DEPARTMENT OF HEALTH AND HUMAN SERVICES

Availability of Draft NTP Monograph on Potential Developmental Effects of Cancer Chemotherapy During Pregnancy; Request for Comments; Announcement of a Panel Meeting To Peer Review Draft Monograph

AGENCY: Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health.

ACTION: Availability of Draft Monograph; Request for Comments; Announcement of a Peer Review Panel Meeting.

SUMMARY: The NTP announces the availability of the Draft NTP Monograph on Potential Developmental Effects of Cancer Chemotherapy During Pregnancy (available at *http://ntp.niehs.nih.gov/go/36639*) that will be peer reviewed by an NTP Peer Review Panel at a meeting on October 19–20, 2011. The meeting is open to the public with time scheduled for oral public comment. The NTP also invites written comments on the draft monograph (see Request for Comments below).

DATES: The meeting to peer review the draft NTP monograph will be held on October 19–20, 2011. The draft NTP monograph should be available for public comment by September 9, 2011. The deadline to submit written comments is October 5, 2011, and the deadline for pre-registration to attend the meeting and/or provide oral comments is October 12, 2011.

ADDRESSES: The meeting will be held at the Rodbell Auditorium, Rall Building, NIEHS, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709. Public comments and any other correspondence on the draft monograph should be sent to Dr. Lori White, NIEHS, P.O. Box 12233, MD K2–03, Research Triangle Park, NC 27709, *Fax*: (919) 541–0295, or *whiteld@niehs.nih.gov*. Courier address: 530 Davis Drive, Room 2136, Morrisville, NC 27560. Individuals with disabilities who need accommodation to participate in this event should contact Dr. White at voice telephone: 919–541–9834 or *e-mail: whiteld@niehs.nih.gov*. TTY users should contact the Federal TTY Relay Service at 800–877–8339. Requests should be made at least five business days in advance of the event.

FOR FURTHER INFORMATION CONTACT: Dr. Lori White, NTP Designated Federal Officer, (919) 541–9834, *whiteld@niehs.nih.gov*.

SUPPLEMENTARY INFORMATION:

Background

The panel will peer review the Draft NTP Monograph on Potential Developmental Effects of Cancer Chemotherapy During Pregnancy, which has been prepared by the NTP Office of Health Assessment and Translation (OHAT, formerly the Center for the Evaluation of Risks to Human Reproduction [CERHR]). Cancer during pregnancy affects 1/1000 to 1/6000 women per year and treatment for cancer frequently involves chemotherapy. The majority of the reviews of pregnancy outcomes in the medical literature have focused on a specific cancer type or a particular agent. Therefore, OHAT has prepared a comprehensive survey of the literature that reviews pregnancy outcomes and follow-up evaluations, when available, of conceptuses exposed to cancer chemotherapy *in utero*. The main body of this document includes the published human data for over 40 different cancer chemotherapy drugs in tables, and it presents a summary of the human developmental effects as well as background information on mechanism of action, placental and breast milk transport, and laboratory animal developmental toxicology for the more frequently used agents in accompanying text. This 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.

Preliminary Agenda and Availability of Meeting Materials

The preliminary agenda and draft monograph should be posted on the NTP Web site by September 9, 2011. Any additional information, when available, will be posted on the NTP Web site (*http://ntp.niehs.nih.gov/go/36639*) or may be requested in hardcopy from the Designated Federal Officer (see **ADDRESSES** above). Following the meeting, a report of the peer review will be prepared and made available on the NTP Web site.

Attendance and Registration

The meeting is scheduled for October 19, from 8:30 a.m. Eastern Daylight Time to 5 p.m., and October 20, from 8:30 a.m. until adjournment. The meeting is open to the public with attendance limited only by the space available. Individuals who plan to attend are encouraged to register online at the NTP Web site (*http://ntp.niehs.nih.gov/go/36639*) by October 12, 2011, to facilitate access to the NIEHS campus. A photo ID is required to access the NIEHS campus. The NTP is making plans to webcast the meeting at *http://www.niehs.nih.gov/news/video/live*. Registered attendees are encouraged to access the meeting page to stay abreast of the most current information regarding the meeting.

