

miller.tom@epa.gov, or by mail at: U.S. EPA Science Advisory Board Staff Office (1400A), 1200 Pennsylvania Ave., NW., Washington, DC 20460. General information about the SAB can be found on the SAB Web site at <http://www.epa.gov/sab>.

SUPPLEMENTARY INFORMATION:

Summary

The EPA's SAB Staff Office is announcing the formation of a new ad hoc committee to help provide advice, through the SAB Executive Committee to the Administrator and other officials in the U.S. Environmental Protection Agency, on ethics issues that might arise in a number of situations involving the generation and/or use of human and animal data. The SAB Staff Office is soliciting nominations to establish the members of the new Committee.

The Board is a chartered Federal Advisory Committee that reports directly to the Administrator. This Committee is being formed to help provide advice to the Agency, as part of the SAB's mission, established by 42 U.S.C. 4365, to provide independent scientific and technical advice, consultation, and recommendations to the EPA Administrator on the technical bases for EPA regulations.

Members of the Bioethics Advisory Committee will help provide advice to the Agency through the SAB's Executive Committee. The Committee will comply with the openness provisions of the Federal Advisory Committee Act (FACA) and all appropriate SAB procedural policies, including the SAB process for panel formation described in the EPA Science Advisory Board (SAB) Panel Formation Process: Immediate Steps to Improve Policies and Procedures—An SAB Commentary (EPA-SAB-EC-COM-002-003), <http://www.epa.gov/sab/pdf/ecm02003.pdf>.

Background

Scientists continue to advance society's ability to understand the many factors that are relevant to the evaluation of risks associated with environmental contamination and change. The scientific study associated with such advances is often accompanied by significant and important debate because it raises new or unique questions of ethics. Therefore, in addition to the EPA's usual practice of evaluating the technical aspects of scientific approaches used to generate data, Agency staff and managers also need to consider the ethical implications of how data are developed and used in support of EPA's mission to protect human health and the environment.

To assist EPA in its consideration of the ethical implications of using various scientific and technical studies in support of its mission, the Agency has asked the SAB Staff Office to form an expert group to advise senior EPA managers on bioethics issues. Therefore, the SAB Staff Office is seeking the public's assistance in identifying and nominating experts to serve on a Bioethics Advisory Committee. Specific projects have not yet been sent to the SAB for consideration by the committee. When specific issues are identified for SAB advice, the initiation of SAB advisory actions will be announced in the **Federal Register**. In order to help the public as it considers appropriate persons to nominate for this committee, this notice describes the Committee's general purview by giving examples of issues that the Committee might be asked to consider. Topics might include: (a) Ethical issues associated with the use of human data obtained using genomics techniques; (b) ethical issues associated with the use of animals to develop data for use in EPA evaluations of risk from environmental agents; and (c) ethical issues associated with intentional dosing of humans to obtain data for use in EPA evaluations of risk from environmental agents. Each of these issues is briefly discussed in the paragraphs that follow. These examples are not intended to be all inclusive and to preclude other types of bioethical issues from being raised to the Committee.

(a) Ethical Issues Associated With the Use of Genomics Data

As used by EPA, the term genomics “* * * is the study of all the genes of a cell, or tissue, at the DNA (genotype), mRNA (transcriptome), or protein (proteome) levels” (Interim Policy on Genomics, U.S. EPA Science Policy Council, June 25, 2002). The Interim Policy on Genomics acknowledges the potential for genomics information to enhance EPA's assessments in support of policy development. The interim policy states that “[g]enomics approaches have the long term promise to aid in the understanding of an organism's response to stressors and to guide the selection of informative bioindicators for monitoring the impact of stressors on human and ecological health. Thus, EPA believes that genomics will have an enormous impact on our ability to assess risk from exposure to stressors and ultimately improve our risk assessments.”

Although EPA is moving rapidly to take advantage of genomics information in support of its mission, the Agency's interim policy notes the current

limitations in our knowledge, understanding, and use of genomics information. As a result, EPA does not consider genomics information sufficient, in and of itself, to serve as the sole basis for decision-making. To realize the potential for genomics information to reduce uncertainties in its assessments, EPA is encouraging research, methods development and evaluation, and data collection relating to gaps in genomics knowledge. The Agency's interim policy finally states that as the Agency “* * * gains experience in applying genomics information and refines its understanding of the use of such information, it will develop guidance to explain how genomics data can be better utilized in informing decision-making and related ethical, legal, and social implications.” As suggested by the interim policy, EPA foresees that it will face a number of ethical issues as it moves forward in the development and use of genomics data in support of its mission and EPA looks for advice from the SAB in addressing such issues.

(b) Use of Animals to Develop Data for Use in EPA Evaluations of Risk From Environmental Agents

Concern has been voiced about EPA's heavy reliance on animal testing protocols to generate test data that is needed to support Agency decision-making. EPA is conducting research that will help it to reduce, refine, and replace animal test protocols that now guide the development of such data. EPA is developing the science that will help it to more selectively apply these test protocols. EPA also works with national and international groups [e.g., the Organisation for Economic Cooperation and Development (OECD) and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)] in this regard.

Notwithstanding EPA's current research into approaches that will allow the reduction, refinement, and replacement of certain animal test protocols, ethical issues will continue to be raised over the animal-based test systems to support decision-making. The Bioethics Advisory Committee can provide a venue where the Administrator can ask for consultations and advisory reviews of this important issue.

(c) Intentional Dosing of Humans To Obtain Data To Be Used in EPA Evaluations of Risk From Environmental Agents

This issue involves the use of data obtained from intentionally dosing