

Board of Governors of the Federal Reserve System, April 12, 2011.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 2011-9165 Filed 4-14-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

### Evaluation of the Potential Developmental Effects of Cancer Chemotherapy During Pregnancy: Call for Information and Nomination of Scientific Experts

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS); National Toxicology Program; National Institutes of Health (NIH), HHS.

**ACTION:** Call for information and nomination of scientific experts.

**SUMMARY:** CERHR is evaluating the scientific evidence regarding the potential developmental effects of cancer chemotherapy during pregnancy. CERHR invites the submission of information about ongoing studies or upcoming publications on the pregnancy outcomes and long-term health of offspring exposed to cancer chemotherapy agents during pregnancy and associated topics that might be considered for inclusion in the evaluation. CERHR also invites the nomination of scientific experts to potentially serve as technical advisors in conducting the evaluation or as members of an *ad hoc* expert panel to be convened to peer review the draft Monograph on Cancer Chemotherapy during Pregnancy (see **SUPPLEMENTARY INFORMATION**). The peer review meeting is tentatively scheduled for August 29–30, 2011 at the NIEHS. When set, the date and location of the meeting will be announced in the **Federal Register** and posted on the CERHR Website (<http://cerhr.niehs.nih.gov>). The peer review meeting will be open to the public with time scheduled for oral public comment.

**DATES:** All information and nominations should be received by May 16, 2011.

**ADDRESSES:** Information and nominations may be submitted to Dr. Kembra Howdeshell, CERHR, NTP, NIEHS, P.O. Box 12233, MD K2-04, Research Triangle Park, NC 27709 (mail), 919-316-4708 (telephone), or [howdeshellkl@niehs.nih.gov](mailto:howdeshellkl@niehs.nih.gov) (email). Courier address: NIEHS, 530 Davis Drive, Room K2161, Morrisville, NC 27560.

**SUPPLEMENTARY INFORMATION:**

### Background

A significant number of pregnant women are diagnosed with cancer each year. The frequency of such diagnoses is difficult to determine, but has been estimated to be between 1 in 1000 to 1 in 6000 pregnancies. Treatment for cancer most often involves some form of chemotherapy. The United States Food and Drug Administration has categorized nearly all chemotherapy agents as Pregnancy Category D, *i.e.*, investigational or post-marketing data show risk to the fetus. The evidence for risk for health effects from exposure to the chemotherapeutic agents usually comes from studies in laboratory animals. The general medical opinion on chemotherapy use during pregnancy is that it should be avoided in the first trimester and that treatment during the second and third trimesters, with the exception of a few chemotherapy agents, presents minimal risk to the fetus.

While some reviews have been published in the medical literature on pregnancy outcomes following chemotherapy during pregnancy, the majority of these reviews focus on specific cancer types or specific chemotherapeutic agents. Thus, CERHR proposes to conduct a comprehensive survey of the literature and systematically evaluate the scientific evidence regarding the developmental toxicity of cancer chemotherapy during pregnancy in humans for the six most frequently diagnosed cancers in pregnant women, *i.e.*, lymphoma, leukemia, and cancers of the breast, ovary, skin, and cervix. This review will evaluate a large literature, including more than 700 papers and approximately 40 chemotherapeutic agents, available on pregnancy outcomes in humans following chemotherapy. The CERHR evaluation will include studies of individual, as well as combinations of, chemotherapy agents and the period of gestation in which they are administered. The document should provide clinicians, patients, and researchers with a comprehensive review of the incidence and types of adverse effects observed in humans exposed *in utero* to cancer chemotherapy. While CERHR recognizes that some chemotherapeutic agents are also used to treat non-cancer health conditions of pregnant women, the focus of the proposed evaluation is on cancer chemotherapy. The NTP Board of Scientific Counselors (BSC) discussed the CERHR evaluation of developmental effects of cancer chemotherapy on June 21, 2010 (75 FR 21003). BSC meeting minutes are available at <http://ntp.niehs.nih.gov/go/9741>.

### Request for Information

CERHR invites the public and other interested parties to submit information on cancer chemotherapy during pregnancy, including data on pregnancy outcomes, long-term health reports of human offspring, and laboratory animal toxicology information from completed, ongoing, or planned studies. This information will be considered in evaluating the potential developmental effects of exposure to cancer chemotherapy during pregnancy. Information should be submitted to CERHR (see **ADDRESSES**).

### Request for Nomination of Scientific Experts

CERHR invites nominations of qualified scientists (*i.e.*, basic scientists, clinicians, and toxicologists) to serve as technical advisors and/or as members of an *ad hoc* expert panel to peer review the draft NTP Monograph on Cancer Chemotherapy during Pregnancy. Scientists serving as technical advisors or on the peer review panel should represent a wide range of expertise including, but not limited to: developmental biology, developmental toxicology, epidemiology, medicine (*e.g.*, obstetrics, oncology, and pediatrics), neurotoxicology, pharmacokinetics, reproductive toxicology, renal toxicology, and biostatistics. Technical advisors and expert panel members should meet criteria to serve as an expert including, but not limited to, formal academic training and experience in a relevant scientific field, publications in peer-reviewed journals, and membership in relevant professional societies. Nomination should include contact information and current curriculum vitae (if possible) and be forwarded to CERHR (see **ADDRESSES**). Final selection of individuals to serve on the peer review panel will be made in accordance with the Federal Advisory Committee Act and Department of Health and Human Services implementing regulations. All technical advisors and panel members serve as individual experts and not as representatives of their employers or other organizations.

