Before swearing in our first panel, I feel compelled to tell all of our witnesses to remember: This is an oversight committee, not a legislative committee. We only have legislative jurisdiction over narcotics. We do oversight and legislation on narcotics.

On the Department of Health and Human Services, we do not write the bills. We are here to talk about the past. What the question is in front of us is what happened there and whether in fact they are inherent to the process, or whether in fact controls can be made to regulate this.

It is a legitimate debate, but it is not about where we are headed legislatively. First, we are here to analyze the past, analyze what has happened, analyze what the different agencies are doing and what the potentials are, that then Energy & Commerce and the Health Committee and others would look at legislatively. I think there was some confusion on the panel as to the role of our hearing and what our committee does. And I think it is important to clarify that.

Now, as you know, it is the practice of this committee to swear in their witnesses. Our first panel is Dr. James Battey, Chair of the NIH Stem Cell Task Force and Director of the National Institute for Deafness and Other Communication Disorders; Mr. Bernard Schwetz, Director of the Office for Human Research Protections; and Chris Pascal, Director of the Office of Research Integrity.

Would you each stand and raise your right hand?

[Witnesses sworn.]

Mr. SOUDER. Let the record show that each of the witnesses responded in the affirmative.

We appreciate that you have joined us, and we will start with Dr. Battey.


STATEMENT OF JAMES F. BATTEY, JR.

Dr. Battey. Good afternoon, Chairman Souder and distinguished members of the subcommittee. I am pleased to be joined here by my two other colleagues from the Department of Health and Human Services. And I appear before you today in my joint roles as a scientist and Chair of the NIH Stem Cell Task Force to discuss the recent events concerning stem cell research fraud that is reported to have occurred in South Korea.

As you know, a review and analysis by the Seoul National University Investigation Committee concluded that human embryonic stem cell lines were not derived from embryos created by somatic cell nuclear transfer, as claimed, that fabricated data was used in
publications, and that there had been ethical violations in the do-
nation of human oocytes used in these experiments.

In 2004, Dr. Woo Suk Hwang and collaborators published an ar-
ticle in the journal Science claiming that they had derived a stable
human embryonic stem cell line, which they referred to as NIGHT–
1, from an embryo generated by somatic cell nuclear transfer. That
is a process, as Mr. Waxman described, where the nucleus is re-
moved from a human oocyte and replaced by the nucleus from a
somatic cell.

Subsequent investigation by the Seoul National University inves-
tigation committee revealed that this claim was not supported by
rigorous DNA testing. In addition, the investigation revealed that
the photographs allegedly taken of the NT–1 cell line were in fact
photographs of an existing stem cell line not derived from an em-
bryo created by SCNT, but instead derived from an embryo pro-
duced by in vitro fertilization.

In 2005, Dr. Hwang and collaborators published a second article
in Science, where they claimed to have made the process or deriv-
ing human embryonic stem cell lines from embryos created by
SCNT much more effort than was reported in the 2004 publication,
where several hundred oocytes were reported to be needed to create
a single stem cell line, which we now know was not created in the
way they described.

In this paper, the authors claimed to have developed an im-
proved protocol for deriving patient-specific embryonic stem cells
from embryos created through SCNT. They reported the creation of
11 human embryonic stem cell lines from 185 embryos created by
SCNT, many of which involved nuclei from cells derived from indi-
viduals with debilitating diseases such as spinal cord injury, juve-
nile diabetes, or congenital inherited deficiencies of the immune
system.

Subsequent review by Seoul National University led the inves-
tigation committee to conclude that the data presented in this 2005
paper was based on only two human embryonic stem cell lines, nei-
ther of which was derived from an embryo created by SCNT. They
concluded that no disease-specific human embryonic stem cell lines
derived from SCNT embryos are represented in this publication,
nor is there any factual basis for believing the Koreans ever suc-
cessfully created any such lines.

While the events in South Korea are deeply troubling to all of us
here and everyone in the scientific community, I think it is impor-
tant to point out that scientific fraud of this type is not common
at all, and is certainly not restricted to the area of stem cell re-
search. As one of your colleagues pointed out earlier, John Darcy
fabricated data in hundreds of publications in the area of cardio-
logy over a decade ago. That doesn't mean that it was inappropri-
te to continue doing work in the area of cardiology.

