

The Many Casualties of Cloning Richard M. Doerflinger

The details of the cloning scandal in South Korea are by now familiar. Dr. Hwang Woo Suk and his colleagues, the only researchers in the world to convince the scientific community that they had cloned human embryos and derived embryonic stem cells (ESCs) from them, are now seen as having perpetrated a massive deception. Investigative reports by Seoul National University and others say that, contrary to past disclaimers, the team solicited over a hundred women (often with cash incentives) and even pressured female researchers to provide human eggs for cloning experiments, at serious risk to the women's health; that from over two thousand eggs the researchers failed to produce even one stem cell line despite hundreds of cloning attempts; and that they covered up their failure by falsifying two major articles in a prestigious U.S. science journal.

In the United States, reactions to this scandal span a wide spectrum. Some cloning advocates claim that this event has no implications beyond the malfeasance of a few Korean researchers. "Despite this apparent setback, the field of embryonic stem cell research and therapeutic cloning remains incredibly promising as demonstrated by some of our nation's leading scientists," says Daniel Perry, president of the Coalition for the Advancement of Medical Research. Others, including the investigative panel in Seoul, believe it has "damaged the foundation of science." The truth surely lies somewhere between these extremes: the scandal implicates far more than a few Korean scientists, but it does not undermine science in general, unless one foolishly equates human cloning with all of science. More broadly, this unfortunate affair offers three sets of lessons—scientific, political, and moral—that we ignore at our peril.

Scientific Myths and Realities

The first obvious conclusion, as noted by the *Washington Post*, is that "the highly touted field of embryonic stem cell research is years behind where scientists thought it was." After eight years of effort around the world to clone human embryos, no one has reliably done so. After years of touting so-called "therapeutic cloning"—the idea that stem cells from

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cloned blastocysts would supply every sick person with his own "biological repair kit"—no one has achieved even the first step toward making this medical dream a reality.

It is generally true that a discovery of fraud in one researcher's claims does not discredit an entire field. But in this case, Dr. Hwang's studies *were* the field of allegedly successful human cloning for research purposes. If his research is a fraud, there is (at present) nothing left of that field. As the *New York Times* has observed, "The technique for cloning human cells, which seemed to have been achieved since March 2004, now turns out not to exist at all, forcing cloning researchers back to square one."

This is at least the *third* time in eight years that we have heard announcements of success in cloning human embryos for their stem cells, only to find that the claim has little basis in fact. Lest we imagine that Korea has a monopoly on misleading claims in this field, it is worth noting that the two previous false starts were announced by an American company, Advanced Cell Technology (ACT). Although ACT's researchers only managed to bring one cloned embryo to the six-cell stage—and whether they created an embryo at all remains uncertain—they were certainly not able to obtain any stem cells. Yet the company announced its research as "the first proof that reprogrammed human cells can supply tissue for transplantation."

Most Americans, and most legislators, probably assume that there are at least established animal models for the use of ESCs from "therapeutic cloning." But there is little in the scientific literature to support this. Some studies published by Advanced Cell Technology and others have been touted as showing benefits from stem cells harvested from cloned animal embryos—but in each case, the study had to achieve its therapeutic goal by implanting the embryo in an animal's uterus and growing it to the fetal stage, then killing the fetus for more developed *fetal* stem cells. Such "fetus farming" is now apparently seen by some researchers as the new paradigm for human "therapeutic cloning," and some state laws on cloning (e.g., New Jersey's) are crafted to allow just such grotesque practices in humans. It may be that "therapeutic cloning" cannot be made to work without conducting the "reproductive cloning" that almost everyone condemns-placing embryos in women's wombs, in this case in order to abort them later for their more developed tissues. This would, of course, compound cloning's exploitation of women as egg factories, by exploiting them as incubators for cloned fetal humans as well.

Other claimed advances for ESCs from cloning have turned out to be a "bait and switch" ploy—that is, the advances were falsely reported to

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have come from cloned embryos, but turned out not to involve cloning at all. In summer 2005, for example, the *New England Journal of Medicine* (*NEJM*) reported that "human nuclear-transfer embryonic stem cells" had been shown to produce new neural tissue in an animal model of brain damage. The two articles cited for this claim, however, clearly report using *existing ESC lines* from fertilized embryos—cell lines eligible for federal funds under the current Bush administration policy. The studies actually received NIH funding, making even more ridiculous the article's claim that "while the United States remains rooted in atavism, Hwang and coworkers have shown that Asia is moving forward." A few years earlier, in July 2003, *NEJM* had already weakened its credibility in this field by announcing a new politically motivated editorial policy of specially "seeking out" manuscripts touting ESCs. "We want to be sure that legislative myopia does not blur scientific insight," wrote the editor, myopically.

