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Revising the Korean Bioethics and Biosafety Act: Should researchers be prohibited from donating oocytes?*

John Michael McGuire**

Ⅰ. Introduction

In May 2006, after completing a five-month investigation into the now infamous stem cell research carried out by Hwang Woo-Suk and his colleagues, Korean prosecutors indicted Hwang on three charges: fraud, embezzlement, and violation of the Korean Bioethics and Biosafety Act (KBBA).[1] The last of these charges relates to allegations that Hwang paid money to procure oocytes for his research after the KBBA went into effect in January 2005. While the KBBA prohibits the commercial trade of gametes, it is alleged that Hwang spent approximately $4000 (US) to purchase oocytes from fertility clinics in 2005.[2]

Some will find it disturbing or at least surprising that Hwang's only punishable offence with respect to the KBBA is his purchase of oocytes for research purposes, for there is a lengthy list of serious grievances against Hwang's oocyte collection procedures. Indeed, the Korean National Bioethics Commission (KNBC) has found that 15 of the 119 women who donated oocytes for Hwang's research did so more than twice,[3] that at least one of them donated four times, that 20 percent of donors developed ovarian hyper-stimulation as a result of the procedures for collecting oocytes, that donors were not properly informed about the risks associated with the oocyte collection procedures, and that junior researches were among those who donated their oocytes.[4]

If one wonders why Hwang has not been indicted for any of these alleged offences, some of which are surely more serious than the violation of the KBBA for which he has been charged, the

* This work was supported by a research fund from Hanyang University (HY-2004-G).
** Division of International Studies, Hanyang University. 02-2220-2282, squiremcguire@gmail.com
1) An English translation of the KBBA is available at http://www.koreabioethics.net/5-2/7.doc
2) Wohn DH. Hwang faces charges of fraud, theft of cash. Joong-Ang Daily : 13 May 2006
3) The actual number may in fact be higher, as Korean prosecutors announced recently that the number of donors for Hwang's research was 136, not 119. Lee HS. More eggs used in Hwang's research than previously found. Korea Times : 15 May 2006
4) Ser MJ, Park SW. 2nd panel cites Hwang's team for ethical lapses. Joong-Ang Daily : 14 January 2006

answer is simply that the KBBA contains no prohibitions on such actions : it contains no restrictions on the number of times that a woman may donate oocytes, no clear requirements on what researchers must disclose to donors in order to obtain informed consent, and no prohibitions on the use of junior researchers as oocyte donors. Precisely because of these shortcomings, women's groups in Korea have called for stricter regulation of oocyte collection procedures, and both the KNBC and the Ministry of Health and Welfare have acknowledged the need for revisions to the KBBA.[5)]

Members of the KNBC met in early February 2006 to create stricter ethical guidelines governing oocyte donation procedures for somatic cell nuclear transfer(SCNT). However, the meeting produced no concrete results because the committee members were reportedly "doubtful of whether the technique [SCNT] should be allowed at all."[6)] Cho Han-Ik, the vice chairman of the KNBC, reportedly said that since Hwang's work on SCNT was fraudulent, questions were raised about whether it would be realistic to write detailed clauses on a research technique that did not exist.[7)] However, the fact that Hwang's research was fraudulent is no reason to believe that his research aims were unrealistic. Indeed, since researchers are already capable of deriving stem cells from human embryos[8)] and of producing human embryos through nuclear transfer,[9)] it seems highly likely that the technique that Hwang sought to develop will one day be realized. Since the technique is currently permitted under existing Korean law, neither the KNBC nor the Ministry of Health and Welfare should wait until the technique becomes a reality, either domestically or abroad, to establish ethical guidelines regulating its use. Moreover, despite the fraudulent and unethical research carried out by Hwang Woo-Suk, the Korean government has recently indicated that it will continue to support stem cell research. Thus, the time is ripe for eliminating the lacunas in the existing legislation to ensure that any future use of this technology in Korea is carried out in an ethically responsible manner.

