HUMAN CLONING AND EMBRYONIC STEM CELL RESEARCH AFTER SEOUL; EXAMINATION EXPLOITATION, FRAUD AND ETHICAL PROBLEMS IN THE RESEARCH

HEARING

BEFORE THE
SUBCOMMITTEE ON CRIMINAL JUSTICE,
DRUG POLICY, AND HUMAN RESOURCES
OF THE
COMMITTEE ON
GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES
ONE HUNDRED NINTH CONGRESS
SECOND SESSION

MARCH 7, 2006

Serial No. 109–169

Printed for the use of the Committee on Government Reform

http://www.house.gov/reform

U.S. GOVERNMENT PRINTING OFFICE

WASHINGTON : 2006
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HUMAN CLONING AND EMBRYONIC STEM CELL RESEARCH AFTER SEOUL; EXAMINATION EXPLOITATION, FRAUD AND ETHICAL PROBLEMS IN THE RESEARCH

TUESDAY, MARCH 7, 2006

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY,
AND HUMAN RESOURCES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:05 p.m., in room 2247, Rayburn House Office Building, Hon. Mark E. Souder (chairman of the subcommittee) presiding.


Staff present: Marc Wheat, staff director and chief counsel; Michelle Gress, counsel; Malia Holst, clerk; Sarah Despres, Tony Haywood, and Naomi Seiler, minority counsels; Earley Green, minority chief clerk; and Teresa Coufal, minority assistant clerk.

Mr. SOUDER. The committee will come to order.

Good afternoon, and I thank you all for being here. We are here to examine the controversial research areas of human cloning and embryonic stem cell research in light of the massive scientific scandal in Seoul, South Korea. The scandal revealed that cloning research widely acclaimed by proponents of human cloning and embryonic stem cell research was a fraud. The scandal also brought to light the disturbing fact that women were paid large sums of money, and female assistants were coerced to donate, if that is the word, their eggs for stem cell and cloning research in violation of the Helsinki agreement.

Embryonic stem cell research and human cloning have been intense political and societal issues for several years now. Embryonic stem cell research requires the destruction of living human embryos to harvest their stem cells, and research cloning involves the deliberate creation of cloned human embryos for sole purpose of destroying them to obtain their stem cells.

Proponents of these research areas promise they will result in therapies and cures for a range of maladies and diseases, although there has been little hard, empirical evidence to support these claims. In fact, there are currently no human clinical trials or therapeutic applications using human embryonic stem cells.

And here I will quote British stem cell expert Professor Lord Winston. “One of the problems is that in order to persuade the pub-
lic that we must do this work, we often go rather too far in promising what we might achieve. 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 contrast to the lack of any therapeutic applications using embryonic stem cells, adult stem cells have provided therapeutic benefits to human patients for at least 67 diseases and conditions. Nonetheless, even in the absence of therapeutic applications for embryonic stem cells, scientists have been very clear that they seek to use stem cells from cloned human embryos as research tools.

Various critics of research cloning and embryonic stem cell research have raised a myriad of objections to the research: The research necessarily requires the destruction of living human embryos, and in the case of cloning, the special creation of embryos to be destroyed for their stem cells. The research necessarily requires a large number of eggs, likely leading to the exploitation of women in order to obtain their eggs for research. Advocates of research cloning/embryonic stem cell research have created unjustified hype of the research that is not supported by current science, but plays on the hopes of suffering patients.

These criticisms were borne out through the cloning research conducted by Dr. Hwang, whose two groundbreaking papers were retracted in January by the peer review journal that initially published them. In addition to admitting that he deliberately fabricated data, Hwang has also admitted the had lied about the circumstances under which he obtained eggs for his research, and that in fact he had used eggs from junior scientists in his laboratory, a violation of the Helsinki declaration, as well as from paid donors.

Skeptics of cloning and embryonic stem cell research consistently warned that the sheer volume of eggs needed to pursue this line of research would make it untenable, and virtually invite ethical lapses by feeling the temptation to exploit women for their eggs. Hwang’s research proves these fears. He initially claimed that he had used only 185 eggs from female donors, which the scientific community agreed was astonishingly low. But investigators now believe that more than 2,200 eggs were obtained from 199 women.

Some donors who have since reported they were in desperate need of money when they were offered and paid more than $1,400 for their eggs. And according to the South Korean National Bioethics Committee, the women had not been properly informed about the risks to their health; 15 to 20 percent of those women developed ovarian hyperstimulation syndrome.

This scientific scandal is not an isolated incident of fabrication, without real application to U.S. research efforts. Rather, it highlights the serious inherent political problems with research cloning and embryonic stem cell research, including but not limited to exploitation, fraud, and coercion. The incident is a siren warning against proceeding in these research areas without most cautiously examining the societal costs necessarily associated with it. It would be quite disingenuous to say otherwise.

Dr. Hwang was not a rogue scientist operating on the fringes of his field with no oversight. He operated in an environment that
proponents of cloning and embryonic stem cell research would like to see adopted in the United States.

Dr. Hwang enjoyed the full support of his Government, which vigorously promoted his research and funded it with tens of millions of dollars. Dr. Hwang also enjoyed enormous popular support and had agreed to conduct his research under accepted ethical protocols. Dr. Hwang suspended his research until ethics laws were enacted by the South Korean Government to demonstrate his willingness to comply with ethical standards. Dr. Hwang’s research was conducted with the approval of two separate Institutional Review Boards.

