of Health (NIH, 2012) began granting funds for the work. Judge Lamberth's ruling in the Federal District court on August 23, 2010 (Lamberth, 2010) provided a temporary injunction against federal funding and created confusion. For example, it immediately called into question the status of NIH grants already awarded and those in the final processes of being approved. It made it seem once again that the safest funding in the US is private funding, which unfortunately closes the results behind proprietary doors and limits the number and nature of labs able to pursue the research. This limitation obviously concerns researchers and those hoping for clinical treatments. The climate of confusion created by the series of appeals and proposals and temporary decisions, alongside unrealized promises for clarifying legislation, has kept researchers nervous and uncertain (Hurlbut, 2010).

The strong reaction to the District Court ruling reinforces the fact that the research community considers this research with human-embryonic stem cells to offer extremely rich possibilities both for advancing scientific knowledge of development and also for developing practical clinical applications. Researchers know that there is a long road ahead before we are likely to have many clinical results, and in fact the results are unlikely to be exactly what we would predict now. Yet uncertainty about the exact nature of expected results does not undercut the fact that gaining the scientific knowledge will surely lead to some valuable clinical applications.

Mistakes of Opponents

It is worth looking more closely at the case that led to the ruling by Judge Royce Lamberth, a self-avowed conservative from Texas who was appointed to the court by President Ronald Reagan. Lamberth based his interpretation in part on his mistaken views about the nature of the research, in part on his interpretation of the congressional intent of the Dickey–Wicker Amendment, and in part on his acceptance of two of the plaintiffs' arguments that they are harmed by federal funding of embryonic stem-cell research.

Since this case depends on some fundamental errors in moral reasoning, including assuming that *is* implies *ought*, as well as *ought* implies *is*, it warrants a closer look. We see an illuminating set of errors related to this case and from this judge who is known to be anti-abortion and sympathetic to conservative interpretations of the nature of life.

The legal case started in 2010 with *Sherley vs. Sebelius* (SvS, 2010) and involved a biologist named James Sherley, who had recently been denied tenure at MIT and moved to the Boston Biomedical Research Institute, and a researcher in Seattle named Theresa Deisher, who founded her company, AVM Biotechnology, "in response to growing concerns about the need for safe, effective, affordable and ethical medicines and therapeutic treatments" (http://www.avmbio tech.com/home.html). Sherley and Deisher were joined by Nightlight Christian Adoptions, plaintiff embryos (Shayne and Tina Nelson, William and Patricia Flynn), and the Christian Medical Association in their suit seeking to halt federal funding on embryonic stem cells.

In identifying the plaintiffs, the suit states that:

> Plaintiff Embryos include all individual human embryos that are or will be "created using in vitro fertilization (IVF) for reproductive purposes and [are] no longer needed for these purposes." 74 Fed. Reg at 32,171. The Embryos are persons that qualify for representation under Fed R. Civ. P. 17 (c). NIH's violation of the Federal Funding Ban will place the lives of these Embryos under a recurring risk of destruction. (SvS, 2010, sec. 9)

The case claims that the NIH was violating both the laws of various states that prohibit embryo research and the clear intent of the congressionally legislated Dickey–Wicker amendment that prohibits "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk or injury or death greater then that allowed for research on fetuses *in utero* …" (LC, 1995–1996, 45 C.F.R. 46.204(b); also Green, 2001).

In fact, the NIH, the National Research Council of the National Academy of Sciences, and other committees had determined that the NIH should fund only human-embryonic stem-cell research on cell lines that have already been developed in laboratories and that had been caused to exist without any use of federal funds and following specific ethical guidelines. No federal funds would be used to "destroy" embryos, but only those embryos that had already been discarded or donated according to established ethical guidelines could be used. The NIH guidelines following the Obama executive order, then, made clear that there is no reason not to study the lines that have come to exist with private donations and private funding.

This is a subtle, but very accurate and important, distinction between the process of generating stem-cell lines and the process of doing research with them, since it is a well-established fact that thousands of embryos are discarded every year, and since once the stem cell lines exist, they are like any other cell lines that are widely used for cancer and other biomedical-research purposes. The fact that those who have caused the embryos to exist can now donate them for research purposes rather than throwing them away has actually been regarded as a very positive ethical step by many (Hall, 2001).