Among the many questions that the KNBC and the Ministry of Health and Welfare will need to address are the following: How many times should an individual woman be allowed to donate oocytes? Exactly what information must researchers provide to donors in order to obtain their informed consent? What sort of physical or psychological screening process should be used for selecting donors? Aside from potential donors who may be ruled out for physical or psychological reasons, are there other groups—for example,

5) Kim CW. Public calls for stricter ova regulation. Korea Times : 12 January 2006
6) Kim JS, Wohn DH. Ethics group rethinks egg questions. Joong-Ang Daily : 3 February 2006
7) Kim JS, Wohn DH. 2006
8) The first successful attempt was in 1998. Thomson JA, Itskovitz-Eldor J, Shapiro SS, Waknitz MA, Swiergiel JJ, Marshall VS, Jones JM. Embryonic stem cell lines derived from human blastocysts. Science 1989; 282(5391) : 1145-1147
9) This was accomplished by a group of British researchers in 2005. Stojkovic M, Stojkovic P, Leary C, Hall VJ, Armstrong L, Herbert M, Nesbitt M, Lako M, Murdoch A. Derivation of a human blastocyst after heterologous nuclear transfer to donated oocytes. Reproductive Biomedicine Online 2005;11(2) : 226-31

family members of patients or researchers themselves—that should be prohibited from donating oocytes? In this paper I focus only this last question and, more specifically, on the question of whether researchers should be prohibited from donating oocytes for research in which they are involved. Let us approach this question by reviewing how it first came to light and why it was later neglected within the Korean scientific community and Korean society as a whole.

Ⅱ. Background : a missed opportunity for ethical debate

In February 2004 a research team headed by Hwang Woo-Suk published an article in *Science* claiming that they had successfully derived a human embryonic stem cell line from a cloned blastocyst.[10] The team alleged in their article that in carrying out this research they had used 242 oocytes donated by 16 volunteers and that the volunteers had received no financial compensation for their donations. However, shortly after the publication of that article, questions arose about whether the donations had been purely voluntary and whether proper procedures had been followed in obtaining informed consent from the donors. In an interview with a reporter from *Nature*, one female member of Hwang's research team, Koo Ja-Min, admitted that she and another co-worker in the same lab were among those who had donated oocytes for the research.[11] Koo later denied that she had donated oocytes, but the admission and subsequent denial left doubts in the minds of many and fuelled suspicions about the ethics of Hwang's procedures for collecting oocytes. Suspicions also grew that some of the oocyte donors had been paid for their donations, contrary to what was claimed in the 2004 publication.

Over the course of the next year and a half, religious and bioethical organizations in Korea made repeated requests for clarification concerning the ethical dimensions of Hwang's research. These requests, which were largely dismissed, failed to resolve the lingering doubts concerning the team's research ethics, and it is likely that the issue would have passed away silently had it not been for a surprising turn of events in November 2005. In that month, Gerald Schatten, one of the co-researchers on the second major publication of Hwang's research team in 2005,[12] suddenly announced that he would no longer work with Hwang because he had come to believe that Hwang had lied when he claimed that co-researchers had not donated eggs and that the donors had not been paid.[13] Following Schatten's surprising announcement, rumours and

10) Hwang WS, Ryu YJ, Park JH, et al. Evidence of a pluripotent human embryonic stem cell line derived from a cloned blastocyst. Science 2004 ; 303 : 1669-1674

11) Cyranoski D, Stem cell research: Crunch time for Korea's cloners. Nature 2004 ; 429 (6987) : 12-14

12) Hwang WS, Roh SI, Lee BC, et al. Patient-specific embryonic stem cells derived from SCNT blastocysts. Science 2005 ; 308 : 1777-1783

13) Weiss R. U.S. scientist leaves joint stem cell project. Washington Post ; 12 November 2005

speculation again spread, and within a few weeks, Hwang was forced to admit that two of the junior researchers on his team had indeed donated oocytes. It was also revealed at that time that some of the donors had been paid for their donations, contrary to what the team had claimed in their 2004 article.[14]

Following Hwang's confession, legitimate questions were raised about the nature and seriousness of Hwang's ethical breaches. Many of the initial reports in the local media that attempted to explain Hwang's ethical shortcomings pointed to the 1964 Helsinki Declaration. It was claimed, for example, that the declaration prohibits consent from a researcher's subordinates because of the possibility that the consent might be the result of coercion.[15] However, others, including the Korean Ministry of Health and Welfare, denied that there was any ethical wrongdoing on the part of Hwang's research team since the junior researchers who donated their eggs were neither coaxed nor coerced into doing so.[16]