Nonetheless, Dr. Hwang’s actions represent the fulfillment of every warning dismissed by proponents of research cloning and embryonic stem cell research. Thousands of eggs were obtained through payments and coercion. Many women suffered terrible side effects after they were not properly informed of the risks. Not a single embryonic stem cell line was obtained for the tens of millions of dollars in Government funds that were invested in research. Anxious patients were misled about the research potential.

As stem cell researcher Ron McKay said about the hype involved with embryonic stem cell research and distortions that are not aggressively corrected by scientists, “To start with, people need a fairy tale. Maybe that’s unfair, but they need a storyline that’s relatively simple to understand.”

Our examination today will include an overview of current Federal policies related to these research areas. In particular, we will hear what if any extra protections exist in the United States that would prevent the type of widespread fraud or exploitation apparent in the Hwang research. Also of special interest to the subcommittee are the huge Federal grants that have been awarded to the University of Pittsburgh researcher Gerald Schatten, who was initially a co-author on one of Hwang’s fraudulent papers.

We will also hear from scientists, ethicists, women’s advocates, and a patient advocate discuss these research areas and the known problems associated with them.

On our first panel today, we have James Battey, Chair of the National Institutes of Health Stem Cell Task force, and Director of the National Institute on Deafness and Other Communication Disorders; Bernard Schwetz, Director of the Office for Human Research Protections; and Chris Pascal, Director of the Office of Research Integrity.

The second panel consists of Dr. Richard Chole, Lindberg professor and chairman, Department of Otolaryngology, Washington University School of Medicine, St. Louis; Judy Norsigian, executive director, Our Bodies Ourselves, co-author of the book, “Our Bodies, Ourselves”; Ms. Diane Beeson, professor emerita, Department of Sociology and Social Services, California State University, East Bay; Mr. Richard Doerflinger, deputy director of secretariat for pro-life activities of the U.S. Conference of Catholic Bishops; Ms. Debra Mathews, assistant director for Science Programs, the Phoebe R. Berman Bioethics Institute; and Mr. Joe Brown, Parkinson’s Action Network State coordinator of Texas.

[The prepared statement of Hon. Mark E. Souder follows:]
Opening Statement of Chairman Mark Souder

“Human Cloning and Embryonic Stem Cell Research after Seoul: Examining exploitation, fraud and ethical problems in the research”

March 7, 2006

Good afternoon, and thank you all for being here.

We are here to examine the controversial research areas of human cloning and embryonic stem cell research in light of the massive scientific scandal in Seoul, South Korea.

This scandal revealed that cloning research widely acclaimed by proponents of human cloning and embryonic stem cell research was a fraud. The scandal also brought to light the disturbing fact that women were paid large sums of money, and female assistants were coerced, to “donate,” if that is the word, their eggs for the stem cell and cloning research, in violation of the Helsinki agreement.1

Embryonic stem cell research and human cloning have been intense political and societal issues for several years now. Embryonic stem cell research requires the destruction of living human embryos to harvest their stem cells, and research cloning involves the deliberate creation of cloned human embryos for the sole purpose of destroying them to obtain their stem cells.

Proponents of these research areas promise they will result in therapies and cures for a range of maladies and diseases, although there has been little hard, empirical evidence to support these claims. In fact, there are currently no human clinical trials or therapeutic applications using human embryonic stem cells.

And here I will quote British stem cell expert Professor Lord Winston: “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… 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.”2

1 WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI: Ethical Principles for Medical Research Involving Human Subjects (Adopted by the World Medical Association General Assembly in June, 1964). One of its principles states, “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.” See http://www.thagan.com/agreement.html (last visited March 6, 2006).
In contrast to the lack of any therapeutic applications using embryonic stem cells, adult stem cells have provided therapeutic benefits to human patients for at least 67 diseases and conditions. Nonetheless, even in the absence of therapeutic applications for embryonic stem cells, scientists have been very clear that they seek to use stem cells from cloned human embryos as research tools.

Various critics of research cloning and embryonic stem cell research have raised a myriad of objections to the research:

- The research necessarily requires the destruction of living human embryos (and in the case of cloning, the special creation of embryos to be destroyed for their stem cells).
- The research necessarily requires a large number of eggs, likely leading to the exploitation of women in order to obtain their eggs for research.
- Advocates of research cloning/embryonic stem cell research have created unjustified “hype” of the research that is not supported by current science, but plays on the hopes of suffering patients.

These criticisms were borne out through the cloning research conducted by Dr. Hwang [pronounced wong], whose two groundbreaking papers were retracted in January by the peer-reviewed journal that initially published them. In addition to admitting that he deliberately fabricated data, Hwang has also admitted that he had lied about the circumstances under which he obtained eggs for his research, and that in fact he had used eggs from junior scientists in his laboratory - a violation of the Helsinki declaration - as well as from paid donors.

Skeptics of cloning and embryonic stem cell research consistently warned that the sheer volume of eggs needed to pursue this line of research would make it untenable, and virtually invite ethical lapses by fueling the temptation to exploit women for their eggs. Hwang’s research proves those fears. He initially claimed that he had used only 183 eggs from female donors, which the scientific community agreed was astonishingly low. But investigators now believe that more than 2,200 eggs were obtained from 119 women.

Some donors who have since reported they were in desperate need of money when they were offered and paid more than $1400 for their eggs. And according to the South Korean National Bioethics Committee, the women had not been properly informed about the risks to their health: 15-20 percent of those women developed ovarian hyperstimulation syndrome.