Yet Sherley and Deisher are self-described social conservatives who are anti-abortion, and they have explained that what they consider "ethical" necessarily rejects any embryo research, including research on those embryos that the owners wish to donate explicitly for such research. They claimed in their suit that funding the research on cell lines will contribute to the destruction of embryos that researchers need and that presumably would not haven been destroyed otherwise, and the research therefore violates the Dickey–Wicker Amendment.

The case was rejected by the District Court initially, but on appeal, it was ruled that Sherley and Deisher did have legal standing to bring such a suit, which placed Judge Lamberth in the position to make a decision. On this point related to violation of the Dickey–Wicker Amendment, Lamberth made two mistakes in reasoning.

First, he made assumptions about how the science works, as if doing stem-cell research involves actually generating new cell lines in every case. This is a failure to understand the nature of stem-cell and cell-culture research. Related to that, he concluded that the process of destroying embryos to generate cell lines and then doing research on those cell lines is all one line of research, rather than separable parts of a larger complex process. To do research on the stem cell lines is necessarily to destroy embryos, he asserted, and there is no such thing as a "piece of research" out of a whole process (Lamberth, 2010; Cohen & Adashi, 2011).

This interpretation has many implications that legal scholars will undoubtedly continue to explore, but it reflects a serious failure to understand stem-cell science. Cell lines are generated, and since the cells can self-replicate, the lines are shared and used over and over by many different labs for many different research questions. There are, in fact, many different "pieces" of research. And the first step in many cases starts with salvaging the cells from blastocyst's cluster of cells that would otherwise be discarded. Lamberth's failure to accept the scientists' explanations of how they do their work and his assumption that stem-cell research always requires destroying embryos that would not be otherwise destroyed are mistaken. Erroneous assumptions also led him to conclude that the research violates Dickey–Wicker, since he mistakenly believed that doing research on the cell lines is the same research as generating the cell lines.

A third factor in Lamberth's ruling relates to the fact that both of the plaintiffs who were ruled by the appeals court to have legal standing in the case work on those uni- or multipotent stem cells found later in the body (called adult stem cells). They were allowed to bring suit against the NIH and Health and Human Services that support embryonic stem-cell research on the grounds that allowing federal funding for what they regarded as illicit embryonic stem-cell research would harm their own chances of obtaining funding for their adult stem-cell research. This is obviously a highly problematic claim for many reasons.

Their extensive claims that adult stem-cell research and even iPS research are scientifically and clinically "better" than embryonic stem-cell research are completely unfounded. Furthermore, though federal funding is limited, there is no evidence that funding was directly shifted from the kinds of work they do to

embryonic stem-cell research or that they were harmed by any slight reduction in access to funds even if they could prove that such reduction occurred.

This part of Judge Lamberth's ruling raises many troubling questions. Does any researcher have a right to file suit against the NIH or other government funding agency because funding has shifted to a new initiative in a way that might have reduced funding for an older way of doing research? Or does that right hold only if the researcher claims (as they two did) that their way is "better science"? And if so, how will that be adjudicated? Surely we will not decide which is the best science through the judicial system! Nonetheless, this case went forward with precisely this kind of claim at its core and with Judge Lamberth's (2010) ruling that possible loss of funding would "threaten the very livelihood of plaintiffs Sherley and Deisher. Accordingly, the irreparable harm that plaintiffs would suffer absent an injunction outweighs the harms to interested parties" (sec. C). His conclusion is astonishing, given the facts of how federal funding processes actually work.

Judge Lamberth has ruled that Sherley and Deisher's case was likely to succeed and therefore could proceed. Fortunately, for the sake of scientific research, the US Circuit Court of Appeals disagreed with Judge Lamberth and held that the case was likely to fail. This sent the case back to Lamberth for reconsideration. On July 27, 2011, he made clear that he was not happy about the higher court decision, but he felt bound by it to accept that:

> This Court, following the D.C. Circuit's reasoning and conclusions, must find that defendants reasonably interpreted the Dickey–Wicker Amendment to permit funding for human embryonic stem cell research because such research is not "research in which a human embryo or embryos are destroyed."

This ruling settles the case related to interpretation and application of Dickey–Wicker, but it does not address other claims in the lawsuit. Some of these are likely to resurface in other arguments and other lawsuits.

For example, these researchers started with the assumption that others hold, namely that, "It is unethical to do research on persons, and embryos are persons." This statement amounts to the claim that "we believe for metaphysical reasons that have nothing to do with science or the research involved that embryos are persons." That is, they are seeking to impose their own personal ethical beliefs on others, and they are doing this by pretending that they have scientific reasons for doing so. The inclusion in their original case of the claim that "Potential donors are not told that many scientists believe that human embryos are human life or that many States hold that human life begins at conception," and then quoting Arkansas's reference to "the life of every unborn child," is legally clever but scientifically false.

