DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Acting Assistant Secretary for Health have taken final action in the following case:

Justin Radolf, M.D., University of Connecticut Health Center: Based on the report of an investigation conducted by the University of Connecticut Health Center (UCHC Report), Dr. Radolf's admissions, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Radolf, Professor at UCHC's Center of Microbial Pathogenesis, engaged in scientific misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grant R01 AI29735–11 and incorporated false claims into a grant application entitled ''Tick Inhibitors of Hemostatis: Novel Therapeutic Agents and an Anti-Tick Vaccine'' to the United States Department of Agriculture (USDA). Dr. Radolf falsified and fabricated preliminary research data to falsely claim that the genes that he proposed to characterize were specifically expressed in the tick salivary gland. Dr. Radolf represented the products of control samples as positive tests for mRNA expression from different genes and presented data as positive for genes that had not been tested.

Specifically, PHS finds that Dr. Radolf falsified and fabricated data in January 2000 by altering the labeling of a figure included in a USDA grant application and by falsifying the text in both the USDA application and in an overlapping application to a state-sponsored program.

This incident of falsification and fabrication is significant because the data was the first direct evidence that the isolated clones represented genes expressed in tick salivary gland, and therefore represented proteins that could be targets of vaccine development to protect the hosts from tick-transmitted microbial diseases. The misinformation of the extent of the progress in this project had the potential to mislead grant reviewers and the scientific community about an area of research that could have led to the prevention of Rocky Mountain Spotted Fever and other tick-transmitted diseases.

The Respondent submitted the following admission to ORI: In January of 2000, I engaged in scientific misconduct involving research supported by the National Institutes of Health. The misconduct occurred during the preparation of grant proposals submitted to the United States Department of Agriculture and Connecticut Innovations, Inc. More specifically, I falsified and fabricated preliminary data by intentionally altering the labeling of an ethidium bromide-stained agarose gel purporting to demonstrate the expression of genes in the salivary glands of feeding Dermacentor andersoni ticks. In so doing, I misrepresented the products of control samples as positive tests for the presence of mRNAs derived from unrelated genes, and I fabricated data to show the expression of genes that, in fact, were not tested. The texts of the two proposals also contained inaccurate statements relating to these falsified and fabricated data. By inaccurately portraying the extent of our progress in characterizing salivary gland proteins that might interfere with tick feeding, my actions would have misled the reviewers of the proposals into thinking that we were closer to the development of an anti-tick vaccine than we actually were.

Truthfulness in the recording, presentation, and reporting of data—the accuracy and reliability of the research record—is the foundation of all scientific research. By intentionally misrepresenting preliminary findings in the two grant proposals, my actions violated this basic precept, compromised my scientific integrity, and placed my 20-year career as a biomedical researcher in jeopardy. My actions also could have compromised the integrity and careers of individuals with whom I work, individuals who place their trust in me and who look to me for scientific leadership. I take full and complete responsibility for this misconduct. I committed this wrongful act without prompting by other individuals and without the consent or knowledge of others. I am deeply remorseful for my behavior and offer my strongest assurance to the Office of Research Integrity that it will never recur.

Dr. Radolf has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed for a period of five (5) years, beginning on March 10, 2003:

(1) To exclude himself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant;

(2) That any institution which submits an application for PHS support for a research project on which Dr. Radolf's participation is proposed or which uses Dr. Radolf in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which Dr. Radolf is involved, must concurrently submit a plan for supervision of Dr. Radolf's duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of Dr. Radolf's research contribution; a copy of the supervisory plan must also be submitted to ORI by the institution; Dr. Radolf agrees that he will not participate in any PHS-supported research until such a supervision plan is submitted to ORI; and

(3) To ensure that any institution employing him submits, in conjunction with each application for PHS funds or report, manuscript, or abstract of PHS funded research in which Dr. Radolf is involved, a certification that the data provided by Dr. Radolf are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the application or report. Dr. Radolf must ensure that the institution sends the certification to ORI.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,

Director, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Preliminary Measure Set for Home Health in the National Healthcare Quality Report—Request for Comments

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Request for comments.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) announces a request for public comment on the Preliminary Measure Set on home health to be used in preparing the National Healthcare Quality Report (NHQR). The NHQR is a congressionally