Request for Comments

The NTP invites written comments on the draft monograph, which should be received by October 5, 2011, to enable review by the panel and NTP staff prior to the meeting. Persons submitting written comments should include their name, affiliation, mailing address, phone, email, and sponsoring organization (if any) with the document. Written comments received in response to this notice will be posted on the NTP Web site, and the submitter will be identified by name, affiliation, and/or sponsoring organization.

Public input at this meeting is also invited, and time is set aside for the presentation of oral comments on the draft monograph. In addition to in-person oral comments at the meeting at the NIEHS, public comments can be presented by teleconference line. There will be 50 lines for this call; availability will be on a first-come, first-served basis. The available lines will be open from 8:30 a.m. until 5 p.m. on October 19 and from 8:30 until adjournment on October 20, although public comments will be received only during the formal public comment periods indicated on the preliminary agenda. Each organization is allowed one time slot. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes at the discretion of the chair. Persons wishing to make an oral presentation are asked to notify Dr. Lori White via online registration at *http://ntp.niehs.nih.gov/go/36639*, phone, or email (see **ADDRESSES** above) by October 12, 2011, and if possible, to send a copy of their slides and/or statement or talking points at that time. Written statements can supplement and may expand the oral presentation. Registration for oral comments will also be available at the meeting, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register on-site.

Background Information on OHAT and NTP Peer Review Panels

The NIEHS/NTP established OHAT to serve as an environmental health resource to the public and to regulatory and health agencies. This office conducts evaluations to assess the evidence that environmental chemicals,

physical substances, or mixtures (collectively referred to as ''substances'') cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels. Assessments of potential adverse effects of environmental substances on reproduction or development carried out by CERHR from 1998–2010 are now conducted by OHAT. OHAT also organizes workshops or state-of-the-science evaluations to address issues of importance in environmental health sciences. OHAT assessments are published as NTP Monographs. Information about OHAT is found *http://ntp.niehs.nih.gov/go/ohat.*

NTP panels are technical, scientific advisory bodies established on an ''as needed'' basis to provide independent scientific peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. The NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide a current curriculum vitae to Dr. Lori White (see **ADDRESSES**). The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service (PHS) Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: August 8, 2011.

John R. Bucher,

Associate Director, National Toxicology Program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from Sandia National Laboratories in Albuquerque, New Mexico, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On July 29, 2011, the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and its contractors and subcontractors who worked in any area at the Sandia National Laboratories in Albuquerque, New Mexico, from January 1, 1949 through December 31, 1962, for a number of work days aggregating at least 250 work days, occurring either solely under this employment, or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation will become effective on September 9, 2011, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 877–222–7570. Information requests can also be submitted by e-mail to *DCAS@CDC.GOV.*

John Howard,

Director, National Institute for Occupational Safety and Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–11–08AJ]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 or send comments to CDC Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Focus Group Testing to Effectively Plan and Tailor Cancer Prevention and Control Communication Campaigns (OMB No. 0920–0800, exp. 1/31/2012)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the CDC's Division of Cancer Prevention and Control (DCPC) is to reduce the burden of cancer in the United States through cancer prevention, reduction of risk, early detection, better treatment, and improved quality of life for cancer survivors. Toward this end, the DCPC supports the scientific development, implementation, and evaluation of various health communication campaigns with an emphasis on specific cancer burdens. This process requires testing of messages, concepts, and materials prior to their final development and dissemination, as described in the second step of the health communication process, a scientific model developed by the U.S. Department of Health and Human Services' National Cancer Institute to guide sound campaign development. CDC is currently approved to collect information for these purposes (OMB No. 0920–0800, exp. 1/31/2012). A three-year extension of the existing generic approval is requested.

The communication literature supports various data collection methods to conduct credible formative,