Thus, in the days and weeks following Schatten's announcement and Hwang's admission, an important debate was beginning to emerge over the ethical propriety of accepting oocyte donations from junior researchers. However, the debate was quickly overshadowed by a larger and more insidious scandal surrounding Hwang and his research team. In December 2005, amid rumours that his landmark papers were based on fraudulent data, Seoul National University (SNU) launched an investigative committee to determine the legitimacy of the research that Hwang and his team had carried out at SNU. In January 2006, after conducting its investigation, the committee announced that Hwang's seemingly ground-breaking research was indeed fraudulent and that Hwang and his team had in fact never obtained stem cells from cloned human embryos. According to Chung Myung-hee, the head of the investigative committee, Hwang's research team possessed "neither the patient-specific embryonic stem cell line described in the 2005 publication, nor the No. 1 embryonic stem cell line, the forerunner cloned cell line described in the 2004 publication."[17]

The devastating announcement of the investigative committee at SNU set in motion an avalanche of unwelcome events for Hwang and his team of researchers. Immediately after that announcement the editors at *Science* retracted the team's 2004 and the 2005 publications. Within the next two months Hwang was ousted from the Korean Society for Molecular and Cellular Biology, stripped of his title of "top scientist," which would have given him $3 million annually in government research funds, and fired from SNU. In April, two of the woman who had donated oocytes for Hwang's research filed law suits against the government and the medical centres at which they

14) Kim TG. Hwang admits in-house donations. Korea Times ; 24 November 2005
15) Sanctity of human life : global ethical standards should be strictly observed. Korea Times ; 25 November 2005
16) Kim CW. Public calls for stricter ova regulation. Korea Times ; 12 January 2006
17) Kim TG. Hwang Faked Stem Cell Papers. Korea Times 10 January 2006

made their donations, claiming they had not been informed about the risks of the oocyte collection procedure.[18] Finally, the Seoul District Prosecutor's Office indicted Hwang on charges of fraud, embezzlement, and violation of the KBBA. If convicted, Hwang could face up to ten years in prison, but the fallout from the exposure of Hwang's fraudulent research is by no means limited only to Hwang and his co-researchers. The scandal surrounding Hwang's research will affect the Korean biotech industry and the stem cell research community for several years to come: investors are likely to stay away from biotech stocks, companies with unproven technologies will find it harder to access capital, and stem cell researchers in Korea will find it harder to publish in top journals as editors will demand greater scrutiny of papers from industrializing or developing countries.[19]

Given these serious developments for Hwang, his colleagues, the Korean biotech industry, the Korean scientific community, and the nascent field of stem cell research, it is understandable that the exposure of Hwang's fraudulent research would have overshadowed the ethical debate that had briefly emerged back in November 2005. However, now that the truth regarding Hwang's fraudulent research has been revealed and his research programs have been terminated, it is time to return to the ethical questions of 1) whether it was wrong for Hwang to have accepted oocyte donations from junior researchers and 2) whether researchers should be prohibited from donating oocytes for research in which they themselves are involved.

Ⅲ. Did Hwang Woo-Suk violate the Helsinki Declaration?

Public and official opinion is clearly divided on the question of whether Hwang acted unethically in accepting oocyte donations from junior researchers. Shortly before Hwang's public disclosure, one Korean lawmaker, Kim Hee-Jung, a member of the National Assembly's Science, Technology, Information and Telecommunications Committee, which overseas biotechnology in the country, claimed that the allegations that Hwang collected eggs from junior researchers, even if true, raise no legal or ethical concerns.[20] This view was also expressed by certain American law firms specializing in issues of genetic engineering: American law firms that were commissioned to review the case asserted that if the oocyte donation from the junior researchers were truly voluntary, no criminal or ethical violation occurred.[21] Immediately following Hwang's admission of the allegations, officials from the Ministry of Health and Welfare, reiterated this suggestion that the donations were not a violation of ethics guidelines "because they

18) KimTH, Misled egg donors sue for compensation. Korea Times ; 21 April 2006
19) Gottweis H, Triendl R. South Korean policy failure and the Hwang debacle. Nature Biotechnology 2006 ; 24(2) : 141-143
20) Kim TG, In-house donation not unethical. Korea Times ; 15 November 2005
21) Controversial oocyte donation "no breach of ethics." Chosun-Ilbo ; 17 November 2005

were made voluntarily."[22]

However, it has also been claimed Hwang did violate either ethical principals or international guidelines in soliciting and accepting donations from junior researchers. The following passage expresses what seems to be a fairly common view:

Under widely accepted international guidelines, scientists do not conduct research on human subjects who are in a dependent relationship with them, in order to avoid exploitation. While Hwang did not break any laws in using eggs from junior researchers on his tem, he clearly violated international standards.[23]

The international standards alluded to in this passage and others like it[24] are those contained in the Declaration of Helsinki, a document typically cited by those who admonish Hwang for using oocytes from junior researchers. That Hwang's actions violated the Helsinki Declaration is also the view of the National Bioethics Commission[25] as well as many others.[26] But is it really so clear that Hwang violated the Helsinki Declaration?