This scientific scandal is not an isolated incident of fabrication, without real application to U.S. research efforts. Rather, it highlights the serious, inherent potential problems with research cloning and embryonic stem cell research, including but not limited to: exploitation, fraud, and coercion. The incident is a stern warning against proceeding in these research areas without most cautiously examining the societal costs necessarily associated with it. It would be quite disingenuous to say otherwise.

Dr. Hwang was not a rogue scientist operating on the fringes of his field with no oversight. He operated in an environment that proponents of cloning and embryonic stem cell research would like to see adopted in the United States:
• Dr. Hwang enjoyed the full support of his government, which vigorously promoted his research and funded it with tens of millions of dollars.
• Dr. Hwang also enjoyed enormous popular support and he had agreed to conduct his research under accepted ethical protocols.
• Dr. Hwang suspended his research until ethics laws were enacted by the South Korean government to demonstrate his willing compliance with ethical standards.
• Dr. Hwang’s research was conducted with the approval of two separate Institutional Review Boards.

Nonetheless, Dr. Hwang’s actions represent the fulfillment of every warning dismissed by proponents of research cloning and embryonic stem cell research: thousands of eggs were obtained through payments and coercion; many women suffered terrible side-effects after they were not properly informed of the risks; not a single embryonic stem cell line was obtained for the tens of millions of dollars in government funds that were invested in the research; anxious patients were misled about the research potential.

As stem cell researcher Ron McKay said about the hype involved with embryonic stem cell research and distortions that are not aggressively corrected by scientists – quote – “To start with, people need a fairy tale. Maybe that’s unfair, but they need a story line that’s relatively simple to understand.”

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Potential U.S. Patient Populations for Stem Cell-Based Therapies (according to the National Academy of Sciences)²

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular disease</td>
<td>58 million</td>
</tr>
<tr>
<td>Autoimmune diseases</td>
<td>30 million</td>
</tr>
<tr>
<td>Diabetes</td>
<td>16 million</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>10 million</td>
</tr>
<tr>
<td>Cancers</td>
<td>8.2 million</td>
</tr>
<tr>
<td>Alzheimer’s disease</td>
<td>5.5 million</td>
</tr>
<tr>
<td>Parkinson’s disease</td>
<td>5.5 million</td>
</tr>
<tr>
<td>Burns (severe)</td>
<td>0.3 million</td>
</tr>
<tr>
<td>Spinal-cord injuries</td>
<td>0.25 million</td>
</tr>
<tr>
<td>Birth Defects</td>
<td>0.15 million</td>
</tr>
</tbody>
</table>

Total patient population = 133.9 million (10% = 13.4 million)

Assume cloning efficiency at 20%; Assume ES extraction=line establishment at 10%; assume conservatively obtaining 10 eggs per donor.

**NEEDED: AT LEAST 670 MILLION EGGS, DONATED BY AT LEAST 67 MILLION WOMEN.**
SOUTH KOREAN STEM CELL CONTroversY TIMELINE

2004

12 February

Hwang, with colleagues from Seoul National University, claims 30 cloned embryos with one being used to create a stem cell line. Announcement of 242 eggs from 16 volunteers. Published in Science (W. S. Hwang et al. Science 303, 1660-1674; 2004). This article was formally retracted by Science on January 11th, 2006. Read the abstract and the retraction notice.

May
First allegations of inappropriate collection of eggs used in study, as a result of investigations by Nature. Hwang denies, but announces self-imposed suspension of research until new South Korean law comes into effect in 2005.

The Korean Bioethics Association calls for Hwang to answer questions about egg sources and funding. (Note that this is 18 months before the Korean press makes claim of improperly obtained eggs by Hwang’s associate.)

Read the news reports in Nature: Korea’s stem-cell stars dogged by suspicion of ethical breach
Stem-cell research: Crunch time for Korea’s clones

2005

January
New South Korean bioethics law comes into effect, and Hwang’s research is the first to be approved by the South Korean government.

Chin Kyo Hun, a professor emeritus at Seoul National University, told the New York Times that, "The bioethics law had little to do with safeguarding bioethics but everything to do with giving Hwang a legal support."


View the South Korea Bioethics & Biosafety Act:

May
Announcement of the creation of 11 patient-specific embryonic stem cell lines. Published in Science (W. S. Hwang et al. Science 308, 1777-1783; 2005). This article was formally retracted by Science on January 11th, 2006.

Read the abstract and the retraction notice.

August
Announcement of first dog cloned, Snuppy. Published in Nature (Lee B. C. et al. Nature 436, 641; 2005). This research was the one aspect of Hwang’s work that was verified in the investigation by Seoul National University.

Read the abstract.

October
Announcement of World Stem Cell Hub, to be headed by Hwang, and involving such stem cell leaders as Gerald Schatten (Hwang’s collaborator on the now-retracted papers) and Ian Wilmut (cloned Dolly the sheep).

Announcement by The Korea Times.

10 November
Korean press reports first allege illegally traded ova by a member of Hwang’s lab. Gerald Schatten of the University of Pittsburgh and a co-author with Hwang tells Science that no ova were inappropriately obtained.

11 November
Schatten tells Science that he will no longer work with Hwang, and states that he has concerns over consent issues related to the 2004 landmark paper.

