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:

Anil Potti, M.D., Duke University School of Medicine: Based on the reports of investigations conducted by Duke University School of Medicine (Duke) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Anil Potti, former Associate Professor of Medicine, Duke, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant R01 HL072208 and National Cancer Institute (NCI), NIH, grants R01 CA136530, R01 CA131049, K12 CA100639, R01 CA106520, and U54 CA112952.

ORI found that Respondent engaged in research misconduct by including false research data in the following published papers, submitted manuscript, grant application, and the research record as specified in 1-3 below. Specifically, ORI found that:

1. Respondent stated in grant application 1 R01 CA136530-01A1 that 6 out of 33 patients responded positively to dasatinib when only 4 patients were enrolled and none responded and that the 4 CT scans presented in Figure 14 were from the lung cancer study when they were not.

2. Respondent altered data sets to improve the accuracy of predictors for response to treatments in a submitted paper and in the research record by:

   - reversing the responder status of 24 out of 133 subjects for the adriamycin predictor in a manuscript submitted to *Clinical Cancer Research*

   - switching the cancer recurrence phenotype for 46 out of 89 samples to validate the LMS predictor in a file provided to a colleague in 2008

   - changing IC-50 and R-code values for the cisplatin predictor in a data set provided to NCI in 2010

3. Respondent reported predictors and/or their validation by disregarding accepted scientific methodology so that false data were reported in the following:

- *Blood* 107:1391-1396, 2006: describing a predictor for thrombotic phenotypes

- *New England Journal of Medicine* 355:570-580, 2006: describing a predictor of lung cancer relapse

- *Nature Medicine* 12:1294-1300, 2006: describing a predictor for the response to the chemotherapeutic drugs topectan and docetaxol

- *Journal of Clinical Oncology* 25:4350-4357, 2007: describing a predictor for the response to the chemotherapeutic drug cisplatin

- *Lancet Oncology* 8:1071-1078, 2007: describing a predictor for the response to the combination of the chemotherapeutic drugs flurouracil, epirubicin, and cyclophosphamide or docetaxol, epirubicin, and docetaxol

- *Journal of the American Medical Association* 299:1574-1587, 2008: describing a predictor for breast cancer relapse

- *Public Library Science One* 3:e1908, 2008: describing a predictor for the response to the chemotherapeutic drugs paclitaxel, 5-fluouracil, adriamycin, and cyclophosphamide

- *Proceedings of the National Academy of Sciences* 105:19432-19437, 2008: describing a predictor of colon cancer recurrence

- *Clinical Cancer Research* 15:7553-7561, 2009: describing a predictor for the response to the chemotherapeutic drug cisplatin

As a result of Duke's investigation, the published papers listed above were retracted.

Respondent has entered into a Voluntary Settlement Agreement with ORI. Respondent neither admits nor denies ORI's findings of research misconduct; the settlement is not an admission of liability on the part of the Respondent. The parties entered into the Agreement to conclude this matter without further expenditure of time, finances, or other resources. Respondent has not applied for or engaged in U.S. Public Health Service (PHS)-supported research since 2010. Respondent stated that he has no intention of applying for or engaging in PHS-supported research or otherwise working with PHS. However, the Respondent voluntarily agreed:

(1) that if the respondent obtains employment in a research position in which he receives or applies for PHS support within five years of the effective date of the Agreement (September 23, 2015), he shall have his research supervised for a period of five years;

(2) 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;

(3) 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 and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(4) 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 period of five years beginning on September 23, 2015.

FOR FURTHER INFORMATION CONTACT:

Acting Director
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Office of Research Integrity
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Donald Wright, M.D., M.P.H.
Acting Director
Office of Research Integrity

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