The only passage in the Helsinki Declaration that bears on this issue is Article 23, which reads as follows:

When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

Notice that Article 23, which is directed towards physicians, does not prohibit physicians from using junior researchers or other dependants as research subjects. The article merely advises physicians to be cautious in how they go about obtaining informed consent from such persons. As such, Article 23 clearly permits physicians to use junior researchers as subjects. It is therefore clear that in procuring oocytes from junior researchers, Hwang did not violate the Helsinki Declaration.

If Hwang Woo-Suk violated Article 23 of the Helsinki Declaration, it could only have been for failing to exercise caution in obtaining informed consent from the junior researchers that donated oocytes. But what does it mean to "exercise caution" in this context? The answer is clearly given by the recommendation contained in the second sentence of the article, namely, that physicians should obtain informed consent from junior researchers through a third party, a qualified person who is independent of the proposed research. It seems in fact that Hwang did not do this. Indeed, Hwang has admitted to

22) Kim CW. Hwang's team in ethical minefield over ova : panel. Korea Times : 2 February 2006
23) Galpern E, Darnovsky M. Eggs vs. ethics in stem cell debate. The Nation (online) : http://www.thenation.com/doc/20051212/galpern.
24) Cyranoski, D. Stem-cell research: crunch time for Korea's cloners. Nature 2004 ; 429(6987) : 12-14
25) Kim CW. Hwang's team in ethical minefield over ova: panel. Korea Times ; 2 February 2006
26) See, for example, south Korean controversy. BBC (on-line) : http://www.bbc.co.uk/religion/ethics/human_cloning/latest/latest_hwang.shtml.

handing the informed consent forms directly to the junior researchers who donated oocytes for his research. Assuming that informed consent was obtained at all, it seems likely that Hwang obtained the informed consent directly, rather than through a third party, as the Helsinki Declaration recommends.

We may conclude, then, that if Hwang violated the Helsinki Declaration, his violation had nothing to do with the fact that he procured oocytes from his junior researchers, but relates rather to the manner in which he obtained informed consent from the junior researchers. This point is of some importance, since a great deal of the public controversy surrounding Hwang's ethical breaches seems to be focussed on the fact that junior researchers donated oocytes rather than on the manner in which informed consent was obtained from the donors.

However, there are at least two reasons why it is not entirely clear that Hwang violated Article 23 of the Helsinki Declaration even in this more limited sense. In the first place, Article 23 states that investigators should be particularly cautious when obtaining informed consent from research "subjects" who are in positions of dependency with respect to the principal investigators. However, the junior researchers from whom Hwang procured oocytes were not in fact research subjects at all; the research subjects in Hwang's project were the oocytes that those researchers donated. As such, the research subjects in this case were not in any position of dependency relative to the investigators; nor were they in any position to give or withhold consent. The point here is more than a mere technicality. There is, as Magnus and Cho point out, a very real need to distinguish between "research subjects" and what they call "research donors." They argue for this distinction precisely by showing how the standard model for research subjects is inappropriate for women who donate oocytes for stem cell research.[27] Article 23 of the Helsinki Declaration is clearly intended to apply to research subjects in the standard sense of the term. If Magnus and Cho are correct in claiming that the standard model of research subject does not apply to women who donate oocytes for stem cell research, then it is not at all clear whether or to what extent Hwang Woo-Suk violated Article 23 of the Helsinki Declaration in failing to obtain informed consent from junior researchers through a third party.

Secondly, Article 23 of the Helsinki Declaration is worded specifically for physicians. It offers guidelines for physicians to follow in obtaining informed consent from research subjects in positions of dependency. And the Helsinki Declaration is a policy document put forth by the World Medical Association (WMA). However, since Hwang Woo-Suk is neither a physician nor a member of the WMA, it is questionable whether he is bound by the Declaration and, hence, whether he can be accused of violating Article 23 of the declaration.

