

The public consultation draft report is the result of work that began in 2004, when SACGHS identified the effect of gene patents and licensing practices on patient and clinical access to genetic tests as a high-priority issue that warranted further study. SACGHS activities in this area were deferred until the completion of a National Academy of Sciences (NAS) study on the granting and licensing of intellectual property rights to genetic and proteomic discoveries and the effects of these practices on research and innovation. In the fall of 2005, NAS released that study's report, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health*. After reviewing the report, SACGHS decided that more information was needed regarding the effects of gene patents and licenses on patient and clinical access to genetic tests. In 2006, a task force was formed by SACGHS to guide its work in this area. The task force commissioned case studies, compiled relevant information through a review of the literature, and consulted with national and international experts and stakeholders.

At the outset of its work, the task force decided to limit the scope of its inquiry to those genetic tests, whether used for diagnostic, predictive, or other clinical purposes, that rely on analysis of nucleic acid molecules to determine human genotype. As such, the kinds of patent claims that the Committee evaluated were nucleic acid-related patent claims associated with genetic tests for human genotype. This report does not address protein-based genetic tests or protein-related patent claims associated with tests designed to infer genotype.

The public consultation draft report presents the Committee's preliminary findings. The draft report also includes policy options. These options do not necessarily correlate with any particular preliminary finding, but rather provide a framework within which to gather public input. The Committee developed these options to present a broad range of possible actions, but has not yet decided which, if any, of these policy options to support.

Before SACGHS can develop specific recommendations for the Secretary, the Committee needs public input on several issues, including whether changes are needed in patenting and licensing practices that affect genetic testing, and the appropriateness, feasibility, and implications of the report's policy options. Members of the public are also invited to recommend specific policy options not included in the presented options and any needed

modifications to existing options. SACGHS also encourages the public to provide any additional information and data regarding the positive or negative effects gene patenting or licensing practices have had, are having, or may have on patient and clinical access to genetic tests.

The Committee will carefully consider public input in finalizing its report and developing any recommendations to the Secretary.

Comments received by May 15, 2009, will be considered by SACGHS in preparing its final report. The public comments and revised report will be discussed during a future SACGHS meeting.

Comments will be available for public inspection at the NIH Office of Biotechnology Activities Monday through Friday between the hours of 8:30 a.m. and 5 p.m.

Dated: March 11, 2009.

**Sarah Carr,**

*Executive Secretary, SACGHS.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention (CDC)

#### Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), CDC announces the following meeting of the aforementioned committee:

**Time and Date:** 11 a.m.–5 p.m., Thursday, March 31, 2009.

**Place:** Audio Conference Call via FTS Conferencing. The USA toll free dial in number is 1-866-659-0537 with a pass code of 9933701.

**Status:** Open to the public, but without a public oral comment period.

**Background:** The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose

estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, most recently, August 3, 2007, and will expire on August 3, 2009.

**Purpose:** This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

**Matters To Be Discussed:** The agenda for the conference call includes: Dose Reconstruction Interview Scripts and Procedures; Special Exposure Cohort Petition Status Updates; Board Subcommittee and Work Group Updates; Update on Board Technical Support Contractor Activities; Future Plans.

Due to administrative matters, this **Federal Register** Notice is being published on less than 15 calendar days notice to the public (41 CFR 102-3.150(b)).

The agenda is subject to change as priorities dictate.

Because there is no public comment period, written comments may be submitted. Any written comments received will be included in the official record of the meeting and should be submitted to the contact person below in advance of the meeting.

**Contact Person for More Information:** Theodore M. Katz, M.P.A., Executive Secretary, NIOSH, CDC, 1600 Clifton Rd. NE., Mailstop: E-20, Atlanta, GA 30333, Telephone (513) 533-6800, Toll Free 1-800-CDC-INFO, E-mail [ocas@cdc.gov](mailto:ocas@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 12, 2009.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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