Very few scientists would agree that life begins at conception in anything like the imputed sense that an individual's *personhood* begins then (Friedrich, 2000). Nor would they agree that the bunch of cells (which for humans is technically defined as an *embryo* up to the eight-week stage and then a *fetus* until it is born) is the same as an "unborn child"—a category, actually, that scientifically does not exist (Sadler, 2011). In *Roe v. Wade* (410 US 113), for example, Mr Justice Harry Blackmun rightly claimed that, "the unborn have never been recognized in the law as persons in the whole sense." The plaintiffs in *Sherley et al. vs. Sebelius* are playing a legal game, of course, but they are engaged in faulty reasoning that we should reject. They are starting from an *ought* and imputing claims about what *is*, which, as we have noted, is a fallacious move in reasoning.

Importantly, other legal decisions have explicitly rejected this claim that imputes a moral or legal status to a cluster of biological cells. For example, in Arizona's case of *Jeters v. Mayo* (1 CA-CV 04-0048, 2005), Judge Kessler ruled and was upheld on appeal that "3 day old embryos are not persons." Even President George W. Bush in his speech of August 9, 2001, while expressing his concern about embryonic-stem-cell research, understood the biological distinction between the early embryo and later stages of development. Bush explicitly accepted that there is a different status for "pre-implantation embryos" (which he also called "pre-embryos"), in which there has been no significant gene expression, no differentiation, and just multiplication of one cell into a cluster of cells.

This is not the place for an in-depth discussion of what counts as a person, or how we define personhood (start with Shoemaker, 2007, 2008), but the

important point here is that developmental biologists agree that the early stages, when there is just a bunch of stem cells in the inner cell mass of the blastocyst, are biologically completely different from later developmental stages (Kail & Cavanaugh, 2010). Blastocysts and their stem cells cannot live independently without being implanted into a uterus, and most do not continue to live at all because they stop dividing or do not implant, or their owners choose not to try to implant them. Apparently, the only reason to pretend that this early blastocyst stage falls under the same description as later developmental stages is to support the a priori belief that "embryos are persons." That is, advocates of this view want to take moral *ought* beliefs and attempt to impose them on others. They are attempting to draw *is* conclusions about the nature of embryos from their personal opinions. This is not good science; nor is it good ethics.

These advocates—such as the Catholic Church (CCC, 2004; NCBC, 2009)—buy into an anti-abortion philosophy that assumes that life begins at fertilization, which they label "conception." In a simple sense, it is true that in normal development, the early steps on the road to development of an individual human organism start with egg and sperm, and fertilization. But, again, the "life" that begins then is biological cell division and only that. For those who insist that fertilization and cell division make a "person," then presumably a lineage of cells derived from a fertilized egg and developing in culture should be a person also. So, those cell lines that already exist because of past research should be considered persons, too, and that claim is either useless or absurd. They are not the same kinds of things as later-stage embryos or fetuses (as humans are called after eight weeks of development) that have differentiated significantly, eventually have developing sensory systems, and later acquire the ability to live independently.

Some of those such as the Nightlife Christian Adoptions group (nightlight.org) do argue that all embryos are persons and that therefore we should preserve all embryos so that they can be adopted. Such advocates may actually believe that there will be enough parents to adopt all the available embryos, but careful studies show that this is just not possible. This wish is not even close to realistic. There are thousands more embryos than would-be adoptive parents (see the research, for example, in Skene, 2009). They claim now that would-be adoption parents wait for embryos that they cannot get, but that is surely in part because of background checks and such regulations, and also because the owners of the embryos do not wish to have their embryos adopted. The numbers just do not add up.

The only possibility to follow through on their logic is government regulation, which will have to be the federal government to control interstate commerce. The government would have to either prohibit anyone from generating "extra" embryos or force the owners to give up any extras for adoption, and then force would-be parents to adopt them. Surely these embryo-rights advocates do not really want to demand federal government intervention in private lives in all these ways. Yet their assumptions about what "ought to be" and therefore the faulty conclusions about what an embryo "is" lead to such impossible conclusions.