The significance of the cloning fraud for human ESC research in general remains uncertain. In 2001, the Biotechnology Industry Organization (BIO) testified to Congress that cloning is essential for gaining any clinical utility from ESCs, because only by cloning can we control the genomes of the stem cells and avoid the immune-rejection problem when those cells are one day used for regenerative purposes. If BIO was right in 2001, then ESCs have been discredited as a route to therapies, at least for the time being, because obtaining ESCs from cloned human embryos still cannot be done. If BIO was wrong, and cloning is (in the words of one recent overview) "a boutique science, one at the fringe of the rapidly expanding world of stem cell biology," why not ban the egregious abuse of human cloning now and debate the other issues relating to ESC research separately?

Clearly, scientists themselves disagree on the importance of research cloning. A recent *NEJM* commentary, for example, fights against "the impression that stem cell biology has been discredited" by the Hwang scandal, arguing that cloning by somatic cell nuclear transfer "plays only a minor role in the wider discipline of stem cell biology." The journal's editor had said exactly the opposite in 2003, claiming that by approving a ban on human cloning, the House of Representatives had voted to "ban research on, and the use of, medical treatments derived from embryonic stem cells." Yet many stem cell experts expressed grave doubts about the feasibility of large-scale "therapeutic cloning" even before the Hwang research was exposed as a fraud. Here are just a few examples:

"The efficiency of making a stem cell line from an embryo made by nuclear transfer [cloning] is vanishingly small, and you're going back

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to the case-by-case, individualized-therapy story again, with enormous costs. The whole idea is to make this therapy internationally available, broadly. Nuclear-transfer procedures just are never going to get us there." [Thomas Okarma, president of Geron, a leading biotech firm involved in cloning research, in *Technology Review*, June 2003]

"For all the handwringing by scientists, you might think that therapeutic cloning is on the verge of curing a disease or two. But that is not the case.... Despite optimistic statements about curing diseases, almost all researchers, when questioned, confess that such accomplishments are more dream than reality." [Gina Kolata, science writer for the *New York Times*, January *5*, 2003]

"Although [cloning by somatic cell nuclear transfer (SCNT)] might, in theory, solve the rejection-biological access problem, it can do so only one person at a time. The amount of time and money needed to create these uniquely cloned solutions makes it unlikely that SCNT will provide a practical, widespread solution to the biological access problem." [Ruth Faden, John Gearhart, and eighteen other ethicists and scientists favoring ESC research, in the *Hastings Center Report*, November-December 2003]

"My view is there are at least three or four other alternatives that are more attractive already....I can't see why, then, you would argue for therapeutic cloning in the long term because it is so difficult to get eggs and you've got this issue of (destroying) embryos as well." [Australian stem cell researcher Alan Trounson, in *The Age*, July 29, 2002]

Beyond cloning, other avenues for obtaining genetically-compatible tissues for human therapies from ESCs also pose formidable problems, both ethical and practical. Certainly no scientist seriously believes that the current supply of "spare" embryos frozen in fertility clinics is adequate for any clinical use. One widely cited study, published in 2003 in *Fertility and Sterility*, estimated that there were as many as 400,000 frozen embryos in fertility clinics as of April 2002. However, that study also found that only 2.8 percent (or about 11,000) of those embryos were designated for possible use in research. Destroying all those embryos solely to obtain stem cells (deemed by the authors a "highly unlikely" scenario) would at most produce only two or three hundred cell lines.

Some propose creating genetically diverse "banks" of embryos produced by fertilization, in an attempt to provide a close genetic match to most patients. Two prominent researchers say that merely determining the "best options for research" (to say nothing of treatments) would require "perhaps 1,000" stem cell lines—about four times as many as are now available

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nationwide. Others say that to reflect the genetic and ethnic diversity of the American population, an ESC bank geared toward treating any major disease must include cell lines from many embryos *created solely in order to be destroyed for those cells*—including a disproportionate number of specially created embryos from African-American couples and other racial minorities, who are underrepresented among fertility clinic clients. Robert Lanza and Nadia Rosenthal, writing in *Scientific American* in 2004, said that "millions" of embryos from fertility clinics may be needed to create cell lines of sufficient genetic diversity. Is anyone in Congress seriously committed to creating and destroying human embryos on such a massive scale?