12 November
Schatten publicly and formally cuts all ties with Hwang and his lab.

Read report in Nature.

Science makes corrections to a table the 2005 paper after the authors request a change. The change is said to not affect the paper’s conclusions.
21 November
Hwang’s associate Sun Il Roh (co-author on 2004 paper) admits that 20 of the original
242 eggs were purchased. Roh also claims that Hwang was unaware of this.

“Korean Stem Cell Crisis Deepens”

22 November
A South Korean television network, MBC, airs a story that details suspicions of
inappropriate ova sources, including junior members of Hwang’s own lab. The main result
of this story is backlash at MBC for criticizing a national ‘hero’, and the station is forced to
apologize and loses much in the way of viewership and sponsors.

Story on the backlash.

24 November
Hwang admits to using ova from paid donors as well as members of his lab. He resigns
his official posts, but continues as researcher.

Hwang admits lies.
Resigns leadership.

30 November
The Internaton Society for Stem Cell Research (ISSCR) announced that it will launch an
‘International Embryonic Stem Cell Research Guidelines Task Force’. The guidelines will
be released at the ISSCR annual meeting in 2006.

Read ISSCR statement.

1 December
MBC raises new concerns by challenging the authenticity of Hwang’s patient-specific
stem cells. The station runs its own DNA tests and believes it has evidence to show that
the stem cells do not match their parent tissue.

On the same day, the South Korean IRB clears Hwang’s name by finding that the eggs
were donated appropriately and without coercion, and that the money given was for direct
expenses.

4 December
MBC apologizes for certain reporting tactics used in their November exposé.

Hwang contacts Science to alert of errors in the 2005 paper. Four pictures were used
redundantly, but Science concludes that the errors do not affect the paper’s conclusions.

5 December
University of Pittsburg officials open an inquiry into the 2005 paper.

11 December
Seoul National University (SNU) opens an investigation of Hwang’s research, as
requested by Hwang.

Statement by SNU.

Hwang enters the University Hospital for treatment for stress and exhaustion.

13 December
Schatten calls on Hwang to retract the 2005 paper on patient-specific stem cells.
Schatten claims to have new information leading to “substantial doubts” about the paper’s
accuracy. Ian Wilmut and 7 other scientists call on Hwang to allow them to independently
validate his results with a paternity-type test.

Schatten demands retraction.
15 December
Hwang’s associate Roh admits that the 2005 paper was a fabrication, and claims that Hwang told him that there were no cloned embryonic stem cells.

Scientific American removes Hwang as research leader of 2005.

Read Scientific American announcement.

16 December
Hwang and Schatten request retraction of 2005 paper. Science waits for letters from all co-authors before retraction can be made.

Hwang claims at press conference that the problems were “human errors”, but that the patient-specific cells were created.

23 December
Interim report of Seoul National University’s investigation indicates that large amounts of the 2005 paper data were fabricated. Only 2 lines led to the 2005 paper, and not 11 as claimed. The investigating panel says that this could only be the result of “deliberate fabrication.”

The investigation panel announces that there is no evidence to suggest the existence of any cloned patient-specific stem cells. The panel claims that the 2 remaining lines do not match patient DNA, but instead match DNA of embryos created by IVF – although it was unclear if these last 2 lines were fabricated by Hwang or by his collaborators.

The final report will be released in mid-January and will included the results of investigation of Hwang’s earlier achievements such as the first cloned human embryo and the first cloned dog.

SNU interim report. Hwang maintains that the 2 lines were indeed patient-specific, and offers the frozen lines for testing. He resigns as professor at Seoul National University.

29 December
Science confirms that the 2005 paper will be retracted, and awaits letters from all co-authors.
31 December
Hwang insists that he has proof that he did create cloned patient-specific stem cells, despite the report from the investigatory panel. Hwang claims that he can “replicate the process any time.”

Hwang claims that his cells were replaced with other, non-cloned cells by researchers at Mizmedi Hospital in Seoul. “If’s certain (stem cells) have been switched…under a detailed plan over quite a long period of time.”

Hwang has filed a complaint with South Korean prosecutors, but they will wait until the University investigation is complete before conducting their own inquiry.

Hwang claims switched cells.

2006

4 January
Korean news station MBC airs new program with specific accusations of Hwang coercing junior researchers.

Story.

10 January
Seoul National University releases final report in Hwang investigation, indicating that both the 2004 and 2005 papers regarding human embryonic stem cells were fabricated. The August, 2005 paper results regarding the first cloned dog stands was verified by DNA fingerprinting.

Summary of SNU final report.
Statement by President of SNU.

12 January
Science formally retracts both of Hwang’s stem cell papers (2004 and 2005) after being notified by all authors.

Read retraction letter.

17 January

The Raelians, a UFO-related cult, offer Hwang a job at their Clonaid science/cloning research laboratories.

News report.
Clonaid support for Hwang.
The article, “Timeline of a Controversy” was a valuable resource source for many parts of this site. It contains further reading as well.

9 February
Hwang Woo-suk and six other professors on his team for their involvement in fabricated stem cell research, a news report said on Thursday, February 9.

**More on Stem Cells**

The future of human embryonic stem cell research will certainly be altered by this series of events in South Korea. Many are now speculating on exactly how the changes will play out.

Where now for stem-cell cloners?

**To learn more about stem cells...**

**Government Reports**

Report by the National Institutes of Health.

**Reports by the President's Council on Bioethics:**

- Cloning.
- Stem Cells.
- Alternative sources to stem cells.