We Should Allow Stem-Cell Research

Some of the owners of extra embryos want to donate their embryos for research (see the research, for example, in Islam et al., 2005). They are going to discard their embryos otherwise, do not want to allow adoption, understand what is involved, and also see the cluster of undifferentiated cells as a potentially rich resource for scientific knowledge. They accept the current NIH guidelines that were established by the Obama executive order. They want to support research in a way that accepts the guidelines not to use any federal funding to "destroy" the embryos, and in ways that make the resulting cells available for research, to gain knowledge, and perhaps eventually to bring clinical results. And they want federal funding to be available for the research so as to yield the highest possible public use and public good. This should be allowed.

In addition, some go further and insist that such research should be not just allowed but also actually conducted. These are two different claims, of course. The first involves assessing harms, while the second involves assessing the balance of harms and benefits. The first is an ethical and policy matter, the second a

pragmatic decision. For the US, I argue here—and have argued elsewhere (Maienschein, 2003; Maienschein & Robert, 2010)—that at this time and given what we know now, we should both allow and conduct human-embryonic stem-cell research.

First, in the US, we accept that behaviors including carrying out research should be allowed if it does not involve significant harm to others. Doing scientific research is parallel to a speech act in this respect, with protections for such acts. We start, then, with the assumption that research is allowed. Then would come the burden for opponents to demonstrate that research does involve harm to others. Building nuclear or biological weapons or explosives in one's basement is not protected, for example. Carrying out research that involves torturing human subjects or violates animal-care guidelines: such research is prohibited. We develop a set of regulatory and legal guidelines to determine the extent and nature of limitations based on understanding of harms.

In the case of embryonic-stem-cell research, the majority of American citizens in repeated polls favor allowing the research and feel that there is no significant harm involved (Gardner, 2010). A minority do argue that embryos are harmed, but given the scientific facts that the pre-implantation of earliest developmental stages involves just a bunch of undifferentiated cells, it is difficult to see how these cells can be harmed, the way one harms a person on the street, for example. The usual sort of argument that the minority do not want to live in a society that would do research on embryos sits alongside other claims that a minority do not want to live in a society that eats meat or wears leather or lets doctors turn off a respirator when the patient has indicated a wish that that happen and when the family or guardians agree. Legally and ethically, as a society, we have decided that these are either not harms or not significant harms. The same should be true with embryo research.

Yes, there is the Dickey–Wicker Amendment to the Health and Human Services Funding bills. And, yes, that Amendment says (to expand on the earlier point) that federal funding will not be used for "(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero*" (LC, 1995–1996). Yet, contra Judge Lamberth, the NIH, National Academy of Sciences, and many other scientific groups hold that embryonic stem-cell research on stem-cell lines generated without federal funding do not violate this legal restriction. Furthermore, the assumed harm to embryos comes in a budget amendment and is not based on any assessment or demonstration of actual harms.

Therefore, in the absence of demonstrated harms, human-embryonic stem-cell research should be allowed. And it should be allowed with federal funding, though there is no entitlement for any particular line of scientific research that it should receive federal funding. That is instead a pragmatic decision, and that is the second point.

Second, human-embryonic stem-cell research should be not only allowed but also actually conducted. Here, we have to show that there are actual benefits as well as no significant harms. That is, deciding what research should be conducted is a pragmatic matter, involving cost–benefit analyses. In this case, there is very significant actual benefit, as can be seen from the research provided by the NIH on their site devoted to stem-cell research (stemcells.nih.gov). Also see the European research (eurostemcell.org) and Chinese research (stemcellschina.com). We have learned a tremendous amount already from having carried out the research. In fact, much of what we know about adult stem-cell development and all the work on induced pluripotent cells builds on the knowledge gained from embryonic stem-cell research. This research should definitely be continued. Insofar as federal and other funding helps generate new knowledge, it is a good investment.

The clinical benefits remain unknown and potential. While groups such as Advanced Cell Technology (ACT, 2010, 2011; Schwartz et al., 2012) are undertaking the first FDA-approved clinical trials with embryonic stem cells, many informal experiments have begun and other carefully designed clinical trials are under preparation. In fact, it is not likely that clinical benefits will come quickly nor easily, and probably not even as originally envisioned. That does not, however, undercut the cost–benefit analysis results that weigh in favor of carrying out the research. And it does not mean that only this kind of research

should be done. Instead, the best results are likely to come from comparative studies, drawing on knowledge generated from embryonic stem-cell research, iPS research, and continuing research on all other stem-cell lines.

Therefore, human-embryonic stem-cell research, carried out with cells from human embryos as well as other cell lines should be allowed and should be carried out.

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