Issues/State-of-the-Art Methodology for the National Research Council's Committee on Risk Assessment Methods

Bernard D. Goldstein

Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey, Piscataway, New Jersey 08854-5635

The following is the abstract of the presentation by Mr. Goldstein. His paper is not available for publication at this time.

The National Academy of Sciences/National Research Council, through its Board on Environmental Studies and Toxicology in the Commission on Life Sciences, has appointed the Committee on Risk Assessment Methods (CRAM). The Committee was established in response to requests from several U.S. government agencies, including the Environmental Protection Agency, the National Institute for Occupational Safety and Health, the Food and Drug Administration, the National Institute of Environmental Health Sciences, and the Agency for Toxic Substances and Disease Registry. CRAM is also supported in part by the American Industrial Hygiene Association and the American Petroleum Institute.

The 17-member committee has expertise in toxicology, epidemiology, occupational health and medicine, risk assessment, statistics, mathematical modeling, genetics, pathology, biochemistry, and pharmacology. The charge to the committee is to assess the scientific basis, inference assumptions, regulatory uses, and research needs in risk assessment. CRAM will gather information and investigate issues largely through a series of narrowly focused, intensive workshops. CRAM has already organized workshops on Maximum Tolerated Dose, Physiologically-based Pharmacokinetic Modeling, and Two-Stage Carcinogenesis Models. Additional workshops on Use of Epidemiological Information in Risk Assessment and Use of Exposure Information in Risk Assessment are planned in the near future.

CRAM will not only focus on cancer risk assessment but will also address the issue of risk assessments for other end points, such as reproductive and developmental toxicity, neurotoxicity, immunotoxicity, etc. The project which began in 1990 will take three years to complete. Separate reports in a series dealing with each issue will be published. These reports will provide guidance to regulatory decision-makers and risk assessment scientists for developing and employing models for risk assessment.