### Background Information on CERHR

The NTP established CERHR in 1998 (63 FR 68782). CERHR is a publicly accessible resource for information about adverse reproductive and/or developmental health effects associated with exposure to environmental and/or occupational exposures. CERHR publishes monographs that assess the evidence regarding whether

environmental chemicals, physical substances, or mixtures (collectively referred to as "substances") cause adverse effects on reproduction and/or development and provide opinion on whether these substances are hazardous for humans. Information about CERHR can be obtained from its homepage (<http://cerhr.niehs.nih.gov>).

Dated: April 7, 2011.

**John R. Bucher,**

*Associate Director, National Toxicology Program.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Meeting of the Presidential Commission for the Study of Bioethical Issues

**AGENCY:** Presidential Commission for the Study of Bioethical Issues, Office of the Assistant Secretary for Health, Department of Health and Human Services.

**ACTION:** Notice of meeting.

**SUMMARY:** The Presidential Commission for the Study of Bioethical Issues will conduct its fifth meeting in May. At this meeting, the Commission will discuss the topic of Federal standards regarding human subjects protection in Federally funded scientific studies.

**DATES:** The meeting will take place Wednesday, May 18, 2011, from 9 a.m. to approximately 4:45 p.m., and Thursday, May 19, 2011, from 9 a.m. to approximately 1:15 p.m.

**ADDRESSES:** The Warwick New York Hotel, 65 West 54th Street, New York, NY 10019. Phone 212-247-2700.

**FOR FURTHER INFORMATION CONTACT:** Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue, NW., Suite C-100, Washington, DC 20005. Telephone: 202-233-3963. E-mail: [Hillary.Viers@bioethics.gov](mailto:Hillary.Viers@bioethics.gov). Additional information may be obtained at <http://www.bioethics.gov>.

**SUPPLEMENTARY INFORMATION:** Pursuant to the Federal Advisory Committee Act of 1972, Public Law 92-463, 5 U.S.C. app. 2, notice is hereby given of the fifth meeting of the Presidential Commission for the Study of Bioethical Issues (PCSBI). The meeting will be held from 9 a.m. to approximately 4:45 p.m. on Wednesday, May 18, 2011, and from 9 a.m. to approximately 1:15 p.m. on Thursday, May 19, 2011, at the Warwick New York Hotel, New York, NY. The

meeting will be open to the public with attendance limited to space available. The meeting will also be webcast at <http://www.bioethics.gov>.

Under authority of Executive Order 13521, dated November 24, 2009, the President established PCSBI to serve as a public forum and advise him on bioethical issues generated by novel and emerging research in biomedicine and related areas of science and technology. The Commission is charged to identify and promote policies and practices that assure ethically responsible conduct of scientific research, healthcare delivery, and technological innovation. In undertaking these duties, the Commission will examine specific bioethical, legal, and social issues related to potential scientific and technological advances; examine diverse perspectives and possibilities for useful international collaboration on these issues; and recommend legal, regulatory, or policy actions as appropriate.

The main agenda item for this fifth meeting is to review Federal as well as transnational standards of human subjects protections in scientific studies supported by the Federal government as requested by President Obama on November 24, 2010.

The draft meeting agenda and other information about PCSBI, including information about access to the webcast, will be available at <http://www.bioethics.gov>.

The Commission welcomes input from anyone wishing to provide public comment on any issue before it. There will be a public comment session in the afternoon on May 18, 2011. Individuals who would like to provide public comment at that time should notify Esther Yoo by telephone at 202-233-3960, or e-mail at [Esther.Yoo@bioethics.gov](mailto:Esther.Yoo@bioethics.gov) before May 9, 2011. To accommodate as many speakers as possible the time for each individual to speak may be limited. If the number of individuals wishing to speak is greater than can reasonably be accommodated during the scheduled meeting, the Commission may randomly select speakers from among those who register to speak.

Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, should also notify Esther Yoo (contact information above) in advance of the meeting. The Commission will make every effort to accommodate persons who need special assistance.

Written comments will also be accepted and are especially welcome. Please address written comments by e-

mail to [info@bioethics.gov](mailto:info@bioethics.gov), or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave., NW, Suite C-100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Dated: April 6, 2011.

**Valerie H. Bonham,**

*Executive Director, Presidential Commission for the Study of Bioethical Issues.*

[FR Doc. 2011-9123 Filed 4-14-11; 8:45 am]

**BILLING CODE 4154-06-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier CMS-10369]

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Solicitation for Applications: Community-based Care Transitions Program; *Use:* The Community-based Care Transitions Program (CCTP) described in Section 3026 of the Affordable Care Act will run for 5 years with a mandated start date of January 1, 2011. This program provides funding to community-based organizations in partnership with acute care hospitals for the provision of care transition services delivered to high risk