DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Michael W. Miller, Ph.D., State University of New York, Upstate Medical University: Based on the report of an investigation conducted by the State University of New York, Upstate Medical University (SUNY UMU) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Michael W. Miller, former Professor and Chair, Department of Neuroscience and Physiology, SUNY UMU, engaged in research misconduct in research supported by National Institute of Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH), grants R01 AA07568–18A1, R01 AA06916, and P50 AA017823–01.

ORI finds that the Respondent engaged in research misconduct by falsifying and/or fabricating data that were included in grant applications R01 AA00616–25 to support the primary hypothesis of the published paper that gestational alcohol exposure had an effect on brain development by affecting the way neurons differentiate and migrate into the cortex, rather than by changes to cell growth or death. Specifically, ORI finds that the Respondent:

- Falsified Figure 5 in NIH grant application R01 AA07568–18A1 by altering the bar graphs to make the experimental results appear valid and consistent with his hypothesis that ethanol exposure in utero alters the transition of cells from Pax6 expression to Tbr2 expression, which is critical to normal brain development. Specifically:
  - a. In the VZ/SZ panel (upper row, right), Dr. Miller decreased the values by 50% for the bar graphs representing control and treated mice for “Tbr2,” “both,” and “both/Ki-67,” to falsely report an equivalent frequency of Tbr2 expressing cells in the right and left panels; this result was required for the experiment to appear valid;
  - b. In the MGE panel (lower row, right), Dr. Miller altered the bar graphs representing control and treated mice for “Ki-67,” “Pax6,” and “both” to falsely report that ethanol increased the frequency of K–67+ cells and to report an equivalent frequency of Pax expressing cells in the right and left panels.
- Fabricated bar graphs in Supplemental Figure 2 and related text in the PNAS manuscript to show that in select layers of the cortex, ethanol induced neuronal death occurred in post-natal day 10 (P10) mice; specifically, Dr. Miller:
  - a. Fabricated bar graphs in Supplemental Figure 2 and related text in the PNAS manuscript to show that in select layers of the cortex, ethanol induced neuronal death occurred in post-natal day 10 (P10) mice;
  - b. Included fabricated text in the PNAS manuscript and the grant application citing results of experiments using 15–25-day-old mice treated with ethanol during the second postnatal week, when these mice were never generated.
- Falsified Figure 6 in a manuscript submitted to PNAS by altering data points for the labeling index of caspase3 and TUNEL in cortex layers II/III and V after exposure to ethanol in postnatal day 7 (P7) mice, such that the two assays confirmed each other. The same data were also included as Figure 4 in NIH grant application R01 AA00616–25 and as Figure E1 in a poster presentation at the 2009 Research Society on Alcholism.
- Increased the value of withdrawal trkA data by approximately 70% to falsely report significance with relation to the ethanol treated value and increase significance with relation to the control;

ORI recommends that the Office of the Secretary, HHS, take appropriate action, including debarment and/or exclusion from any contracting or subcontracting with the Government referred to as “covered transactions” pursuant to HHS’ Implementation (2 CFR part 376 et seq) of OMB Guidelines to Agencies on Governmentwide Debarment and
volumes, or abstracts involving PHS-
application for PHS funds, or report, reporting PHS-funded research
applications (including supplements, advance review of any PHS grant
research; and confirming the integrity of Respondent's
supervision of Respondent's duties is
submitted to ORI for approval; the
supervision plan must be designed to
ensure the scientific integrity of
Respondent's research as outlined below: Respondent agrees that he shall not participate in any PHS-
supported research until such a
supervision plan is submitted to and
approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan; the requirements for Respondent's
supervision plan are as follows:
i. A committee of 2–3 senior faculty
members at the institution who are familiar with Respondent's field of
research, but not including
Respondent's supervisor or
collaborators, will provide oversight and
guidance for two (2) years immediately
following the period of exclusion; the committee will review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at six (6) month intervals setting forth the committee meeting dates. Respondent's compliance with appropriate research standards, and confirming the integrity of Respondent's research; and

ii. The committee will conduct an
advance review of any PHS grant
applications (including supplements, resubmissions, etc.), manuscripts
reporting PHS-funded research
submitted for publication, and abstracts; the review will include a discussion with Respondent of the primary data represented in those documents and include a certification to ORI that the data presented in the proposed application/publication is supported by the research record;

(3) That any institution employing
him during the two (2) years during which the supervisory plan is in effect
shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-
supported research in which
Respondent is involved, a certification to ORI that the data provided by
Respondent are based on actual experiments or are otherwise
legitimately derived and that the data, procedures, and methodology are
accurately reported in the application, report, manuscript, or abstract; and

(4) 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 for a period of three (3) years, beginning on
February 6, 2012.

FOR FURTHER INFORMATION CONTACT:
Director, Division of Investigative
Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

John Dahlberg,
Director, Division of Investigative
Oversight, Office of Research Integrity.

The Centers for Disease Control and
Prevention (CDC) publishes a list of
information collection requests under
review by the Office of Management and
Budget (OMB) in compliance with the
Paperwork Reduction Act (44 U.S.C.
Chapter 35). To request a copy of these
requests, call the CDC Reports Clearance
Office at (404) 639–7570 or send an
e-mail to omb@cdc.gov. Send written
comments to CDC Desk Officer, Office of
Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806.

Burden estimates are based on the
following information:

• Number of communities/sites: 4
• Number of schools across 4 communities/sites: 44 (12 in 3 communities, 8 in 1 community)
• Number of students in each middle school: 600 (200 per grade)
• Number of school staff in each school: 40
• Number of schools implementing the standard model of TDV prevention: 22 (across 4 sites/communities)
• Number of schools implementing the comprehensive model of TDV prevention: 22 (across 4 sites/communities)

Population: The study population
includes students in 6th, 7th and 8th
grades at 44 schools in the four
participating sites. At most, schools are expected to have 6 classrooms per grade, with an average of 30 students per classroom yielding a population of 23,760 students (44 schools * 3 grades * 6 classrooms per grade * 30 students per classroom).

The sampling frame for parents, given
that we would only include one parent
per student, is also 23,760 for the three
years of data collection covered by this