In short, supporters of expanded federal funding for human ESC research may have an agenda without an exit strategy. Of course, scientists may learn a great deal about various diseases with a limited number of embryonic stem cell lines, but this is not the way such research is typically sold to the public to gain its political and financial support. Stem cells are sold, rather, as replacement tissues for failing body systems, as biological saviors for over 100 million ailing Americans. Yet if mass production of ESCs from human cloning poses enormous practical and ethical problems, and the same may be true of efforts to make ESCs "therapeutic" without cloning, no one should assume that ESCs are the holy grail of regenerative medicine. As to human cloning research itself, it of course remains possible that someone will solve the seemingly intractable technical problems and manage to make the procedure work. But the prospect of making it "efficient," separating it from the exploitation of women, and deriving cost-effective therapies from it in our lifetimes seems remote.

No More Political Free Ride

While many researchers are beginning to appreciate that human cloning for medical treatments may be a failure, the world of politics is another matter. The political agenda for cloning has long been divorced from the facts, and this problem is, if anything, getting worse. It was *after* the South Korea scandal—after the last two years of "progress" in human cloning research was found to be illusory—that Senator Orrin Hatch (R.-Utah) declared: "This is probably the most promising medical-healthcare scientific research, as far as I'm concerned, in the history of the world."

To win public support and government funding, advocates for human cloning and ESC research have long made hyped claims and exaggerated promises to legislators and the general public. Some scientists and science organizations have acted like snake-oil salesmen, marketing the dream of

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"miracle cures" around the corner—and people (other than politicians) are beginning to notice.

In 2004, the state of California witnessed an especially cynical and shameless campaign by researchers and venture capitalists to put the state over \$6 billion into debt to fund this research. Only now are voters beginning to realize the truth, as reported in the *San Francisco Chronicle*:

Much of the California electorate was sold last year on the idea that human embryonic stem cells might be turned into amazing cures for incurable diseases, propelling Proposition 71 to easy victory in the Nov. 2004 election. Now, it's increasingly clear that stem cell transplants for diabetes or Parkinson's or Alzheimer's are nowhere close, maybe decades away.

Leading supporters, afraid of political backlash, have been issuing disclaimers to reduce people's unrealistic expectations about this research producing cures any time soon. In some cases they are also shifting the blame for those expectations onto others.

British stem cell expert Lord Winston, for example, has warned his colleagues that the political hype in support of ESCs and cloning needs to be reined in:

One of the problems is that in order to persuade the public that we must do this work, we often go rather too far in promising what we might achieve. This is a real issue for the scientists. I am not entirely convinced that embryonic stem cells will, in my lifetime, and possibly anybody's lifetime for that matter, be holding quite the promise that we desperately hope they will.

In response, one of Lord Winston's scientific colleagues has protested that this was not the scientists' fault: "It is true that Alzheimer's is not a promising candidate for stem cell therapies," says Dr. Stephen Minger of King's College London, "but it was not scientists who suggested it was—that was all politics in the U.S. driven by Nancy Reagan." But in the United States, Mrs. Reagan was backed by myriad scientific and patient advocacy groups who want public funding of ESC research, including the Juvenile Diabetes Research Foundation, the American Society for Reproductive Medicine, and the Alzheimer's Association. These groups must have known about the scientific consensus against an ESC therapy for Alzheimer's, but they chose to ignore it. Dr. Ronald McKay, a stem cell scientist at the NIH, explained the discrepancy between political message and scientific fact in this way: "To start with, people need a fairy tale."

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Some cloning supporters have even argued that the Bush administration is to blame for the Korean hoax. Because our government is not "paying for and regulating" ESC research of this kind, claimed prominent bioethicists Arthur Caplan and Glenn McGee, the landmark research was done in another country with no safeguards.

But every part of this argument is demonstrably false. Not only President Bush, but President Clinton and a seemingly unanimous consensus in Congress over the past decade have opposed funding the special creation of human embryos for research purposes. President Clinton rejected such funding in an executive order of December 2, 1994. Every year since then, Congress has annually approved a ban on funding any research that harms or destroys human embryos; and the only serious effort to weaken that ban, in 1996, would have left in place the funding ban on research involving cloning or other creation of embryos solely for research. Even the major bills seeking to overturn President Bush's policy on ESC research deal only with "spare" embryos produced by in vitro fertilization, and some of them explicitly state that "the research involved shall not result in the creation of human embryos."