The scientific community must remain as vigilant as we can be
to ensure that the risk of scientific fraud is minimized. It is also
important to note that such fraud is sometimes revealed, often re-
vealed, when other reputable scientists cannot reproduce results
that are subsequently revealed to be fabricated, and the great ma-
jority of scientists around the world are deeply committed to rigor-
ous standards of proof and verification. The Rosetta Stone of
science is reproducibility in another independent laboratory. And this is where scientific fraud is typically uncovered. The scientific enterprise absolutely depends on such standards. And while the stem cell research fraud in South Korea is completely unacceptable, it does not reflect on the potential of human embryonic stem cell research one way or the other. The vast majority of my scientific colleagues are honest and hardworking in pursuing their research, which they deeply hope will ultimately benefit the human condition.

I thank you very much for your time, and I will do the very best I can to answer any questions that the subcommittee may have for me.

[The prepared statement of Dr. Battey follows:]
Testimony
Before the Subcommittee on Criminal Justice,
Drug Policy and Human Resources
Committee on Government Reform
United States House of Representatives

Recent Events Concerning Stem Cell
Research Fraud in South Korea

Statement of
James F. Battey, M.D., Ph.D.
Director, National Institute on Deafness and
Other Communication Disorders, and
Chair, NIH Stem Cell Task Force
National Institutes of Health
U.S. Department of Health and Human Services
Good afternoon, Chairman Souder and Distinguished Members of the Subcommittee. I appear before you today, in my roles as scientist and Chair of the National Institutes of Health (NIH) Stem Cell Task Force, to discuss the recent events concerning stem cell research fraud that is reported to have occurred in South Korea. As you know, a review and analysis by the Seoul National University Investigation Committee concluded that human embryonic stem cell lines were not derived from embryos created by somatic cell nuclear transfer (SCNT), as claimed, that fabricated data was used, and that there had been ethical violations in the donation of human oocytes used in the experiments.

In 2004, Dr. Woo Suk Hwang and collaborators published an article in the journal Science claiming that they had derived a stable human embryonic stem cell line (NT-1) from an embryo generated by somatic cell nuclear transfer (SCNT). Subsequent investigation by the Seoul National University Investigation Committee revealed that this claim was not supported by DNA testing. In addition, the investigation revealed that the photographs allegedly taken of the NT-1 cell line were in fact photographs of an existing stem cell line derived not from an SCNT embryo, but instead derived from an embryo produced by in vitro fertilization.

In 2005, Dr. Hwang and collaborators published a second article in Science, where they claimed to have made the process of deriving human embryonic stem cell lines from embryos created by SCNT much more efficient than was reported in the 2004 publication. In this paper, the authors claimed to have developed an improved protocol for deriving patient-specific embryonic stem cells from embryos created through SCNT. They reported the creation of eleven human embryonic stem cell lines from 185 embryos created by SCNT, many of which involved nuclei from cells derived from individuals with spinal cord injury, juvenile diabetes, or congenital hypogammaglobulinemia, an inherited
immunodeficiency disorder. Subsequent review by Seoul National University led the Investigation Committee to conclude that the data presented in this 2005 paper was based on only two human embryonic stem cell lines, neither of which was derived from an embryo created by SCNT. They concluded that no disease-specific human embryonic stem cell lines derived from SCNT embryos are represented in this publication, nor is there any basis for believing the Koreans ever successfully created any such lines.

While the events in South Korea are extremely troubling, scientific fraud is not common, though it is also not restricted to this one area. There have been reports in recent years of fraudulent research in other areas of science as well. The scientific community must remain vigilant to ensure that the risk of scientific fraud is minimized. It is also important to note that such fraud is sometimes revealed when other reputable scientists cannot reproduce results that are subsequently revealed to be fabricated, and that the great majority of scientists around the world are deeply committed to rigorous standards of proof and verification. The scientific enterprise absolutely depends upon such standards. And while the stem cell research fraud in South Korea is unacceptable, it does not reflect on the potential of human embryonic stem cell research one way or the other. The vast majority of scientists are honest and hardworking in pursuing their research to benefit the human condition.

I thank you for your time. I will answer any questions that you may have.