

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Establishment of the 2015 Dietary Guidelines Advisory Committee

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

Authority: Establishment of the 2015 Dietary Guidelines Advisory Committee is authorized under 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Committee will be governed by provisions of the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees.

SUMMARY: The U.S. Department of Health and Human Services announces establishment of the 2015 Dietary Guidelines Advisory Committee (hereafter referred to as the Committee or 2015 DGAC). The 2015 DGAC is an expert advisory committee that has been established to assist the Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) perform a single, time-limited task.

FOR FURTHER INFORMATION CONTACT: Designated Federal Officer, 2015 DGAC, Richard D. Olson and/or Alternate Designated Federal Officer, 2015 DGAC: Kellie (O'Connell) Casavale, Ph.D., RD; Office of Disease Prevention and Health Promotion, OASH/DHHS; 1101 Wootton Parkway, Suite LL100 Tower Building; Rockville, MD 20852; Telephone (240) 453-8280; Fax: (240) 453-8281. Lead USDA Co-Executive Secretary, Colette I. Rihane, M.S., R.D., Director, Nutrition Guidance and Analysis Division, Center for Nutrition Policy and Promotion; U.S. Department of Agriculture; 3101 Park Center Drive, Room 1034; Alexandria, VA 22302; Telephone: (703) 305-7600; Fax: (703) 305-3300. USDA Co-Executive Secretary, Shanthy A. Bowman, Ph.D.; Nutritionist, Food Surveys Research Group, Beltsville Human Nutrition Research Center, Agricultural Research Service, USDA; 10300 Baltimore Avenue, BARC-West Bldg 005, Room 125; Beltsville, MD 20705-2350; Telephone: 301-504-0619. Additional information about the 2015 DGAC is available on the Internet at www.dietaryguidelines.gov.

SUPPLEMENTARY INFORMATION: Under Section 301 of the National Nutrition Monitoring and Related Research Act of 1990 (7 U.S.C. 534), the Secretaries of HHS and USDA are required to publish jointly, at least every five years, a report

entitled *Dietary Guidelines for Americans*. Under the referenced legislation, it is stipulated that HHS and USDA are required to work jointly and collaboratively to publish a report that (1) contains nutritional and dietary information and guidelines for the general public; (2) is based on the preponderance of scientific and medical knowledge current at the time of publication; and (3) will be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program.

Dietary Guidelines for Americans was issued voluntarily by HHS and USDA in 1980, 1985, and 1990. Since enactment of the authorizing legislation, the *Dietary Guidelines for Americans* have been published with revisions in 1995, 2000, 2005, and 2010. The Secretaries of HHS and USDA have established and utilized a Dietary Guidelines Advisory Committee to provide advice and make recommendations regarding the *Guidelines* since the 1985 edition.

After appropriate consultation between HHS and the General Services Administration (GSA), it was determined that formation of the 2015 DGAC is in the public interest in connection with the performance of duties imposed on the Department by law, and that such duties can best be performed through the advice and counsel of a federal advisory committee. The Secretary of Health and Human Services approved for the 2015 DGAC to be established as a discretionary Federal advisory committee; the Committee charter was approved by the Secretary on January 9, 2013. To comply with the provisions of FACA, the charter will be filed with the appropriate Congressional committees and the Library of Congress fifteen calendar days after notice of this action being taken has been published in the **Federal Register**.

Objectives and Scope of Activities. The 2015 DGAC will provide independent, science-based advice and recommendations for development of the *Dietary Guidelines for Americans, 2015*, which forms the basis of Federal nutrition programs, nutrition standards, and nutrition education for the general public. A variety of services and tools will be made available to the Committee to support development of recommendations that promote health and reduce chronic disease risk for Americans. The USDA Nutrition Evidence Library will assist the Committee in conducting and creating a transparent database of systematic reviews reflecting the most current research available on a wide range of food and nutrition-related topics to inform its recommendations.

The 2015 DGAC is established to accomplish a single, time-limited task. The Committee will be terminated after delivery of its final report to the Secretaries of HHS and USDA or two years from the date that the Committee charter is filed, whichever comes first.

Membership and Designation. The Committee will consist of not more than 17 members, with the minimum number being 13; one or more members will be selected to serve as the Chair, Vice Chair, and/or Co-Chairs. Individuals will be selected to serve as members of the Committee who are familiar with current scientific knowledge in the field of human nutrition and chronic disease. Expertise will be sought in specific specialty areas that may include but are not limited to cardiovascular disease; type 2 diabetes; overweight and obesity; osteoporosis; cancer; pediatrics; gerontology; maternal/gestational nutrition; epidemiology; general medicine; energy balance, which includes physical activity; nutrient bioavailability; nutrition biochemistry and physiology; food processing science, safety and technology; public health; nutrition education and behavior change; and/or nutrition-related systematic review methodology.

Members will be invited to serve for the duration of the Committee. Individuals who are appointed to serve as members of the Committee will be jointly agreed upon by the Secretaries of HHS and USDA. All appointed members of the 2015 DGAC will be classified as special government employees (SGEs).

Administrative Management and Support. The HHS Assistant Secretary for Health and USDA Under Secretaries of the Food, Nutrition, and Consumer Services (FNCS) and Research, Education and Economics (REE) will provide guidance and oversight for the Committee's function and activities.