Is all research in the life sciences necessarily

27) Magnus D, Cho MK. Issues in oocyte donation for stem cell research. Science 2005 308(5729) : 1747-1748

subject to the requirements of the Helsinki Declaration? If so, in virtue of what is this case? A recent survey of Korean biotech researchers sheds some light on this question. In November 2005, SciOn, a science survey group affiliated with the Biological Research Information Center (BRIC) of POSTECH, polled 960 scientists involved in research in the biotechnology sector in Korean universities, government-affiliated research centers, hospitals and venture firms. The survey showed eight out of ten Korean biotechnology researchers are not even aware of the requirements of the Helsinki Declaration; indeed 46 percent had apparently never even heard of the Helsinki Declaration.[28] If eight out of ten biotech researchers in Korea are unaware of the requirements of the Helsinki Declaration, then it is clearly not the case that Korean researchers in the life sciences have in any meaningful sense embraced or agreed to follow the Helsinki Declaration. On what basis, then, can one say that research in the life sciences in Korea is subject to the requirements of the Helsinki Declaration? In the absence of any clear answer to that question, it is senseless to blame Hwang Woo-Suk for failing to act in accordance with Article 23 of that declaration.

Ⅳ. Should the KBBA prohibit donations from researchers?

Regardless of whether or not Hwang Woo-Suk violated Article 23 of the Helsinki Declaration, there remains the forward-looking question of whether the KBBA should be revised to include provisions of the sort articulated in Article 23. Should the KBBA be revised explicitly to prohibit the sort of donations made by Hwang's junior researchers. There are, in fact, two related questions that need to be disentangled here. The first is whether the KBBA should be revised merely to include guidelines on obtaining informed consent when dealing with junior researchers or, alternatively, whether it should be revised to include a much stronger regulation, one that prohibits oocyte donations from researchers? The second question is whether, if such donations should be prohibited, the prohibition should apply only to junior researchers or to all female researchers on a given research team? Let us consider both of these questions, beginning with the latter.

While the KNBC is currently considering implementing a prohibition on donations by junior researchers, some believe that the ban should apply to all researchers, co-workers, and even relatives of the research staff. For example, in a statement to a US Congressional Subcommittee that was convened in response to the Hwang Woo-Suk scandal, Judy Norsigian, Director of Our Bodies Ourselves, outlined a set of guidelines that she believes should be implemented if stem cell research goes forward. Among the various guidelines that she listed was the following: No relatives or co-workers of those doing research on

28) Study Shows Bioethics Awareness Lacking. Donga-Ilbo : 25 November 2008

eggs should be allowed to provide eggs for research.[29]

In order to decide between these two types of prohibition, one needs to be clear about the rationale for having a prohibition on oocyte donation from researchers at all. Some bioethicists argue that donors and researchers should be kept at arms length so that principal investigators cannot influence donors, either directly or inadvertently.[30] If this is the principal concern, then it would seem that a stronger prohibition of the sort that Norsigian advocates is justified since any female relative or co-worker of a stem cell researcher could be influenced, even if inadvertently, by members of a research team. But is it not excessively paternalistic to prohibit women from donating oocytes simply because they might be intentionally or inadvertently "influenced" by members of a research team? Surely most women who might be influenced by members of a research team would still be capable of exercising their own autonomy and making their own decisions about whether or not to donate oocytes.

There is indeed an important distinction between influence and coercion. While it is easy to see why women who might be coerced by members of a research team need to be protected, it is far less obvious that women who might merely be influenced need such protection. A paternalistic prohibition on oocyte donation seems far more justifiable in the case of junior researchers or co-workers, women who are in vulnerable positions with respect to other members of the research team. Moreover, the reasoning that supports a prohibition on any female researcher donating oocytes leads to intolerable extremes. Indeed, why should the prohibition be restricted only to relatives and co-workers when even acquaintances of members of the research team might be influenced? If women who might be influenced by researchers need protection, should not every woman who has ever come into contact with a researcher be prohibited from donating oocytes? Furthermore, the rationale for prohibiting all female researchers from donating oocytes would seem to lead to the conclusion that researchers should also be prohibited from advertising in order to recruit oocyte donors since advertising too is clearly a form of influence. But if researchers can neither advertise nor accept donations from women they are acquainted with, then it is difficult to see how researchers could possibly recruit donors. Indeed, such prohibitions would effectively undermine this sort of research.

