Mr. Soudér. Thank you.
Director Pascal. Did I say that correctly? Or Pascal? Thank you.

STATEMENT OF CHRIS B. PASCAL

Mr. Pascal. Chairman Souder and distinguished members of the subcommittee, I appreciate the opportunity to talk to you today about research misconduct and the work of the Office of Research Integrity in the Department of Health and Human Services.

ORI is charged with overseeing allegations of research misconduct in biomedical and behavioral research supported by the U.S. Public Health Service. ORI has over 10 years of experience in reviewing misconduct allegations and making findings of research misconduct.

PHS-supported research institutions and ORI make findings of research misconduct when evidence demonstrates that fabrication, falsification, or plagiarism has occurred in PHS-funded research. ORI has made more than 160 findings of misconduct since 1992, and has reviewed hundreds of additional allegations of misconduct that did not result in misconduct findings.

In May 2005, HHS published a new, more comprehensive regulation governing research misconduct investigations entitled, "Public Health Service Policies on Research Misconduct," codified at 42 CFR part 93, which can be found on the ORI Web site. This new regulation replaces the previous regulation from 1989 for dealing and reporting research misconduct.

ORI is aware of the controversy regarding Dr. Hwang's human stem cell research project at Seoul National University and the findings of fraud by the Seoul National University investigation committee. However, based on current information available to ORI, ORI has no jurisdiction in this matter since the research was not supported by PHS funds, and ORI does not have jurisdiction over non-PHS-supported research.

Had the actions been under the purview of HHS, ORI has a staff of scientists and additional consultants who have developed extensive knowledge and exploits in overseeing and assessing allegations of research misconduct, primarily through evaluating investigations conducted by the PHS-funded research institution.

By law, direct investigations are usually initiated by the research institutions that receive allegations of research misconduct. These allegations are generally made by members of the grantee institution who are part of the particular laboratory or department conducting the research. And I might add that ORI considers these individuals to be heroes in coming forward with allegations of research fraud because without them, it would continue and grow. And those individuals take great risk to come forward.

One or more members of the team may suspect misconduct and then report it to the grantee institution directly. Sometimes the investigator suspecting fraud will report to ORI, and then ORI will refer the matter to the appropriate grantee institution for review. Grantee institutions are required by the HHS regulations to report allegations to ORI when they reach the formal stage of investigation of the process, and when admissions of misconduct are made by the accused scientist.
In conducting the investigation, the institution must promptly secure the research records—without access to the research records and to the original data, it is very difficult to solve these cases—and other relevant documents in order to have a sound basis to identify and evaluate any evidence of research misconduct.

When an institution has completed its investigation, it must submit a written report to ORI. ORI will then engage in a thorough oversight review of the report and, depending on the quality and thoroughness of the investigation, may accept the institution's report and find either misconduct or no misconduct based on the institution's findings.

If ORI believes further investigation is required, we may request and review the grantee institution's entire investigation record, including the research data, copies of interviews or tapes of interviews, and other relevant documents. When the analysis is completed, ORI may find no misconduct and close the case, or propose findings, PHS findings of research misconduct.

ORI findings of no misconduct, as well as open cases that are under review, are considered confidential, both by the ORI regulation and other Federal law, and ORI does not discuss these cases publicly. When HHS makes a finding of misconduct, however, it formally announces the finding, which is then published in the Federal Register, summarized on the ORI Web site and in our newsletter, and the finding is listed in the NIH Guide for Grants and Contracts. In ORI's view, it is important to make these findings public. Otherwise, scientists can move around to other institutions and commit fraud again if it is not public information.

HHS takes findings of research misconduct seriously and takes appropriate action. Findings of research misconduct typically result in remedial HHS administrative actions that may include debarment or suspension from PHS-funded research, which means they cannot come back to the Public Health Service and get new funding for a period of time. And in very serious cases, they could be precluded from doing so for life.

ORI also strives to correct the research record that may have been corrupted by fraudulent studies. As you heard earlier today, Science withdrew two articles that were published because of the fraud, and we think that is very important to making sure that the scientific record is accurate and honest for other scientists and the public to rely upon.