Management and support services for the 2015 DGAC primarily will be provided by Office of Disease Prevention and Health Promotion (ODPHP) within the Department of Health and Human Services. The ODPHP is a program office within Office of the Assistant Secretary for Health (OASH), which is a staff division in HHS Office of the Secretary. Responsibility for administrative services will be shared with staffs of the USDA FNCS and REE. USDA administrative leadership and Nutrition Evidence Library support will come from the Center for Nutrition Policy and Promotion within FNCS. REE agencies will provide administrative and data analysis support.

A copy of the charter for the 2015 DGAC can be obtained from the designated contacts. A copy of the charter also will be made available on the FACA database after the document is filed with the appropriate Congressional committees and the Library of Congress. The FACA database is a shared management system that is maintained by the GSA Committee Management Secretariat. The Web site for the FACA database is <http://fido.gov/facadatabase/>.

Dated: January 30, 2013.

Howard K. Koh,

Assistant Secretary for Health.

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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:

Bryan William Doreian, Ph.D., Case Western Reserve University: Based on the admission of the Respondent, ORI found that Dr. Bryan William Doreian, former postdoctoral fellow, Department of Dermatology, Case Western Reserve University (CWRU), engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant T32 HL07887 and National Institute of Neurological Disorders and Stroke (NINDS), NIH, grant R01 NS052123.

ORI found that the Respondent engaged in research misconduct by falsifying data that were included in:

- Doreian, B.W. "Molecular Regulation of the Exocytic Mode in Adrenal Chromaffin Cells." Submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, August 2009; hereafter referred to as the "Dissertation."
- Doreian, B.W., Fulop, T.G., Meklemburg, R.L., Smith, C.B. "Cortical F-actin, the exocytic mode, and neuropeptide release in mouse chromaffin cells is regulated by myristoylated alanine-rich C-kinase substrate and myosin II." *Mol Biol Cell*. 20(13):3142-54, 2009 Jul; hereafter referred to as the "*Mol Biol Cell* paper."
- Doreian, B.W., Rosenjack, J., Galle, P.S., Hansen, M.B., Cathcart, M.K.,

Silverstein, R.L., McCormick, T.S., Cooper, K.D., Lu, K.Q. "Hyperinflammation and tissue destruction mediated by PPAR- γ activation of macrophages in IL-6 deficiency." Manuscript prepared for submission to *Nature Medicine*; hereafter referred to as the "*Nature Medicine* manuscript."

As a result of the Respondent's admission, the Respondent will request that the following paper be retracted: *Mol Biol Cell*. 20(13):3142-54, 2009 Jul.

ORI finds that Respondent falsified numerical values in the *Mol Biol Cell* paper, the submitted *Nature Medicine* manuscript, and the Dissertation by altering the number of samples or the experimental results to improve the statistical results. Specifically, ORI finds that Respondent:

1. Falsified the quantification of immunofluorescence for the ratio of phosphorylated to unphosphorylated MARCKS protein in response to different stimuli in Figure 2 of the *Mol Biol Cell* paper and in Figure 12 of the Dissertation by falsifying the sample number as n=15.
2. Falsified the quantification of immunofluorescence for filamentous actin in response to different stimuli in Figure 3 of the *Mol Biol Cell* paper and in Figure 13 of the Dissertation by falsifying the sample number as n=15.
3. Falsified the quantification of the effect of blebbistatin on catecholamine release as determined by patch clamp analysis in Figure 22 of the Dissertation by stating that 14 cells had been assayed when only 8 cells had been assayed.
4. Falsified the Pearson's cross-correlation analysis in Figure 7 of the *Mol Biol Cell* paper and in Figure 25 of the Dissertation, used to calculate the degree of spatial correlation between pan-chromogranin A/B (CgA/B) and the endosomal membrane, by stating that 20 or more cells had been tested for each condition when only 9-18 cells had been tested for each condition.
5. Falsified RT-PCR values for iNOS and TNF-alpha expression recorded on spreadsheets and presented in Figures 5e and 5f of the *Nature Medicine* manuscript showing the effect of hyper-inflammatory macrophage generation on tissue destruction, by falsifying the numeric values to fit the hypothesis of the manuscript.
6. Falsified ELISA graphs for the concentration of TNF- α in the aAB IL-6 mice and their controls in Figure 6j of the *Nature Medicine* manuscript showing the effect of rosiglitazone treatment in the mice, by multiplying the experimental values by 100 to match the magnitude of the values presented in Figures 21, 6h, and 6i of the *Nature Medicine* manuscript.

7. Falsified the RT-PCR results presented in the *Nature Medicine* manuscript for quantification of iNOS and TNF- α RNA expression by claiming that the results represent the rmean of three identical experiments when the three experiments were normalized differently to yield the desired result. Specifically, false results were presented for peritoneal macrophages treated in vivo with rosiglitazone and/or inhibitors of PPAR γ signaling Figures 1g, 1h, and 1i, and for iNOS RNA expression in IL6^{-/-} macrophages treated in vitro with either SOCS3 antisense oligonucleotides in Figure 2g or the STAT3 decoy in Figure 2j.

Dr. Doreian has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of three (3) years, beginning on January 15, 2013:

(1) To have his research supervised; Respondent agreed that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which his participation is proposed and prior to his participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of his duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of his research contribution; he 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 and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract;

(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; and

(4) To request that the following paper be retracted: *Mol Biol Cell*. 20(13):3142-54, 2009 Jul.

FOR FURTHER INFORMATION CONTACT:
Director, Office of Research Integrity,