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March 10, 2006

James F. Battey, Jr., M.D., Ph.D.
Chair
NIH Stem Cell Task Force
Director
National Institute on Deafness and
Other Communication Disorders
National Institutes of Health
Bethesda, MD 20892

Re: Subcommittee Hearing, "Human Cloning and Embryonic Stem Cell Research after Seoul: Examining exploitation, fraud and ethical problems in the research"

Dear Dr. Battey:

Thank you very much for your testimony on March 7, 2006 before the Subcommittee on Criminal Justice, Drug Policy and Human Resources. Due to the limited amount of time available for the hearing, however, we were unable to address all of the issues involved. To better help the Subcommittee understand these significant issues, we are submitting to you the attached list of questions for the record.

In order to help the Subcommittee move forward with its work on this subject, we request that you respond to these questions in writing no later than the close of business on Friday, April 7, 2006. Your answers will be included in the written record.

Thank you very much for your time and assistance. If you have any questions, you may have a member of your staff contact Malia Holst at 202-225-2577.

Sincerely,

Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources

1. Regarding the scientific process at issue in the Korean scandal:
   - *Was it the process of somatic cell nuclear transfer, SCNT (a process for creating cloned embryos), that was supposedly achieved?*
   - *Was it supposedly the same process that was used to create Dolly, the cloned sheep?*
   - *And in this case, it was supposedly used to produce cloned human embryos for research purposes?*

2. The results in Korea, which we now know were a fraud, were used to tout the promise of cloning for research, by advocates and politicians.
   - *Is there any proof that SCNT has ever been successfully used to produce human embryonic stem cell lines?*

3. The Korean studies were hyped as revolutionary advances. Even putting aside the issue of fraud here, *are you concerned that the promise of embryonic stem cell research is being oversold by some advocates?*

4. A common figure tossed around regarding the "promise" of embryonic stem cell research is that it can provide cures for 100 million people.
   - *Is there any scientific evidence to actually support that claim?*

5. Addressing the notion that embryonic stem cells can "become any kind of cell type in the body."
   - I*s that supported by evidence or current science?*
   - *How many cell types have actually been achieved?*

6. How much money was spent on human embryonic stem cell research in 2005? What portion of that went to the University of Pittsburgh researcher Gerald Schatten?

7. University of Pittsburgh researcher Gerald Schatten is doing work on approved Bush stem cell lines as well as on primate embryos.
   - *How is Schatten's grant award categorized (as being all embryonic stem cell research, or is the primate research categorized as something else)?*

8. Where does Gerald Schatten's $16.1 million grant award fall in terms how it compares to other large grant awards for all types of embryonic stem cell research?

9. How does Schatten rank in terms of NIH grant awards for ESCR in monkeys and the approved stem cell lines? How many grants has he been awarded? Is he the top single grantee for ESCR grants?

10. Gerald Schatten's successful grant application makes reference several times to the Korean research.

- *Was Schatten's grant award contingent upon what was still viewed at the time of the grant application as successful Korean research in these areas?*

11. What are the 2005 figures for ESCR grant awards (i.e., how many grants, total dollar amt, smallest grant award and largest grant award)?

12. In your oral testimony before the Subcommittee on March 7, 2006, you stated that you had finished a response to the Subcommittee's letter of October 8, 2002 within a "matter of weeks." The Subcommittee was seeking a "detailed report" providing comprehensive information on the medical applications of adult and embryonic stem cells as well as cells from cloned embryos and aborted fetuses. However, the Subcommittee did not receive a response to this letter seeking critical information until twenty months after it was sent, during which time the Subcommittee staff made numerous inquiries and additional Charimen's letters were sent.[1]

You said in your testimony that although you had completed the letter in a matter of weeks, the extreme delay was caused by other officials in the agency. Please provide the names of all employees and/or officials who held up this letter, listing contact information for each person/office with how long they delayed the response and the reasons why. If you are unable to answer this question fully and completely, provide the Subcommittee staff with the appropriate names and contact information for the appropriate official/s who can answer this question completely.

13. In May of last year, Chairman Souder inquired with Secretary Leavitt about matters concerning your temporary resignation at the beginning of last year, then "un-resignation," as Chair of the NIH Stem Cell Task Force, while you were a job candidate to head the California Institute for Regenerative Medicine, the California stem cell center established as the result of that state's controversial Propostion 71.

During your period of "resignation," you continued to make appearances and presentations on stem cell research. At the very least, this gives an appearance of impropriety, but we have concerns that this was a clear conflict of interest, and a violation of HHS's own ethics guidelines, which state the following:

> "An employee may engage in outside activities that require the use of professional qualifications readily identified with his or her NIH position, *provided his/her outside work does not create a real or apparent conflict of interest* or interfere with regularly assigned official Government duties."

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[1] Letter from Mark Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, Committee on Government Reform, to Tommy Thompson, Secretary, Health and Human Services, April 20, 2004; Letter from Tom Davis, Chairman, Committee on Government Reform, and Mark Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, Committee on Government Reform, to Thommy Thompson, Secretary, Health and Human Services, on June 17, 2004.

Based on information provided to the Subcommittee through a document request, it appears that HHS's own legal counsel advised you against continuing to speak on these matters during your extra-government job candidacy [documented in emails in the Subcommittee's possession]. As the Hwang scandal is demonstrating, it's clear that we have to be vigilant in guarding against impropriety among the leaders working in this field.

- Explain your justification for continuing to make stem cell presentations while at the same time, seeking a high profile job at the California Institute for Regenerative Medicine.

14. During the period of your "recusal" as head of the NIH Stem Cell Task Force, and while you were a candidate for the job to head the California Institute for Regenerative Medicine, you gave at least twelve presentations on stem cell research, including one at an *Investors'* Conference for the California Biomedical Council, speaking on a panel listed in the conference brochure as "Opportunities in Stem Cell Research," "organized in recognition of the importance of the California Stem Cell Research Initiative and to stimulate thinking about its likely impact on healthcare delivery and job creation."

You are also listed as a participant in the National Institute of General Medical Sciences workshop, "Human Embryonic Stem Cell Research: Recent Progress and Future Directions of NIGMS Grantees?" The purpose of this meeting was "to provide an opportunity for NIGMA grantees conducting human embryonic stem cell research to report on their recent progress, to exchange information, and to identify problems, challenges and opportunities associated with this emerging area of research."

Among the sixty-eight participants in this important stem cell research grantee meeting, you are the only Institute Director listed, and of the fifty-eight researcher grantees participating in the meeting, ten are California-based. All of the California researchers' affiliated institutions would have been candidates for multi-million dollar grants from the California Institute for Regenerative Medicine at the time of this meeting. The California Institute for Regenerative Medicine has since awarded $15.9 million in grants to California institutions represented at this workshop.

- *Explain your justification for how this does not present a conflict of interest.*