**Report by the National Bioethics Advisory Commission (NBAC):**

- Volume 1: Report and Recommendations of the NBAC (Sept 1999).
- Volume 2: Commissioned Papers (Jan 2000).
- Volume 3: Religious Perspectives (June 2000).

**Indiana University**

Report by the Indiana University School of Medicine Adult Stem Cell Task Force.

**US Legislative Measures on Stem Cells**

The US congress has considered multiple bills regarding measures to ban cloning, as well as measures to increase embryonic stem cells eligible for cloning. None of these have become law, but one is still under consideration, HR 810.

In addition, many states have passed legislation in the past 4 years both to ban and allow various types of stem cell research. Eight states have even allocated funding to support stem cell research, some including embryonic stem cells.

**International Stem Cell Developments**

Twenty-one countries now have legislation that is permissive toward embryonic stem cell research. These include:

- Australia
- Belgium
- Brazil
- China
- Finland

The Netherlands
Singapore
South Africa
South Korea
Spain
<table>
<thead>
<tr>
<th>Country</th>
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<tbody>
<tr>
<td>France</td>
<td>Sweden</td>
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<td>Canada</td>
<td>Switzerland</td>
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<td>Israel</td>
<td>Thailand</td>
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<td>Japan</td>
<td>The United Kingdom</td>
</tr>
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</table>

To see a map highlighting these countries, as well as links to read the various legislative measures, see mhibit. Several treaty proposals regarding a ban on human cloning have been introduced to the United Nations, the most recent in 2004. None have yet been accepted.
Research Opportunity for Adults with Insomnia

DuPont Clinical Research is currently offering a clinical research study of an investigational medication for insomnia in adults aged 18 and older. You may be able to participate if:

- You have trouble falling asleep or staying asleep
- You experience drowsiness or have trouble functioning during the day as a result of sleeplessness
- You have a regular bedtime that is between 8:00 pm and 1:00 am
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- Stroke
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Mr. SOUDER. I will now yield to the ranking member, Mr. Elijah Cummings, for his opening statement.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

Just yesterday a disgraced researcher, Dr. Hwang Woo Suk, admitted to prosecutors in South Korea that he had directed a subordinate at the World Stem Cell Hub to fabricate research results. This was the first admission by Dr. Hwang of his personal involvement in fabricating claims made by his research team in two landmark papers on embryonic stem cell research published in the journal Science.

An investigative team at Seoul National University already had determined that Hwang’s claims that he had developed 11 patient-specific stem cell lines were in fact false. Dr. Hwang also acknowledged that donated eggs used in the research were coerced from junior members of his research team, and that some donors had been paid large sums of money.

Throughout the investigation, however, Dr. Hwang acknowledged no personal involvement in the scientific fraud. The fraud, exploitation, and coercion for which Dr. Hwang has now admitted personal responsibility have earned him a resounding international rebuke, including from Seoul National University where he was employed.

We can only hope that Dr. Hwang’s humiliation will serve to deter other scientists who might contemplate seeking glory through reporting fraudulent research, exploiting employees, and coercing women to donate their eggs without informed consent.

In a sense, this case offers a measure of vindication to the broader scientific community, demonstrating that it is difficult at best to fool one’s peers for very long. Ultimately, the very nature of scientific research tends to ensure that the truth about claims of major scientific advances will surface.

In this very high profile case, questions have been raised as to whether the claims of Dr. Hwang’s teams should have been verified in advance by the publishing journal. In any case, it was mere months before questions about Dr. Hwang’s methods and results began to be called into question publicly. In fact, it is almost startling how quickly many of Dr. Hwang’s claims have been thoroughly debunked, including yesterday through his own admission of scientific fraud.

But the case of Dr. Hwang is no cause for celebration, even if opponents of embryonic stem cell research seem to have difficulty containing their glee. Opponents of the research have been eager to portray the Korean scandal as proof that not only is this field a research uniquely prone to ethical pitfalls, but that the research itself is inherently bogus, offering nothing more than false hope to patients.

Mr. Chairman, I join the mainstream of the United States and the international scientific community in drawing a different lesson and conclusion. This research, which will go forward with or without the U.S. funding and oversight, needs the oversight that the broader U.S. oversight would bring. Our own National Institutes of Health is, without question, the entity best equipped to ensure that embryonic stem cell research proceedings with scientific integrity and in a way that ensures that women who donate their eggs are
protected from coercion, exploitation, and undisclosed risk of adverse health effects.

In the absence of strong Federal leadership, several States, including California and Maryland, have taken steps toward adopting guidelines for conducting embryonic stem cell research. The National Academy of Sciences has adopted guidelines as well.

But accountability for U.S. research will come with substantial support for this research, and that support will also help to ensure that important lines of research that offer relatively less profit potential are pursued.

In closing, Mr. Chairman, it is important that we recognize that fraud and ethical misconduct are hardly unique to science, and that scientific fraud is not unique to embryonic stem cell research. Our goal therefore should not be to use this controversy as a justification to impede the search for important new knowledge that could yield therapies and cures for many major diseases. Rather, our objective should be to ensure that as research in this important field inevitably proceeds in and beyond the United States, it does so with the benefit of strict Federal guidelines and a rigorous oversight.

With that, Mr. Chairman, I thank our witnesses for appearing today, and I yield back.