Moreover, the claim that the lesson of the cloning scandal is the need for the United States to engage in regulated cloning ignores the fact that South Korea did have laws and regulations in place to prevent the most egregious abuses—laws allowing more independent oversight, for example, than cloning supporters have built into Proposition 71 in California. But these regulations were simply ignored by researchers obsessed with reaching their goal. And there is no evidence that American scientists are more conscientious about ethical guidelines. Even after concerns about Hwang's practices were raised by Korean and American ethicists who *support* cloning research, U.S. researchers continued to enthuse about collaborating with him right up to the most recent reports of complete fraud. For example, the very issue of *Science* carrying Hwang's 2005 study also published an ethical analysis by David Magnus and Mildred K. Cho of Stanford University raising concerns about informed consent, the risks to egg donors who cannot benefit directly from the research, and even the use of the term "therapeutic cloning" to describe research that may be decades away from providing therapies. Korean ethicist Koo Young-mo raised even more specific concerns in an interview with the Korea Times: "Let me raise a worst-case scenario. If some of the donors suffer from ovarian hyperstimulation syndrome and they bring Hwang to court with the dubious consent form, Hwang may be in trouble." Yet when Hwang offered to collaborate with U.S. researchers and provide them with ESCs from cloning, researchers like Dr. George

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Daley of Harvard responded enthusiastically: "Given the access that [the Koreans] apparently have to a very willing set of egg donors, they may be much more efficient at generating these cells than anybody else."

The broader political lesson from the Korean scandal, and from scandalous behavior here in the United States, is that political leaders, patient advocacy groups, and all of us must stop hearing only what we want to hear about "miracle cures." We need to be aware of the human costs of this agenda here and now, not only its alleged "promise" down the road. Whatever one's views on the morality of research cloning and embryo destruction, we cannot have a serious debate if scientists and politicians continue to make grandiose claims unjustified by the evidence.

The Trouble with the "New Ethic"

Beyond politics, the most important lesson of the cloning scandal is moral. Researchers, devoted to increasing human knowledge and bettering the human condition, have long been tempted to "cut corners" on ethics, including the ethics of protecting human research subjects, to achieve their admittedly important goals. A founder of modern scientific medicine, Dr. Claude Bernard, cautioned in 1865:

The principle of medical and surgical morality...consists in never performing on man an experiment that might be harmful to him to any extent, even though the result might be highly advantageous to science, i.e., to the health of others.

Likewise, in the wake of the grotesque German experiments of the 1940s, the Nuremberg Code insisted: "No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur." Researchers in the United States have not always followed this moral principle. We have only to think of the Tuskegee syphilis experiments, the deliberate injection of hepatitis virus into mentally retarded children at the Willowbrook home, and the Cold War radiation experiments on unsuspecting Americans in the 1950s.

What is new in recent years is the dominance of a "new ethic" that would justify such abuses *in principle*—a utilitarian calculus that relativizes and demeans the worth of individual human lives in the name of research that aims to benefit mankind. As a 1970 editorial in *California Medicine*, called "A New Ethic for Medicine and Society," put it:

The traditional Western ethic has always placed great emphasis on the intrinsic worth and equal value of every human life, regardless of its

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age or condition. This ethic has had the blessing of the Judeo-Christian heritage and has been the basis for most of our laws and much of our social policy.... This traditional ethic is still clearly dominant but there is much to suggest that it is being eroded at its core and may eventually be abandoned.... It will become necessary and acceptable to place relative rather than absolute values on things such as human lives.

Tragically, this new utilitarianism has become virtually the official ethic of those seeking to justify human embryo research and human cloning in both the public and private sectors.

Peter Singer of Princeton University, hailed by some as the most influential ethicist in the world, recently predicted that the old ethic honoring the sanctity of life will effectively be dead by 2040—and that in retrospect, "2005 may be seen as the year in which that position became untenable," because people realize that a sanctity of life ethic would not allow us to benefit from the wonderful new breakthrough in cloning from South Korea. Singer is famous, of course, for his logical consistency in realizing that if life is not sacred before birth, it is not sacred afterward either.

