

"As to diseases ,make a habit of two things — to help, or at least *do no harm*." — Hippocrates, *The Epidemics* —

THE REAL LESSON OF THE KOREAN CLONING SCANDAL

While details of the Korean cloning scandal involving disgraced scientist Hwang Woosuk continue to unfold, there is no doubt regarding the central fraud he perpetrated – surely to be ranked among the great scandals in the annals of scientific research.

With the fraud now undeniable, proponents of human cloning research have been everywhere – in print, online, on cable and via the airwaves – to teach us all what lessons we are to draw from the cloning scandal. However, the real lessons to be drawn from this scandal are precisely the opposite of those offered by cloning advocates.

Recall that up to the time the scandal broke in November, 2005, human cloning advocates had for years been promising any number of miraculous cures for any number of diseases. In their view, the only thing preventing researchers from reaching this promised land of medical miracles was the opposition offered by a benighted but vocal minority – mostly composed of religious zealots – who oppose human cloning and the destruction of any human life in the name of research. The miracle cures were in sight, just around the corner, waiting to be discovered – if only these people would get out of the way and allow cloning researchers to do their work, ideally with taxpayers footing the bill.

For a long time, however, there was little hard empirical evidence to support the hype used to promote human cloning for research.

That all seemed to change in early 2004, when Seoul National University researcher Hwang Woo-suk announced – in the pages of *Science*, one of the world's most prestigious scientific journals – that he had succeeded in creating a human embryo by cloning and extracting a viable embryonic stem cell line from it. While the number of human eggs he required to achieve this breakthrough remained a real obstacle, here at last was real evidence (it seemed) that so-called "therapeutic" cloning might be feasible.

Even more dramatic was Hwang's announcement just over a year later, in May 2005 (again in *Science*), that he had created eleven stem cell lines from embryos cloned from different patients with different diseases. Hwang reported a vastly improved efficiency rate in creating these 11 lines, meaning far fewer eggs were required to make each clone.

Immediately, in the field of cloning and regenerative medicine, Hwang was at the center of world attention. He was lionized at home and in the West, by the media and by fellow scientists.

But things began to unravel in November 2005, with charges by U.S. scientist and collaborator Gerald Schatten that Hwang may have unethically obtained the eggs used in the

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PH: 202-347-6840 Fax: 202-347-6849 www.stemcellresearch.org research. These initial charges of ethical violations were soon overtaken by evidence of outright fraud, and by year's end the scientific community had to conclude that Hwang had lied – he could provide no stem cell lines from cloning, and he fabricated data to cover up his failure. Most disturbing, Hwang's team had paid many women for their eggs, and even induced junior researchers on the team to provide eggs to advance their careers. Many of the women thus exploited suffered serious side effects from the drugs used on them to achieve hyperovulation. And the numbers of eggs obtained were many hundreds more than Hwang initially claimed.

Now cloning advocates are back to where they were before Hwang perpetrated his hoax -- they still have a lot of hype, but very little hard evidence that human cloning is the future of regenerative medicine.

Having come full circle, what lessons are we to draw from this whole sorry business? Perhaps that we should slow down and be more cautious in rushing to pursue such an ethically controversial line of research? After all, Hwang's team labored for several years, obtained thousands of eggs at the expense of serious heath risks to the women "donors" --- and failed to develop even one stem cell line. Perhaps advocates should tone down the hype, and be a bit more skeptical about human cloning ushering in a new age of medicine?

Of course not! The lesson to be learned from this debacle, cloning enthusiasts insist, is that now more than ever the debate over cloning should end, and the government should start funding this research as much and as soon as it can. Only in this way, they argue, can the research be regulated so a scandal like this never happens again. We should not let one instance of misbehavior discredit the whole field of human cloning for research.

This argument assumes, however, that Hwang was a rogue scientist, working totally unregulated on the fringes of his field.

In fact, Hwang was at the very center of his field. He was not one bad apple threatening to spoil the whole bunch – his now-discredited findings were the whole bunch, the only hard evidence of a future for human "therapeutic" cloning. That's why he was lionized by fellow scientists at home and abroad.

Hwang had the full backing, both rhetorical and financial, of his government and the Korean public. An institutional review board at Seoul National University was charged with guaranteeing the scientific and ethical integrity of his work. Long-established international guidelines clearly rejected the behavior that Hwang engaged in when collecting the eggs necessary to his research. His research was subject to the (supposed) strict scrutiny of other scientists during the peer review process at *Science*. In January 2005, a Korean law went into effect outlawing coercion and financial incentives to obtain women's eggs. The environment Hwang worked in bears more than a passing resemblance to the one cloning advocates want adopted here in the wake of the scandal: government funding, peer review, and outside regulation.

It didn't work.

While Hwang's behavior is shocking, it was not totally unforeseen. Skeptics of research cloning and embryonic stem cell research consistently warned that the sheer number of eggs needed to pursue this research would invite ethical lapses, by fueling the temptation to exploit women for their eggs. Those fears have been borne out and the skeptics proved right. Press reports suggest that even after the law banning payments and coercion to obtain eggs took effect, Hwang's team simply ignored it in their increasingly desperate effort to obtain eggs for their experiments.

While cloning advocates now profess shock at Hwang's ethical violations, claiming to see in them a clear case for government regulation – meaning, of course, government funding – of cloning, many seemed oddly indifferent when allegations of those violations first surfaced.

New Scientist reporter Peter Aldhous says that many scientists he contacted at the time -- prior to the separate revelations of data fraud -- agreed that Hwang's ethical violations in collecting eggs would not prevent them from working with him in the future, provided "they could be satisfied that acceptable standards would be met." The ethical violations involving exploitation of women don't "sound like a hanging offense," said University of Chicago law professor Richard Bernstein. Hwang "didn't fudge any scientific research."

Likewise, when it later revoked its choice of Hwang as "research leader of the year," *Scientific American* wrote that "even when [the ethical] charges were borne out, we respected that the ethics of accepted practice in this area of science were still somewhat murky, and we declined to judge him too quickly. However, scientific fraud is an unforgivable offense against the enterprise of research, and...completely invalidates the selection of Dr Hwang."

All this is very revealing of a certain mindset distressingly prevalent among advocates of research cloning. It was not for lack of government funding that Hwang was able to cross clear ethical boundaries, but rather a willingness to turn a semi-blind eye on ethical lapses, provided the desired results are produced. As long as his results were deemed true and helpful, the ethically unsavory means needed to achieve them – the exploitation of women, including female members of his own team – were deemed tolerable. Wrong, perhaps, but tolerable nonetheless. Certainly not sufficient to disqualify Hwang and others from continuing such research and producing such results.

Against this mindset, no amount of regulation could be enough. Peer review becomes meaning-less when the peers all agree to look the other way if ethical lapses are required for "progress." Hwang's case was not so much an aberration as the culmination of the methods used to promote this research generally. His fraudulent claims were different only in degree, not in kind, from the hype, exaggerations and distortions used to sell human research cloning and embryonic stem cell research.

The real lesson to be drawn from the Hwang scandal is that this avenue of research cloning, whose biggest "success" is now seen as a sham built on exploitation of women, should be abandoned for more realistically promising and ethically non-controversial research avenues such as adult and cord blood stem cells. No amount of guidelines and regulation can make an inherently unethical procedure such as human cloning into an ethical one. And no amount of good money thrown after bad will make false promises true.

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