[The prepared statement of Hon. Elijah E. Cummings follows:]
Representative Elijah E. Cummings, D-MD
Ranking Minority Member
Subcommittee on Criminal Justice, Drug Policy and Human Resources
Committee on Government Reform
U.S. House of Representatives
109th Congress

Hearing on “Human Cloning and Embryonic Stem Cell Research After Seoul: Examining Exploitation, Fraud and Ethical Problems in the Research”

March 7, 2006

Mr. Chairman,

Just yesterday, disgraced researcher Dr. Hwang Woo Suk (“WONG WOO SOOK”) admitted to prosecutors in South Korea that that he had directed a subordinate at the World Stem Cell Hub to fabricate research results.

This was the first admission by Dr. Hwang of his personal involvement in fabricating claims made by his research team in two landmark papers on embryonic stem cell research published in the journal *Science*.

An investigative team at Seoul National University already had determined that Hwang’s claims that he had developed eleven patient-specific stem cell lines were, in fact, false. Dr. Hwang also acknowledged that donated eggs used in the research were coerced from junior members of his research team and that some donors had been paid large sums of money. Throughout the investigation, however, Hwang acknowledged no personal involvement in scientific fraud.

The fraud, exploitation and coercion for which Hwang has now admitted personal responsibility have earned him resounding international rebuke, including from Seoul National University where he was employed. We can only hope that Dr. Hwang’s humiliation will serve to deter other scientists who might contemplate seeking glory through reporting fraudulent research, exploiting employees, and coercing women to donate their eggs without informed consent.

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Thank you, Mr. Chairman. I yield back my time.

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Mr. SOUDER. I would like to yield to the vice chairman of the committee, Mr. McHenry.

Mr. MCHENRY. Thank you, Mr. Chairman. Thank you so much for holding this hearing today.

Recent events in South Korea have brought to light and global attention has been brought to the issue of human cloning and embryonic stem cell research. A number of concerns have been raised surrounding this subject here and abroad, including the ethical dilemma of destroying life; fraudulent scientific procedures, as has been mentioned by Ranking Member Cummings, as well as exploitation of women. All these are very serious subject matters that we must address here today in this hearing.

As a part of this discussion, it is important to make the distinction between human embryonic stem cell research and adult stem cell research. Adult stem cells and the research derived from adult stem cells do not destroy human life, and do not take the essence of life from the host being; whereas in embryonic stem cell research, that is the case. Life is taken from that fertilized egg, and that life is destroyed.

Embryonic stem cell research is the purposeful creation of human embryos destined to be destroyed for scientific research, in this case, in the name of stem cell research. Adult stem cells have provided therapeutic benefits and cures to 67 diseases and conditions such as diabetes, damaged heart tissue, strokes, cancers, Parkinson's, and spinal cord injuries, among others. We need to focus in the successes of adult stem cell research, an ethical approach that provides cures and therapies, instead of focusing on this all-too-political, it seems, issue of embryonic stem cell research.

Beyond the fact that there are currently no clinical trials or therapeutic applications using embryonic stem cells, there are a number of complications due to this approach, such as immune rejections and the inability to obtain pure cultures. The fact that this process is so inefficient means an outrageous number of eggs will be required for this approach.

And I would like to hear from our panel today as to their estimates on how many eggs would be required to actually move forward with major cures and major therapies. Some have said that even for a disease that touches 17 million people or 20 million people, you would have to have roughly 850 million eggs harvested, which means if you had 10 women willing to donate their eggs, you would have to have about 85 million women in this country donate their eggs.

It is a staggering sum. And this also goes back to the other issue that is of major substance, and that is the exploitation of women, which has been brought to light with the controversy and the fraud perpetrated out of South Korea.

I would like to welcome our witnesses today. I thank you for taking the time to be here. And this issue today is not simply about South Korean research fraud. It is about the larger issue of stem cell research and what is an ethical, realistic, and moral approach that moves science forward while keeping to ethics in medicine and science.
Thank you all again for being here today. And again, Mr. Chairman, thank you so much for your hosting this meeting today.

[The prepared statement of Hon. Patrick T. McHenry follows:]
GR Subcommittee: “Human Cloning & Embryonic Stem Cell Research after Seoul:
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Statement of Congressman Patrick McHenry

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Mr. SOUDER. Thank you. I will now yield to the distinguished ranking member of the full Committee.

Would you yield to Ms. Norton?

Ms. NORTON. I yield to the ranking member.

Mr. WAXMAN. Well, I thank you both very much for this chance to make an opening statement.

We are going to hear testimony today about the ethical issues around embryonic stem cell research and therapeutic cloning. In particular, we will focus on the scandal in South Korea regarding fraudulent research and abuses of research subjects.

Many opponents of stem cell research would like to use the South Korean experience as a basis for banning embryonic stem cell research. The story of Dr. Hwang's fraudulent research in South Korea is shocking because we rely on scientists to discover the truth, not subvert it. We need to condemn the fraud, figure out what happened, and learn how we can keep it from happening again. And we need to make sure that this research is well-regulated and thoroughly scrutinized.

But banning future stem cell research would be a gross overreaction. Unfortunately, though the vast majority of researchers are honest, fraud sometimes occurs in scientific and medical research. In fact, among Members of Congress, while most are honest, there are some who are not.

In 1983, a cardiology researcher at Harvard was found to have fabricated much of his data. In 1996, it was revealed that reports of a re-implanted ectopic pregnancy by British physicians were fraudulent. And in 2002, it was discovered that a rising star physicist working on carbon-based semiconductors had fabricated most of the data.