Most embryo research advocates are not so radically consistent, but the implications of their ethical reasoning are radical indeed. Even government advisory panels that have endorsed embryo research—such as the NIH Human Embryo Research Panel and the National Bioethics Advisory Commission (NBAC)—have been forced by the evidence to concede that the early human embryo is a "human life," because the evidence from embryology has only become more and more persuasive on that point. "What is clear," says one summary of recent findings published in *Nature*, "is that developmental biologists will no longer dismiss early mammalian embryos as featureless bundles of cells." These advisory bodies even concede that early human life deserves our "respect." Yet instead of concluding that experimental destruction of nascent life is thus off limits, they have used a cost-benefit analysis to argue that this respect is overridden by the health needs of born persons with devastating diseases.

When a member of the NIH Human Embryo Research Panel asked in 1994 whether the panel should really base its recommendations for federally funded embryo research on the principle that "the end justifies the means," the panel's chief ethicist, Professor Ronald Green of Dartmouth, quoted the godfather of situational ethics, Joseph Fletcher: "If the end doesn't justify the means, what does?" As a guide to its ethical approach, the NIH panel cited an article by Green arguing that there are no realities "out there" in human beings that require us to respect *anyone* as a person.

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It is the task of the educated and articulate members of society, he wrote, to decide which qualities in others are morally relevant, based on their own enlightened self-interest. If we deny "personhood" or moral worth to too many people, we may risk denying it to ourselves or others we care about; if we bestow it on too many people, we may deprive ourselves and other persons of the benefits of harmful experimentation on those people.

By this reasoning, if respecting a particular kind of human subject would prevent us from pursuing especially promising research, this is sufficient reason for refusing to respect that individual as a person. This approach turns the Nuremberg Code upside down: The dignity of a human subject will never stop researchers from doing research they think is extremely promising, because the promise of the research justifies defining those subjects out of the community of persons so we can make use of them.

And what seems to happen over and over again is that the drive for results—for Nobel Prizes and miracle cures—tends to swallow up all countervailing values and erode all limits, as it did in South Korea. Even NBAC conceded in 1999 that "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." But NBAC and its allies ignored the evidence available even then that such "alternatives" might exist; and as stem cells from adult tissues and umbilical cord blood have saved thousands of lives and begun to treat dozens of conditions, they have only become more hardened against giving due attention to this progress.

In short, once one has used the unique medical promise of a certain approach to justify acts that everyone agrees *would otherwise be unethical*, one has a vested interest in resisting any evidence that may rebut that claim of unique promise.

Even the South Korean researchers' willingness to deceive the public about their results is justifiable in principle under the new ethic. The utilitarian calculus relativizes not only life, but truth as well. The same *California Medicine* editorial that hailed the new ethic in 1970 observed that because the "old ethic" treating human life as inviolable had not yet been completely displaced, it was necessary (and therefore, of course, acceptable) to resort to "subterfuge":

Since the old ethic has not yet been fully displaced it has been necessary to separate the idea of abortion from the idea of killing, which continues to be socially abhorrent. The result has been a curious avoidance of the scientific fact, which everybody knows, that human life

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begins at conception and is continuous whether intra- or extra-uterine until death. The very considerable semantic gymnastics which are required to rationalize abortion as anything but the taking of a human life would be ludicrous if they were not often put forth under socially impeccable auspices. It is suggested that this schizophrenic sort of subterfuge is necessary because while a new ethic is being accepted the old one has not yet been rejected.

Cloning advocates have brushed aside moral concerns about human life, and ignored the indignity of creating new lives just to destroy them. Even if human embryos are "lives" in a biological sense, we are told, they do not have the value of persons—and they must be sacrificed to help born patients who really matter. Ironically, born patients (and adult women, exploited for their eggs) have joined embryos in being victimized by this agenda. In any case, we should not be surprised when an ethic that dismisses "Thou shalt not kill" in the quest for cures applies the same calculus to "Thou shalt not bear false witness." If the embryo's "merely biological" life can be trampled to benefit more valuable lives, "merely factual" truth can be sacrificed for the higher truth of Progress.

While the Hwang scandal itself does not undermine the foundations of science, this ethic—an ethic unfortunately tempting to researchers in this country as well—*does* threaten to undermine those foundations. For science is nothing without an absolute commitment to the facts.

By demeaning life, we learn to demean truth, rendering science itself meaningless. If American ESC researchers have not learned this important lesson, a sound ethical response must come from the broader society and its policymakers. That response should begin with a complete ban on human cloning, and with legislation to prevent the mistreatment of women as egg factories for research or as surrogate incubators for unborn children being grown for their body parts. Only by respecting fellow human beings of every age and condition, and by refusing to treat them as mere instruments for achieving our research goals, will we promote a human progress worthy of the name.

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