Let us assume, then, that if researchers are to be prohibited from donating oocytes, the prohibitions should be restricted to those female members of the research team that are in subordinate positions or positions of vulnerability with respect to principal investigators. And let us

29) Statement by Judy Norsigian to the Subcommittee on Criminal Justice, Drug Policy and Human Resources of the Government Reform Committee, the U.S. House of Representatives. Hearing on Human Cloning and Embryonic Stem Cell Research after Seoul: Examining Exploitation, Fraud, and Ethical Problems in the Research. 7 March 2006

30) Cyranoski D. 2004 : 13

now ask the more fundamental question of whether such prohibitions should be implemented at all.

The principal reason for advocating such a prohibition, as we have noted, is to protect those women who are in positions of vulnerability. It is recognized that such prohibitions are paternalistic in nature but such paternalistic practices may be justified insofar as they prevent the greater evil of vulnerable women being exploited for oocytes. Are there any reasons for opposing the prohibition on oocyte donations from junior researchers?

It should noted, in the first place, that a prohibition on oocyte donations by junior researchers goes beyond anything explicitly mentioned in either the Helsinki Declaration or the stem cell research guidelines recently set forth by the National Academy of Sciences in the US.[31] As noted above, Article 23 of the Helsinki Declaration may not relate specifically to oocyte donors since it concerns informed consent procedures for research subjects in vulnerable positions and oocyte donors seem not to fit the model of "research subjects." However, Article 23 does provide clues for how one might deal with those who belong to the category of "research donors." The suggestion, implicit in Article 23 is not that women in vulnerable positions should be prohibited from donating oocytes, but rather that women in such positions who wish to donate oocytes must give their informed consent through a third-party, someone who is knowledgeable of the research in question, but independent of the researchers involved in this project.

While this proposal seems to be a reasonable way of balancing the concerns for the protection of vulnerable women with the concern of excessive paternalism, one might wonder whether, in the context of Korean culture, the proposal would provide sufficient protection for junior researchers. There is clearly a good deal of cultural relativity with respect to the concept of informed consent, and bioethicists have noted that the concept is generally accorded less importance in countries in East Asia than in most western countries.[32] It is possible that in a culture in which informed consent is not taken very seriously, the requirement that informed consent for oocyte donations by junior researchers be obtained through a third party might do little to reduce the possibilities for coercion. For example, if Hwang Woo-Suk had been required by law to obtain informed consent from his junior researchers through a third party it seems that it would have been easy for him to do so and that the requirement would hardly have reduced the chances of junior researchers being coerced. Thus, if the principal objective is to prevent women from being coerced into donating oocytes, then in the context of Korean culture there may be reason to advocate a total prohibition on oocytes donations from junior researchers.

However, it should also be noted that such a prohibition is not only stronger than anything

31) Guidelines for Human Embryonic Stem Cell Research. Washington, DC : National Academies Press, 2004

32) Corrigan O, Liddell K, McMillan J, Stewart A, Wallace S. Ethical, legal, and social issues in stem cell research and therapy : A briefing paper from Cambridge Genetics Knowledge Park. Cambridge Genetic Knowledge Park, 2006

contained in the international ethical guidelines mentioned above, it is also seems to be out of step with Korean public opinion as well. In November 2005, as the ethical scandal surrounding Hwang's work was beginning to emerge, the Korea Times conducted an online poll to determine how Koreans felt about the possibility that Hwang used donations from junior researchers. Of the 1,546 people who responded, 1042 or approximately 67 percent said that they would continue to support his research even if he had used donations from junior researchers; only 33 percent of respondents felt that the donations by junior researchers was ethically problematic.[33]

One should not conclude that because a majority of Koreans may be indifferent to the ethical issues involved in oocyte donations by junior researchers that a prohibition on such donations is unjustified in Korea. Ethical principles are not, and should not be, determined simply by public opinion. At the same time, it would be a grave mistake to ignore public opinion. Korea's abortion laws provide an excellent example of the futility of enacting strict laws, however well justified on moral grounds, that are out of step with public opinion. While abortion is technically illegal in Korea, the abortion law is widely regarded as a dead law, since the nation's abortion rate has been astonishingly high despite the existence of the law. According to a National Fertility and Family Health Survey of 7010 married women aged 15 to 44, in 1985, 53 percent of married women had had an abortion.[34] That the abortion law is so ineffective in prohibiting or even deterring abortion is surely related to the fact that the law is out of step with public opinion. For example, a national survey of Korean women conducted in 1971 found that 81 percent of women had a strong preference for legalizing abortion.[35] Thus, if abortion practices in Korea provide any indication of what happens to ethics laws that are at odds with public opinion, there is reason to wonder whether a total prohibition on oocyte donations by junior researchers would be effective in preventing such donations.