The answer to these instances of fraudulent research was not to ban or deny funding for research on heart disease, ectopic pregnancy, and semiconductors. The right answer is to create and uphold high standards of oversight. When doubts emerge, disclosure, investigation, and corrections must happen swiftly and openly. That is the right response whether the fraud involves heart disease or stem cell research.

We are also going to hear questions raised today about the potential benefits to be gained from various types of stem cell research. Those who oppose embryonic stem cell research often claim that because we do not yet know what therapies it will yield, we should not allow it to proceed.

That is a flawed line of reasoning. If we followed this to its logical conclusion, it would mean that the Federal Government should only fund research into cures and therapies that we already know about. The argument also understates that we do know about embryonic stem cells.

Decades of research have established the potential that these cells hold for addressing serious illnesses such as Alzheimer's, Parkinson's, and even cancer. I say potential, not promise, because there are no promises in any form of research. But what scientists have already learned about stem cells indicates great potential, which is an argument for moving ahead.

Opponents of embryonic stem cell research claim that there is still much to learn from adult stem cells and therefore we should
focus our efforts there. It is true that adult stem cells may hold potential, and I fully support researching the possibilities of adult stem cells. But evidence tells us that the potential of adult stem cells may be limited because they are already more specialized than other types of stem cells. We should indeed move forward with research on adult stem cell lines, but this is no argument against pursuing study of other types of stem cells with even more potential.

The third issue we will discuss today is the safety of women who donate oocytes or eggs for stem cell research. Egg donation relates to a specific type of research called somatic cell nucleic transfer (SCNT). This technique involves removing the nucleus of an unfertilized egg and replacing it with the nucleus of an adult cell.

SCNT has two benefits compared to stem cell research on embryos from a fertility clinic. First, the possible outcome of this research is the production of tissues that are genetic match to the patient, reducing the risk of rejection such as that we have often seen with organ recipients.

Second, the technique holds great potential for studying genetic and other diseases because scientists could potentially develop cells using nuclei from people who have the disease. This would not generally be possible using embryos donated from fertility clinics because researchers cannot select the genes for such cells.

Witnesses today will discuss their concerns about the safety of the women who donate eggs for this research. Some of these concerns are legitimate. The drugs and techniques used are identical to those used by women undergoing fertility treatments, but they are not without risk. And I believe that we need to carefully examine research and monitor safety.

I also agree that we need to think carefully about how egg donors for research should be compensated. We must respect the contribution that these women make, and we must ensure that they participate voluntarily. As with any new field of research, the safety and ethics of human participants are paramount.

What we must not do, however, is become paralyzed into inaction. Stem cell research, including research using embryonic cells, may help cure diseases that cause untold suffering to millions of Americans and hundreds of millions more around the world. With strict scientific and ethical oversight, embryonic stem cell research, including SCNT, should be supported with Federal funds.

Thank you, Mr. Chairman.

[the prepared statement of Hon. Henry A. Waxman follows:]
Opening Statement of
Rep. Henry A. Waxman
Before the Subcommittee on Criminal Justice, Drug Policy, and
Human Resources
Hearing on Human Cloning and Embryonic Stem Cell Research
after Seoul: Examining exploitation, Fraud and Ethical Problems in
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The argument also understates what we do know about embryonic stem cells. Decades of research have established the potential that these cells hold for addressing serious illnesses such as Alzheimer's, Parkinson's, and cancer. I say "potential" – not "promise" – because there are no promises in any form of research. But what scientists have already learned about stem cells indicates great potential - the argument for moving ahead is not merely theoretical.

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Mr. SOUDER. Congresswoman Schmidt.

Ms. SCHMIDT. Thank you. Thank you, Chairman Souder, for holding this important hearing on the abuse in human cloning and embryonic stem cell research.

As a strong supporter of reasonable science, true women’s health, and the culture of life, this topic is very dear to my heart. I commend you, Chairman Souder, for bringing these panels of experts together to shed light on the dangerous practices that some researchers are willing to use to advance their agenda. They, with the help of the media, have unfairly raised the hopes of many Americans, who have been led to falsely believe that embryonic stem cell cures are possible in the near future.

While scientists were touting Hwang’s research as groundbreaking and necessary for the medical miracles around the corner, Hwang was actually falsifying data and possibly exploiting women for their eggs. How many of these promises were ill-founded?

While it now appears that no scientist has effectively created stem cell lines using cloned embryos, adult stem cell treatments march ahead showing great promise for numerous diseases. The facts have shown that cord blood stem cells and adult stem cells are making great advances in curing diseases today, while clinical trials in embryonic stem cells are still years away.

In the light of this fraud and abuse, and the fact that embryonic stem cell research is just not producing the results that were promised, I am proud to have co-sponsored H.R. 596, the Stem Cell Therapeutic and Research Act of 2005, or the cord blood bill, and H.R. 1359, the Cloning Prohibition Act.

Again, Mr. Chairman, I applaud your leadership on these issues, and I look forward to learning more about them to working with you for a rightful resolution.

Mr. SOUDER. Thank you.

Ms. Norton.

