

Dated: October 27, 2003.

James Scanlon,

Acting Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 03-28434 Filed 11-12-03; 8:45 am]

BILLING CODE 4151-05-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Privacy and Confidentiality.

Time and Date: 9 a.m.–5 p.m. November 19, 2003; 8:30 a.m.–12:30 p.m. November 20, 2003.

Place: Silver Spring Hilton Hotel, 8727 Colesville Road, Silver Spring, MD 20910.

Status: Open.

Background: The National Committee on Vital and Health Statistics is the statutory public advisory body to the Secretary of Health and Human Services in the area of health data, statistics, and health information policy. Established by section 306(k) of the Public Health Service Act (42 U.S.C. 242K(k)), its mandate includes advising the Secretary on the implementation of the Administrative Simplification provisions (Social Security Act, title XI, part C, 42 U.S.C. section 1320d to 1320d-8) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191.

The NCVHS Subcommittee on Privacy and Confidentiality monitors developments in health information privacy and confidentiality on behalf of the full Committee and makes recommendations to the full Committee so that it can advise the Secretary on implementation of the health information privacy provisions of HIPAA.

Purpose: This meeting of the Subcommittee on Privacy and Confidentiality will receive information on the implementation of the regulation "Standards for Privacy of Individually Identifiable Health Information" (45 CFR parts 160 and 164), promulgated under the Health Insurance Portability and Accountability Act of 1996.

The regulation and further information about it can be found on the Web site of the Office for Civil Rights, at <http://www.hhs.gov/ocr/hipaa/>. The regulation has been in effect since April 14, 2001. Most entities covered by the regulation were required to come into compliance by April 14, 2003.

The first day of the meeting will be conducted as a hearing, in which the Subcommittee will gather information about the impact of the regulation on public health reporting and on health care providers,

health plans and consumers. The Subcommittee will invite representatives of affected groups to provide information about how the regulation has affected the level of privacy and confidentiality for protected health information, best practices for implementation of the regulation, and information that might help to identify and resolve barriers to compliance. The format will include one or more invited panels and time for questions and discussion. The Subcommittee will ask the invited witnesses for examples of the effect the regulation has had on individuals and on entities subject to the regulation. The first day will also include a time period during which members of the public may deliver brief (3 minutes or less) oral public comment about the implementation of the regulation. To be included on the agenda, please contact Marietta Squire (301) 458-4524, by e-mail at mrawlinson@cdc.gov or postal address at 3311 Toledo Road, Room 2340, Hyattsville, MD 20782 by November 12, 2003.

The second day of the meeting will be conducted in two parts. The first part will be a hearing in which the Subcommittee will gather information about the effects of the regulation on organizations involved in health research activities. The Subcommittee will invite representatives of affected groups to provide information about how the regulation has affected the level of privacy and confidentiality for protected health information, best practices for implementation of the regulation, and information that might help to identify and resolve barriers to compliance. The second part will consist of Subcommittee discussion of the testimony it has heard and deliberations about possible recommendations to the Secretary.

Persons wishing to submit written testimony only (which should not exceed five double-spaced typewritten pages) should endeavor to submit it by that date. Unfilled slots for oral testimony will also be filled on the days of the meeting as time permits. Please consult Ms. Squire for further information about these arrangements.

Additional information about the hearing will be provided on the NCVHS Web site at <http://www.ncvhs.hhs.gov> shortly before the hearing date.

FOR FURTHER INFORMATION CONTACT:

Information about the content of the hearing and matters to be considered may be obtained from Kathleen H. Fyffe, Lead Staff Person for the NCVHS Subcommittee on Privacy and Confidentiality, Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, 440D Humphrey Building, 200 Independence Avenue, SW., Washington DC 20201, telephone (202) 690-7152, e-mail Kathleen.Fyffe@hhs.gov or from Marjorie S. Greenberg, Executive Secretary, NCVHS, NCHS, CDC, Room 2413, Presidential Building IV, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone (301) 458-4245.

Information about the committee, including summaries of past meetings and a roster of committee members, is available on the Committee's Web site at <http://www.ncvhc.hhs.gov>.

Dated: October 27, 2003.

James Scanlon,

Acting Deputy Assistant Secretary for Science and Data Policy, OASPE.

[FR Doc. 03-28436 Filed 11-12-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Delegation of Authority

Notice is hereby given that I have delegated to the Commissioner of Food and Drugs the authority, vested in the Secretary of the Department of Health and Human Services, under section 353 of the Public Health Service Act (42 U.S.C. 263a), as amended, to implement CLIA's complexity categorization provisions, which includes, but is not limited to the following:

- (a) Interpreting the CLIA provisions related to complexity categorization;
- (b) Holding public workshops and meetings on CLIA complexity categorization; and,
- (c) Developing and issuing implementing rules and guidance for CLIA complexity categorization.

The existing delegation of authority to the Administrator, Centers for Medicare & Medicaid, concerning CLIA is unaffected.

This delegation is effective upon date of signature. In addition, I ratify and affirm any actions taken by the Commissioner of Food and Drugs or his subordinates which involved the exercise of the authorities delegated herein prior to the effective date of this delegation.

Dated: October 31, 2003.

Tommy G. Thompson,
Secretary.

