

The changes are as follows:

I. Under Part R, Health Resources and Services Administration make the following changes:

A. Delete the Bureau of Primary Health Care (RC) in its entirety and replace with the following:

Bureau of Primary Health Care (RC): Serves as a national focus for efforts to assure the availability and delivery of health care services in medically underserved areas and to special service populations. To this end, the Bureau, through its Field staffs: (1) Assists States through program and clinical efforts to provide health care to underserved populations; (2) administers the Community Health Centers Program; (3) provides through project grants to State, local, voluntary, public and private entities, funds to help them meet the health needs of special populations such as migrants, the homeless, substance abuse problems, and victims of black lung disease; (4) provides leadership and direction for the Bureau of Prisons Medical Program, the National Hansen's Disease Program, the Coast Guard Medical Program CHAMPUS Program, and the Cuban and Haitian Refugee Program; and (5) administers the *National or Health Service Corps Program* which assures accessibility of health care in underserved areas.

B. Delete the Division of Federal Occupational Health (RCB) in its entirety.

II. Under Part B, Program Support Center, make the following changes:

1. Under Section P-10 Organization, add the following line: "6. Federal Occupational Health service."

II. Under Chapter P-20 Functions, add the following new clause: "(7) provides occupational and environmental health services."

III. Under Section P-20 Functions, add Chapter "PG" to establish the "Federal Occupational Health Service (PG)," to read as follows:

Federal Occupational Health Service (PG): (1) Provides consultation on, and stimulates the development of, improved occupational health and safety programs throughout the Federal Government; (2) provides evaluation, consultation, and direction to Federal managers concerning the management and delivery of the full scope of agency occupational health programs in relation to established standards; (3) provides nationwide assistance in planning, implementing and monitoring health programs for Federal agencies on a reimbursable basis including improved environmental, education, promotional, clinical and managerial services and the development and incorporation of automated information management systems; (4) conducts research studies, science and engineering ventures, training, and demonstration projects; (5) develops occupational health standards and criteria for occupational health programs; (6) conducts activities designed to promote productivity and reduce absenteeism, lost time and related

liability within the Federal work force; (7) provides mechanisms for the development and operation of shared services that promote joint contracting, cost comparison, analysis and program formulation; (8) plans, develops, implements, and operates occupational health programs, including Employee Assistance Programs (EAPs), fitness and wellness, environmental surveillance, medical monitoring, and disability management components; and (9) maintains relationships with health officials in other Federal and occupational health related policy and program development and implementation.

IV. *Continuation of Policy:* Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to the Health Resources and Services Administration and the Program Support Center that relate to this reorganization heretofore issued and in effect prior to this reorganization continue in full force and effect.

V. *Delegations of Authority:* All delegations and redelegations of authority made to officials and employees of affected organization components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

VI. *Funds, Personnel, and Equipment:* Transfer of organizations and functions affected by this reorganization shall be accompanied by direct and support funds, positions, personnel, records, equipment, supplies and other resources.

This reorganization is effective upon date of signature.

Dated: July 3, 2001.

Tommy G. Thompson,
Secretary.

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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:

David R. Jacoby, M.D., Ph.D., Harvard Medical School (HMS) and Massachusetts General Hospital (MGH): Based on the report of an investigation conducted by HMS and MGH and additional analysis carried out by ORI in its oversight review, the U.S. Public

Health Service (PHS) found that Dr. Jacoby, former Instructor, Department of Neurology, MGH, engaged in 15 acts of scientific misconduct by plagiarizing and falsifying research data taken from another scientist's different experiment in a published journal article for use in a program project grant application submitted to, and funded by, the National Institutes of Health (NIH).

Specifically, Dr. Jacoby plagiarized an image of a Southern blot analysis of genomic DNA that appeared as Figure 3A in Balagué, C., Kalla, M., & Zhang, W.-W. "Adeno-Associated Virus Rep78 Protein and Terminal Repeats Enhance Integration of DNA Sequences into the Cellular Genome." *J. Virology* 71:3299-3306, 1997. Dr. Jacoby first falsified the image by adding molecular weight markers and lane labels that misrepresented the image as his own experimental data. He further falsified the image using computer software to intensify a band he claimed was a site-specific integration and to remove identifiable background spots present in the original image. The effect of Dr. Jacoby's falsifications was to misrepresent the image as data from his own experimental analysis of clonal cell lines derived from the infection of a human cell line with a recombinant hybrid virus incorporating two transgenes and adeno-associated virus genes into a herpes simplex virus amplicon. Dr. Jacoby's falsified image was material to his research because it supported his claim that the transgene DNA had integrated into the cell genome at a specific site. These plagiarized and falsified results were reported in:

1. Appendix material supporting an application for a Program Project Grant, Molecular Etiology of Early Onset Torsion Dystonia, 1 P01 NS37409-01A1, submitted by Dr. Jacoby's supervisor; Dr. Jacoby's supervisor relied upon falsified written and oral information provided to her by Dr. Jacoby in her description of his recent research progress;

2. Three presentations by Dr. Jacoby's supervisor to colleagues at MGH in May 1998 regarding the status of the research in her laboratory; Dr. Jacoby's supervisor relied upon falsified written and oral information provided to her by Dr. Jacoby in her description of his recent research progress; and

3. A grant application to NIH for continuation of Dr. Jacoby's Clinical Investigator Award grant, 5 K08 NS01887-03, signed by Dr. Jacoby on May 29, 1998.