Ms. NORTON. Thank you very much, Mr. Chairman. I want to thank you for focusing the subcommittee on an unusually thorough-going example of the worst kind of scientific fraud because what we have in the Hwang—I hesitate to call it South Korean example because I would hate to think that is characteristic of the science of our friends in South Korea, but it is certainly an example the likes of which I don’t think anyone has ever seen before, a massive scientific fraud at every level, fraud that was so good, as it were, if you would forgive the use of the phrase, that even other scientific researchers around the world were fooled by it.

It is a kind of case study in what can happen when nobody is watching very closely, and when scientific research at the cutting edge goes totally and absolutely unregulated. It was very troublesome to see and to count the violations and to see that they ranged from what scientists were doing to violations of individual human rights acknowledged to be important and necessary to the world.

So I welcome laying this matter out in detail, although I must say I was fascinated with what my good friends on the other side focused on. I mean, you would have thought this was not the Congress of the United States that could do something about the issue that we are describing today.
I mean, we are not a television program. Any reasonably literate person or anybody who looks at television has been scandalized by what happened in South Korea. I am pleased we are focusing on this matter not because of any evidence I know of that anything close to it is happening here, but because I have no reason to believe that what happened in South Korea could not or would not happen here, at least to some degree. And I believe it is urgent to move this Congress and this subcommittee from what we cannot do anything about to what we can and must do something about.

This is a national issue, my friends. On a national scientific issue of this kind, the burden is on the Federal Government, first and foremost, to offer leadership and guidance. So if you are really concerned about South Korea, this is the time to focus on remedy, if ever there was.

This much is clear: We cannot legislate against science any more than we can legislate against the weather. But we can ourselves enact reasonable measures in order to make sure that Congress does not—that science does not march ahead in violation of every ethical measure that both science universally has accepted and that are a matter of documented international human rights.

Instead, very frankly, I must say that time after time, I see the Congress trying to stop science. I am embarrassed by the congressional approach to the march of science. It is as if we were still in the 19th century. Science is marching ahead, and it requires deeply analytical, very deep thinking about how to harness science when we know good and well it is marching.

And how do we know it is marching ahead? Well, next door you have heard my good colleague from Maryland talk about what is happening in that State. A Republican Governor, Governor Robert Ehrlich, has proposed spending $20 million on stem cell research in the coming year. That is happening all over the United States. The States are joining the advanced countries of the world, marching ahead to make use of embryonic cell research.

I can only hope that in the countries of our allies, the national legislatures have been more enlightened than to sit by and describe the problem, while parts of their countries march ahead and do whatever they want to do. We could affect how Maryland, how California, and how every other State in the United States goes about this work because we are the Federal Government.

I have every confidence that Mr. Cummings’ colleagues in Maryland are going to take up the slack and do the appropriate guidance. I don’t think there is a State in the Union that would allow this work to go forward without redoubling their efforts in every way to make sure that what happened in South Korea cannot happen here.

So I don’t need to add to the disagreement on the ban on embryonic research. You are not going to change peoples’ minds on that. You haven’t done it in the States, some of which are governed by Republicans.

But I want to ask this question: Unbelievably, Mr. Chairman, no bill has passed this Congress outlawing, banning, even human cloning. Can we agree on that? Can we get everybody to raise their hands on that? Isn’t there any part of this issue where we would be prepared to meet our obligations, instead of going over and over
again the polarizing issue of shall we ban what we can't ban and what our States are telling us we can't ban because we are going ahead and doing it.

So I believe that this hearing is important because perhaps it could lead to more than beating our chests against the obvious. There is no disagreement in the United States of America or among anybody in this Congress that what happened in South Korea should not happen here.

Hearings are for remedies. I will be interested in whether any of the witnesses today are prepared to help this Congress move forward on urgently needed remedies. And I Tim Howard, Mr. Chairman.

Mr. SOUDER. Ms. Foxx.

Ms. FOXX. Thank you, Mr. Chairman. I want to tell you how pleased I am that you are having the hearing today.

I might get the reputation around here for being the person who always brings up the issue of language and how important it is to us. But I hear a lot of very inflammatory terms being used about banning future stem cell research, and legislating against science, and that we are not doing the kinds of things that we should be doing.

We have not at all banned—talked about banning stem cell research in the Congress. We have encouraged stem cell research, adult stem cell research. I am really curious about the word “therapeutic cloning” being used. I don’t know how the destruction of human life could ever be called therapeutic.

I think that what you are doing here today is calling attention to what I think is a microcosm of the fraud that has been perpetrated in relation to embryonic stem cell research itself. I think focusing on what has happened in Korea and the fraud that happened there can, I think, enlighten people about this issue of embryonic stem cell research and the negative things about that. So I think we can change peoples’ minds. I think we can enlighten people. And I think we can do it in a way that is respectful of human life and not destructive of human life.

So I applaud you for holding the hearing, and look forward to our shedding some light on this issue that is the truth, rather than letting something like this continue to be a fraud. We have allowed—unfortunately, people in very sad circumstances think that by the use of embryonic stem cell research, we are going to have a cure right around the corner. And we know that it has brought no cures, whereas adult stem cell research has.

So thank you for doing this, and thank you for calling attention to the issue.

Mr. SOUDER. Thank you. I ask unanimous consent that all Members have 5 legislative days to submit written statements and questions for the hearing record, and that any answers to written questions provided by the witnesses also be included in the record.

Without objection, it is so ordered.

I also ask unanimous consent that all exhibits, documents, and other materials referred to by the Members and the witnesses may be included in the hearing record, and that all Members be permitted to revise and extend their remarks.

Without objection, it is so ordered.