Ⅴ. Conclusion

Recent public investigations into the human embryonic stem cell research of Hwang Woo-Suk and his colleagues have brought to light a plethora of ethical problems associated with that research as well as numerous deficiencies in the existing legislation designed to prevent such problems, the KBBA. In this paper I have focussed on only one of those ethical problems: the issue of oocyte donations by Hwang's junior researchers. I have attempted to answer the following two questions concerning those donations: 1) Did Hwang violate ethical guidelines in accepting oocyte donations from junior researchers? 2) Should the KBBA be revised to prohibit oocyte donations from junior researchers?

33) Kim CW, Citizens polarized. Korea Times : 24 November 2005
34) Lim JK, A review of induced abortion [in Korean]. Ingu Pogon Nonjip 1988; 8(2) : 57-95
35) Abortion Policies: A Gobal Review. New York: UN Population Division 2002

With respect to the first question, it is widely assumed that in accepting oocyte donations from junior researchers, Hwang violated the Helsinki Declaration, an international code of ethics concerning research in the life sciences. However, this is incorrect: Hwang did not violate the Helsinki Declaration in accepting oocytes from junior researchers. He may have violated Article 23 of the Helsinki Declaration for the manner in which he obtained informed consent from his junior researchers, but even this is not clear, given that Article 23 relates to research subjects, while the junior researchers that donated oocytes for Hwang's project were not research subjects but rather research donors. Moreover, given that the Helsinki Declaration, a policy statement put forward by the WMA to which Hwang does not belong, is neither enforced nor even recognized by the majority of biotech researchers in Korea, the declaration is of questionable significance for evaluating the ethical shortcomings of Hwang's work.

Concerning the second question, there are in fact two separate issues that need to be distinguished. One is whether stem cell researchers should be prohibited from donating oocytes for research projects in which they themselves are involved; the other is whether such prohibitions should apply to all female researchers or only to those in positions of dependency with respect to principal investigators. I have argued that a prohibition on donations from all female researchers would be overly paternalistic and that the rationale for such a prohibition would lead to excessive restrictions on oocyte donations that would ultimately obstruct stem cell research. With respect to the other question, I have argued that there is indeed a legitimate reason for revising the KBBA to prohibit oocyte donations from junior researchers, namely, to protect women in positions of vulnerability from being exploited as oocyte donors. While such a prohibition is paternalistic, the paternalism is justified in these cases in order to prevent the greater evil of exploitation. However, it should be acknowledged that there currently is insufficient public support in Korea for a prohibition of this sort and that without significant public support the prohibition may be ineffective in preventing the exploitation of oocyte donors. ME

Revising the Korean Bioethics and Biosafety Act: Should researchers be prohibited from donating oocytes?

John Michael McGuire*

Recent public investigations into the human embryonic stem cell research of Hwang Woo-Suk and his colleagues have brought to light a plethora of ethical problems associated with that research as well as numerous deficiencies in the existing legislation designed to prevent such problems, the Korean Bioethics and Biosafety Act (KBBA). In response to these revelations, the Korean National Bioethics Commission and the Korean Ministry of Health and Welfare are currently in the process of revising the KBBA to ensure that future stem cell research in Korea is carried out in an ethically responsible manner. In this paper I focus on one of the ethical problems raised by Hwang's research: the issue of oocyte donations by junior researchers. I address the following two questions: 1) Did Hwang violate ethical guidelines in accepting oocyte donations from junior researchers? 2) Should the KBBA be revised to prohibit oocyte donations from junior researchers? With respect to the first question, I argue that, contrary to popular opinion, Hwang did not violate the Helsinki Declaration in accepting oocytes donations from junior researchers. In response to the second question, I argue that the KBBA should indeed be revised to prohibit junior researchers from donating oocytes for research in which they themselves are involved.

key words : Korean Bioethics and Biosafety Act, Hwang Woo-Suk, Oocyte donors, Informed consent, The Helsinki Declaration

* *Division of International Studies, Hanyang University.*