In addition, Dr. Jacoby subsequently altered the falsified image described above further by changing the location

of the molecular weight markers to make it appear more consistent with the expected experimental results. Dr. Jacoby then submitted the plagiarized and falsified results to a MGH colleague who included them in a presentation at the First Annual Meeting of the American Society of Gene Therapy, held in Seattle, Washington, on May 30, 1998.

During the institutional investigation in 1998, Dr. Jacoby presented another falsified image as data from his own experiment. Specifically, he used computer software to scan Figure 3A in Balagué et al. and then alter the locations of three major bands in an effort to conceal the origin of the falsified image (i.e., Figure 3A) and to deceive investigating officials into believing that the results were from an independent experiment. Dr. Jacoby then used the different band locations as "evidence" of the differences between Figure 3A by Balagué et al. and the data purportedly from his own experiment by presenting the falsified image: (1) To the Chief of MGH's Neurology Service; (2) to a scientist assisting the Inquiry Committee by attempting to reproduce Dr. Jacoby's experiment; and (3) to the Inquiry Committee as data from his own independent experiment.

After the institution concluded that Dr. Jacoby had engaged in scientific misconduct, Dr. Jacoby forged the signature of the institutional official for the MGH Grants and Contracts Office and knowingly included false and material information on his NIH non-competing renewal application for a Clinical Investigator Award, 5 K08 NS01887-05. Specifically, after ceasing to work in his supervisor's laboratory and after being told by his supervisor that she would no longer serve as his mentor on the Clinical Investigator Award, Dr. Jacoby (1) listed his former supervisor as his mentor on his 5 K08 NS01887-05 application; (2) claimed that he was continuing to conduct grant-funded research in her laboratory; (3) forged the signature of the MGH institutional official to avoid detection by MGH; and then (4) submitted the completed application directly to NIH on or about August 1, 2000.

Dr. Jacoby's actions amount to significant and serious falsifications in the proposing and reporting of research. His falsifications gave NIH reviewers inaccurate information for their evaluation of the progress made by the research group at MGH in its PHS-supported research. His falsifications also substantially hindered the progress of the PHS-funded research project. Finally, his falsifications induced NIH to conditionally approve Dr. Jacoby's 5

K08 NS01887-05 grant at a time when he was no longer conducting research.

Accordingly, PHS further finds that Dr. Jacoby engaged in a pattern of dishonest conduct through the commission of 15 acts of data falsification and plagiarism, including additional steps taken to conceal the true nature and origin of the research data, that further demonstrates a lack of present responsibility to be a steward of Federal funds.

Dr. Jacoby has entered into a Voluntary Exclusion Agreement with PHS in which he has voluntarily agreed for a period of five (5) years, beginning on June 12, 2001:

(1) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government as defined in 45 C.F.R. Part 76 (Debarment Regulations);

(2) 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 FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443-5330.

Chris B. Pascal,

Director, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Agency Information Collection Activities: Proposed Submission to the Office of Management and Budget (OMB) for Clearance; Comment Request; Reinstatement of a Previously Approved Information Collection

AGENCY: Administration on Aging, HHS.

The Administration on Aging (AoA), Department of Health and Human Services, provides an opportunity for comment on the following proposal for the collection of information in compliance with the Paperwork Reduction Act (PRA; Public Law 96-511):

Title of Information Collection: Grantee Data Collection for the Evaluation of the Alzheimer's Disease Demonstration Grants to States Program.

Type of Request: Reinstatement of a previously approved collection for which approval has expired. This request significantly streamlines and reduces the amount of data collected as compared to previously approved requirements.

Use: Data is collected on client demographic and health characteristics, client service use, and program characteristics to adequately evaluate the implementation, progress and process of the Alzheimer's Disease Demonstration Grants to States Program (Section 398 of the Public Health Service Act, Pub. L. 78-410 as amended). Data is used by the grantee states to manage and evaluate their own programs. The data is also used by the AoA to evaluate and describe all projects funded by this initiative and address the program's statutory evaluation and Government Performance and Results Act (GPRA) requirements. Findings are used to manage the program and better target future activities, as well as to provide a final evaluation of each set of grants to Congress as set forth by statute.

Frequency: Client Intake Form—only once per client, data submitted quarterly, Service Use Form—quarterly, Agency Service Profile Form—annually.

Respondents: Agencies of State Governments and Territories that have been designated by the Governor as the sole applicant for the State and who have applied for a grant under this program.

Estimated Number of Responses: Client Intake Form—5000/year, Service Use Form—2500/year, Agency Service Profile Form—125/year.

Total Estimated Burden Hours: Client Intake Form—100 hours/state/year, Service Use Form—420 hours/state/year, Agency Service Profile Form—1.25 hours/state/year.

Additional Information or Comments: The Administration on Aging plans to submit to the Office of Management and Budget for reinstatement of a previously approved collection for which approval has expired, for the Alzheimer's Disease Demonstration Grants to States Program, pursuant to requirements set forth by statute. Written comments and recommendations for the proposed information collection should be sent within 60 days of the publication of this notice directly to the following address: Office of Program Development, Administration on Aging, Attention: Melanie Starns, 330 Independence Avenue, SW., Rm. 4270, Washington, DC 20201.