### Findings of Scientific Misconduct

**Office of the Secretary, HHS.**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**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: Lois Bartsch, Ph.D., University of Nebraska Medical Center: Based on the report of an investigation conducted by the University of Nebraska Medical Center (UNMC) and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Lois Bartsch, Ph.D., former postdoctoral research trainee, Department of Genetics, Cell Biology, and Anatomy, UNMC, engaged in scientific misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grants P30 CA36727 and R01 CA77876 and National Center for Research Resources (NCRR), NIH, grant P20 RR016409.

- Falsified DNA sequence files by deleting a nucleotide and changing nucleotide designations and reported the altered file as the ACI rat p16Cdkn2a sequence with a CpG dinucleotide polymorphism in the upstream region to GenBank, in grant application CA118151, and in the poster presented to Cold Spring Harbor Laboratory (CSHL);
- Fabricated the claim in grant application CA118151 that GenBank entries for the human p16Cdkn2a gene had a CpG polymorphism near the transcription start site;
- Falsified the differential methylation of CpG dinucleotides near the transcription start site of p16Cdkn2a DNA and reported that tumor tissue was more methylated than normal tissue in ACI rats treated with estrogen and that the ACI allele was more methylated than the BN allele in tumor tissue from (BN × ACI)F1 animals treated with estrogen in grant application CA118151.

#### Trans No. | Acquiring | Acquired | Entities
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20080979 | Vicat, S.A | William Douglas Walker | Walker Concrete Company, Inc.
| | | | Walker Construction Products, Inc.

#### TRANSACTIONS GRANTED EARLY TERMINATION—04/10/2008

| Trans No. | Acquiring | Acquired | Entities |
|---|---|---|---|
20080921 | Tom L. Ward | SandRidge Energy, Inc | SandRidge Energy, Inc.
20080970 | WellPoint, Inc | Trident Capital Fund-V, LP | Resolution Health, Inc.

#### TRANSACTIONS GRANTED EARLY TERMINATION—04/11/2008

| Trans No. | Acquiring | Acquired | Entities |
|---|---|---|---|
20080952 | Schneider Electric SA | George O. McDaniel III | ECP Tech Services, Inc.
20080985 | Centene Corporation | Celtic Capital | Celtic Group, Inc.
20080993 | Walgreen Co | I-trax, Inc | I-trax, Inc.
20080994 | Aurora Equity Partners III LP | NuCO2 Inc | NuCO2 Inc.
20080996 | Reyes Holdings, LLC | Ron L. Fowler | Mesa Distributing Co., Inc.
20081005 | Cortec Group Fund IV, LP | E&B Giftware Holdings, LLC | E&B Giftware LLC.
20081005 | Humana Inc | OSF Healthcare System | OSF Health Plans, Inc.

#### TRANSACTIONS GRANTED EARLY TERMINATION—04/14/2008

| Trans No. | Acquiring | Acquired | Entities |
|---|---|---|---|
20080941 | Welsh, Carson, Anderson & Stowe X, L.P | Local Insight Regatta Holdings, Inc | Local Insight Regatta Holdings, Inc.
20080942 | Local Insight Regatta Holdings, Inc | Welsh, Carson, Anderson & Stowe X, L.P | Local Insight Media, L.P.
20080943 | Welsh, Carson, Anderson & Stowe IX, L.P | Superholdco | Superholdco.
20080944 | Welsh, Carson, Anderson & Stowe VIII, L.P | Superholdco | Superholdco.
20080960 | C. R. Bard, Inc | Specialized Healthcare Products International, Inc | Specialized Healthcare Products International, Inc.

#### TRANSACTIONS GRANTED EARLY TERMINATION—04/15/2008

| Trans No. | Acquiring | Acquired | Entities |
|---|---|---|---|
20081009 | Accretive II, LP | AlphaStaff Group, Inc | AlphaStaff Group, Inc.

#### TRANSACTIONS GRANTED EARLY TERMINATION—04/16/2008

| Trans No. | Acquiring | Acquired | Entities |
|---|---|---|---|
20080990 | Baker Brothers Life Sciences, L.P | Genomic Health Inc | Genomic Health Inc.
20081015 | Wells Fargo & Company | The Toronto-Dominion Bank | Flaron Credit Company, Inc.