[FR Doc. 03-28435 Filed 11-12-03; 8:45 am]

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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 Assistant Secretary for Health have taken final action in the following case:

Timothy R. Smith, Ph.D., Michigan State University: Based on the findings of Michigan State University, the respondent's admission, and analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Timothy R. Smith, Ph.D., former Postdoctoral Fellow, Department of Biochemistry and Molecular Biology at Michigan State University, engaged in scientific misconduct in research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH) grant P01 GM57323, entitled "Oxygen utilizing membrane heme proteins."

Specifically, PHS found that Dr. Smith falsified and fabricated data involving research into the physical interaction of prostaglandin endoperoxide synthase-2 (PGHS-2) with cell membranes, and the effects of arachidonate and nonsteroidal anti-inflammatory drugs (NSAIDs) on PGHS-2 structure.

Dr. Smith committed scientific misconduct by falsifying and fabricating data for the following tables and figures in his 2000 doctoral dissertation and in a paper in the *Journal of Biological Chemistry* (275:40407-40415, 2000) entitled "Arachidonic Acid and Nonsteroidal Anti-inflammatory Drugs Induce Conformational Changes in the Human Prostaglandin Endoperoxide H₂ Synthase-2 (Cyclooxygenase-2)" (*JBC* paper):

I. *JBC* paper Table II, entitled "Comparison of inter-residue distances as determined by EPR spectroscopy and as calculated from the x-ray crystal structures" (and corresponding Dissertation Table 6 entitled "EPR determined and X-ray crystal modeled inter-nitroxide distances of PGHS-2 MBD mutants");

II. *JBC* paper Table III entitled "Changes in inter-nitroxide differences between PGHS-2 holoenzyme and the apoenzyme, and the arachidonate, flurbiprofen, and SC58125 complexes" (and corresponding Dissertation Table 7), entitled "Relative changes in inter-nitroxide distances for NSAID and arachidonate complexes compared to the unliganded enzyme";

III. *JBC* paper Figure 4 (binding curves) (and corresponding Dissertation Figure 20 entitled "Binding curves for the association of heme, flurbiprofen and arachidonic acid with PGHS-2 double mutants");

IV. Dissertation Table 8 entitled "EPR determined inter-nitroxide distances for

NSAID and arachidonate complexes of PGHS-2 MBD mutants;'

V. Dissertation Table 9 entitled "Relative changes in inter-nitroxide distances for NSAID and arachidonate complexes compared to the unliganded enzyme;'

VI. Dissertation Table 10 entitled "Kinetic properties and NSAID sensitivities of PGHS-2 active site mutants;'

VII. Dissertation Table 12 entitled "Relative PGHS-2 protein incorporation of PGHS-2 into liposomes of varying composition;'

IX. Dissertation Table 13 entitled "EPR determined inter-nitroxide distances for detergent solubilized and liposome reconstituted PGHS-2 mutants;'

X. Dissertation Figure 27 entitled "Lipid and activity profile of sucrose gradient fractions."

The research misconduct was significant for several reasons. First, the *JBC* paper was novel in that it reported that binding of arachidonate and NSAIDs induced structural changes in PHS-2. For the naturally occurring fatty acid arachidonate, this had not previously been shown. These results could be interpreted as having important implications for understanding the catalytic mechanism of this enzyme. In addition, a considerable expenditure of other researchers' time and resources was prompted by using results generated from the falsified and fabricated data in the *JBC* paper.

Dr. Smith has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed:

(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 for a period of three (3) years, beginning on October 27, 2003;

(2) to exclude himself voluntarily from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government defined as "covered transactions" in the debarment regulations at 45 CFR part 76 for a period of three (3) years, beginning on October 27, 2003. During the three (3) year period of voluntary exclusion, PHS grant funds may be used to pay for page charges for any written work currently being prepared for submission and/or publication on which Dr. Smith is listed as an author only if (i) such written work is unrelated to the misconduct

findings described in the Agreement, (ii) Dr. Smith is not listed as first author, and (iii) the publication does not state that Dr. Smith was supported by a PHS grant. Dr. Smith must certify that all data supporting such written work is true and accurate to the best of his knowledge; and

(3) to submit a letter within 30 days of notification of this action to *JBC* requesting retraction of the following paper: Smith, T., McCracken, J., Shin, Y.K., & DeWitt, D. "Arachidonic Acid and Nonsteroidal Anti-inflammatory Drugs Induce Conformational Changes in the Human Prostaglandin Endoperoxide H₂ Synthase-2 (Cyclooxygenase-3)." *J. Biol. Chem.* 275:40407-40415, 2000. Dr. Smith agreed that the retraction will state that he alone was responsible for the falsification and fabrication of the results and will specifically list the falsified figures delineated on page 1 of the Agreement (Findings I, II, and III). Dr. Smith must submit a draft of the retraction letter for ORI approval prior to sending it to *JBC*. This requirement for retraction will be noted on the ALERT System until Dr. Smith sends a copy of the retraction letter to ORI.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (301) 443-5330.

Chris B. Pascal,

Director, Office of Research Integrity.

[FR Doc. 03-28377 Filed 11-12-03; 8:45 am]

BILLING CODE 4150-31-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Head Start Survey Under Emergency Review by the Office of Management and Budget (OMB)

Title: Survey of Salaries and Other Compensation of Head Start Grantees and Delegate Agencies Nationwide.

OMB No. New request.

Description: A committee of the U.S. House of Representatives requested that the Secretary of Health and Human Services conduct a review of the financial management of Head Start grantees nationwide. The House Education and the Workforce Committee is interested in knowing the salaries and benefits of the top 25 Head Start executives and the amount of their salary and benefits financed using Federal Head Start dollars. To be responsive to the House of