In those research misconduct cases that result in criminal fraud charges, which has happened a couple of times, and civil proceedings of false claims, ORI works collaboratively with the Department of Justice and other Federal law enforcement agencies, including the HHS Office of the Inspector General. Accused scientists who wish to contest findings of research misconduct are offered a due process administrative hearing to defend themselves.

In order to promote research integrity and responsible research practices, ORI has an active education program. We collaborate with the scientific community, and we provide resources to institutions to develop their own educational products.

ORI believes that its educational programs and collaborations with the research community can help prevent research mis-
conduct. It will not ever eliminate it just because of the nature of the human condition.

For example, ORI has a collaboration with the Association of American Medical Colleges to fund scientific and academic societies to hold workshops and conferences on research integrity issues, or develop guidelines or educational programs describing appropriate normative standards for conducting and reporting research.

ORI has a collaboration with the Council of Graduate Schools to fund pilot projects at 10 institutions to provide formal training to graduate students in the responsible conduct of research. ORI has published a booklet on responsible conduct of research that has been translated into Chinese and Japanese, as well as in English.

Finally, ORI has an active program of evaluation and research studies, partly in collaboration with the National Institutes of Health within HHS, to determine what scientific practices are working well and to learn what practices can be improved. It is important to study the science of science itself in order to improve how you conduct research.

Although any individual case of research misconduct can have serious consequences for biomedical research, it is ORI's experience that the great majority of scientists are dedicated to conducting research in a responsible and professional manner, and are committed to producing research results that will benefit all Americans and healthcare consumers around the world.

Thank you for the opportunity to discuss ORI's work, and I would be pleased to answer any questions you have.

[The prepared statement of Mr. Pascal follows:]
The Role of the HHS Office of Research Integrity in Investigating Research Misconduct

Statement of
Chris B. Pascal, J.D.
Director
Office of Research Integrity
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 2:00 p.m.
Tuesday, March 7, 2006
Chairman Souder and Distinguished Members of the Subcommittee, I appreciate the opportunity to speak to you today about research misconduct and the work of the Office of Research Integrity (ORI) in the Department of Health and Human Services (HHS).

ORI is charged with overseeing allegations of research misconduct in biomedical and behavioral research supported by U.S. Public Health Service (PHS) funds. ORI has over 10 years of experience in reviewing misconduct allegations and making findings of research misconduct. PHS-supported research institutions and ORI make findings of research misconduct when evidence demonstrates that fabrication, falsification, or plagiarism has occurred in PHS-funded research. ORI has made more than 100 findings of misconduct since 1992 and has reviewed hundreds of additional allegations that did not result in misconduct findings. In May 2005, HHS published a new, more comprehensive regulation governing research misconduct investigations entitled, “Public Health Service Policies on Research Misconduct” (“the HHS regulation”), codified at 42 CFR part 93, which may be found on the ORI website at: http://ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf. This new regulation replaces the previous regulation from 1989 (42 CFR part 50 subpart A) for dealing with and reporting research misconduct.

ORI is aware of the controversy regarding Dr. Woo Suk Hwang’s human stem cell research project at Seoul National University and the findings of research fraud by the Seoul National University Investigation Committee. However, based on the information currently available to ORI, ORI has no jurisdiction in this matter, since the research was not supported by PHS funds, and ORI does not have jurisdiction over non-PHS-supported research.

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HHS takes findings of research misconduct seriously and takes appropriate action. Findings of research misconduct typically result in remedial HHS administrative actions that may include debarment or suspension from PHS-supported research, supervision or certification of the responsible researcher’s future work, and prohibition from PHS advisory committee service. ORI also strives to correct the research record that may have been corrupted by fraudulent studies, requesting that scientific journals publish retractions or corrections of papers containing falsified or fabricated findings. In those research misconduct cases that result in criminal fraud charges and civil proceedings of false claims, ORI works collaboratively with the Department of Justice and other Federal law enforcement agencies, including the HHS Office of the Inspector General. Accused scientists who wish to contest findings of research misconduct are offered an administrative hearing by HHS.

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Although any individual case of research misconduct can have serious consequences for biomedical research, it is ORI’s experience that the great majority of scientists are dedicated to conducting research in a responsible and professional manner and are committed to producing research results that will benefit all Americans and health care consumers around the world.

Thank you for the opportunity to discuss ORI’s work with you. I would be pleased to answer any questions you may have.