#### TRANSACTIONS GRANTED EARLY TERMINATION—04/17/2008

| Trans No. | Acquiring | Acquired | Entities |
|---|---|---|---|
20081014 | O’Reilly Automotive, Inc | CSK Auto Corporation | CSK Auto Corporation.
Dr. Bartsch has entered into a Voluntary Exclusion Agreement (Agreement) in which she neither admits nor denies ORI’s finding of scientific misconduct; the settlement is not an admission of liability on the part of the respondent. In accordance with the terms of the Agreement, she has voluntarily agreed, beginning on April 15, 2008:

(1) To exclude herself 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 referred to as “covered transactions” pursuant to HHS’ Implementation (2 CFR Part 376 et seq.) of OMB Guidelines to Agencies on Government-wide Debarment and Suspension (2 CFR Part 180) for a period of two (2) years; and

(2) To exclude herself permanently 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 or contractor to PHS for a period of three (3) years.

FOR FURTHER INFORMATION CONTACT:
Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852 (240) 453–8800.

Chris B. Pascal,
Director, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions and Delegation of Authority

Notice is hereby given that I have delegated to the Principal Deputy Assistant Secretary, Deputy Assistant Secretaries, Program Directors, Program Commissioners, Deputy Director/Commissioner, Office of Child Support Enforcement, and Staff Office Directors the following authority vested in me by the Secretary of Health and Human Services in the memorandum dated August 20, 1991, Delegations of Authority for Social Security Act Programs; 31 U.S.C. 1535; and HHS General Administrative Manual, Chapter 8–77.

(a) Authorities Delegated.
1. Authority to administer approved cooperative research, experimental, pilot or demonstration projects under the provisions of sections 1110 and 1115 of the Social Security Act.
2. Authority to approve interagency agreements to procure, provide or exchange services, supplies or equipment.
(b) Limitations.
1. The authority listed in #1 above shall be exercised under the condition that projects may be approved and administered by the Office of Planning, Research and Evaluation (OPRE), by the program/staff office or jointly by OPRE with the program/staff office.
2. Where all or any part of an experimental, pilot, demonstration, or other project is wholly financed with Federal funds made available under sections 1110 or 1115 of the Social Security Act, without any State, local or other non-Federal financial participation, that project must be approved by the Secretary of Health and Human Services.
3. This delegation of authority does not include the authority to approve/disapprove projects under section 1115 of the Social Security Act or approve/disapprove waivers of State Plan requirements or costs that would not otherwise be included as expenditures under the provisions of sections 1115(a)(1) and (2) of the Social Security Act.
4. The authority to approve interagency agreements to procure, provide, or exchange services, supplies, or equipment requires the concurrence of the ACF Chief Financial Officer if it exceeds $250,000 (including amendments) within a fiscal year or if it requires the signature of the Assistant Secretary, ACF, or the Secretary of HHS.
(c) Effective Date.
This delegation is effective upon the date of signature.
(d) Effect on Existing Delegations.
As related to this delegation of authority, this delegation supersedes all previous delegations of authority involving the administration of the cross-program authorities delegated herein.
I hereby ratify and affirm any actions taken by the Principal Deputy Assistant Secretary, Deputy Assistant Secretaries, Program Directors, Program Commissioners, Deputy Director/Commissioner, Office of Child Support Enforcement, and Staff Office Directors, which involved the exercise of the authority delegated herein prior to the effective date of this delegation.

Dated: April 22, 2008.
Daniel C. Schneider,
Assistant Secretary for Children and Families.

[FR Doc. E8–9898 Filed 5–5–08; 8:45 am]
BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET No. FDA–2008–N–0259]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed collection of information concerning requests by sponsors of investigational new drugs and applicants for new drug approvals or biologics licenses for fast track designation as provided in the guidance for industry on fast track drug development programs.

DATES: Submit written or electronic comments on the collection of information by July 7, 2008.

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:
Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR