(Billing Code: 4150-31)

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:

Mepur H. Ravindranath, Ph.D., John Wayne Cancer Institute: Based on the report of an investigation conducted by the John Wayne Cancer Institute (JWCI) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Mepur H. Ravindranath, former Director of the Laboratory of Glycoimmunotheraphy, JWCI, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), awards R21 CA107316 and R03 CA107831.

ORI found that the Respondent engaged in research misconduct by falsifying results reported for research supported by U.S. Public Health Service (PHS) grants R21 CA107316 and R03 CA107831, in progress reports for those grants and in two publications in scientific journals.

It is expressly understood that by entering into a Voluntary Settlement Agreement (Agreement), Respondent is not admitting to any of the allegations made against him by JWCI and/or ORI, or any of their respective agents, employees, associates, or related persons, including but not limited to the findings made by ORI listed in the Agreement. Respondent agreed to enter into the Agreement and not to contest the findings contained therein solely because contesting the findings would cause Respondent undue financial hardship and stress, and Respondent wished to seek finality.

Specifically:

1. Respondent falsified the number of subjects accrued in the double-blind study reported in the paper Ravindranath, M.H., Muthugounder, S., Presser, N., Ye, X., Brosman, S., & Morton, D.L. "Endogenous immune response to gangliosides in patients with confined prostate cancer." *Int. J. Cancer* 166:368-377, 2005 (subsequently referred to as the "*IJC* paper) and later reviewed in Ravindranath, M.H. Yesowitch, P., Sumobay, C., & Morton, D.L. "Glycoimmunomics of human cancer: Current concepts and future perspectives." *Future Oncology* 3(2):201-214, 2007 (subsequently referred to as the "*Future Oncology* paper"), by reporting data of 7 of 63 patients with serial bleeds taken at different points in time and reporting that the values from the 7 patients were for different patients. This same reporting data of individual patients with serial bleeds taken at different points in time and reporting that those values were for different patients was presented in the CA107316 and CA107831 final reports.

2. The methodology used for the Tables of ANOVA results comparing Log Titers of IgM antibodies for the different subject groups in the *IJC* and *Future Oncology* papers and the CA107316 and CA107831 final reports is incorrect and false, since the papers and reports fail to state that the results are not for a simple ANOVA but include various degrees of repeated measures on the variables.

3. In Table 1 of the CA107831 Final Report, Respondent reported mean log titer values for GM1b for healthy, BHP, and T3/4 CaP patients. These values exactly matched with values published for a different ganglioside, GM1, for healthy, BHP, and T3/4 CaP patients, earlier in the *IJC* (Table II) and *Future Oncology* publications. The only exception was the log titer value for T1/2 CaP patients for GM1b (n = 20), which matched with the earlier published mean log titer value for GT1b (6.22 ± 1.40; n = 36). ORI finds the pairwise-difference in the log titer values of GM1b between the T1/2 CaP and healthy patients, claimed to be significant ($p<0.01$), to therefore be incorrect and false. Respondent contends otherwise.

4. Because Respondent included serial bleed values from individual patients in Table 1 of the *IJC* paper, the summary data for anti-ganglioside antibody values, and the statistical analyses derived from them in Tables II and III of the *IJC* paper, Tables 1 and 2 of the *Future Oncology* paper, published Tables A and B of the CA107316 final report, and Tables 1 and 2B of the CA107831 final report are incorrect and false. The inclusion of

serial bleeds from individual patients in Table 1 of the *IJC* paper and their inappropriate impact on the antibody values reported in Table II of the *IJC* paper were reported in detail by Respondent to the Managing Editor in *IJC* in e-mail communications dated September 24 and 29, 2008.

Dr. Ravindranath has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of three (3) years, beginning on July 2, 2012:

(1) to have any PHS-supported research supervised; Respondent agreed that prior to the submission of an application for PHS support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for 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 contribution; Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that any institution employing him 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, that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract, and that the text in such submissions is his own or properly cites the source of copied language and ideas; and

(3) to exclude himself voluntarily 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 FURTHER INFORMATION CONTACT:

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John Dahlberg,
Director
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