address the two issues outlined above in their review of the criteria and identify areas of consensus, areas of debate, and the knowledge gaps that create the debate. Dr. Lucier then turned the meeting over to Dr. Brown.

Plenary Session II was devoted to the presentation of public comments concerning the BRC criteria. Written comments had been received from the following individuals/organizations and distributed to the ad hoc Working Group prior to the meeting:

North American Insulation Manufacturers Association
Chlorobenzene Producers Association
Dr. Stephen DeVito, US EPA
Dr. E. E. McConnell

Public comments were made during Plenary Session II by the following individuals:

Dr. Charles Axten—NAIMA
Dr. Nathan Karch—Karch & Associates
Dr. Matthew Bogdanffy—Haskell Laboratory
Dr. James Sherman—Chlorobenzene Producers Association
Dr. Myra Karstadt—Center for Science in the Public Interest
Dr. Frank Mirer—United Auto Workers
Dr. E. E. McConnell—Private Consultant

Comments made during the public comment period ranged from recommending retention of the current criteria with no change, to revising the existing criteria to require the incorporation of available mechanistic data. (A copy of the written public statements provided by the above listed individuals is available upon written request to the NTP Liaison Office, NIEHS, P.O. Box 12233, MD A3–01, Research Triangle Park, NC 27709–2233). Following the public comment session, Dr. Brown directed that each breakout group was to meet individually and, based on the charge given to the ad hoc Working Group by Dr. Lucier, address the BRC criteria.

Upon completion of the discussions of the three breakout groups, the full ad hoc Working Group reconvened in the final Plenary III session. Each breakout group made a report on their deliberations and recommendations.

Each breakout group had addressed the two issues outlined in the charge given by Dr. Lucier. Breakout group 1 stated in their report that the existing criteria were found not to be adequate and suggested revision of the criteria to include use of available mechanistic data that is relevant for improving hazard identification. The report from breakout group 2 stated there was unanimity from their members that the criteria should be updated and that mechanistic data should be utilized in the listing process. Group 2 recommended significant revisions to the existing criteria including the incorporation of additional listing categories. Breakout group 3 report stated that their members were of the general consensus that the current criteria are adequate for the stated purpose of the BRC, however minor revisions and clairifications to the existing criteria were considered to be appropriate. In summary, it was the recommendation of breakout groups 1 & 3 that the existing two categories of the current criteria for listing substances in the BRC should remain with revisions to category 2 to allow for all scientific evidence to be considered. This will allow for the best scientific judgment to be used in consideration of substances for listing in the BRC. Breakout group 2 recommended a more significant expansion of the current criteria which included the incorporation of additional listing categories of ''presumptive evidence of carcinogenic activity'' and ''laboratory animal carcinogen presumed not to be a human carcinogen''.

Based on the reports from the three breakout groups and the ensuing discussions during the final plenary session of the entire ad hoc Working Group, the NIEHS/NTP determined that, while there was not complete agreement concerning the adequacy of the current criteria for listing substances in the BRC, it was the general consensus of the entire ad hoc Working Group that the existing criteria should be revised and clarified. The recommended revisions are to permit consideration of more mechanistic information in listing substances in the BRC. As indicated in the three breakout group reports, the area of debate was how extensive the modifications should be. The discussions during Plenary Session III indicated that the majority of the ad hoc Working Group members felt the revised criteria should maintain the current 2 categories with revisions to assure that all scientific evidence is considered to allow for the best scientific judgment. It was also apparent from these discussions that there was consensus that the BRC is a hazard identification document and not to be used as a quantitative risk assessment for the listed substances. It is based on these considerations and recommendations that the NIEHS/NTP has proposed revised criteria for listing substances in the BRC. These proposed revisions are consistent with the discussion and recommendations of the majority of the ad hoc Working Group and the current legislation regarding the Biennial Report on Carcinogens. These proposed revised criteria will be available to the public for review and comment and presented to the NTP Board of Scientific Counselors at their June 29, 1995, meeting. The Board will review the report and recommendations; receive public comment on the report; and develop Board recommendations concerning the selection criteria. Further review will include the PHS Environmental Health Policy Committee and the NTP Executive Committee.

The ad hoc Working Group made several additional general recommendations concerning the Biennial Report on Carcinogens. These included recommending that a formal mechanism be established for the re-evaluation of substances previously listed in the BRC to determine if listing is still warranted. As a result of this recommendation, the NTP will evaluate the current procedures for de-listing a substance and, if necessary, revise it. It was also recommended by the Working Group that the NTP should stimulate discussion (e.g., workshops, discussion papers) on the use of mechanistic data in hazard identification. The recent NTP workshop on ''Mechanism-Based Toxicology in Cancer Risk Assessment: Implications for Research, Regulation and Legislation'' held January 11–13, 1995, and the upcoming Workshop on Validation and Regulatory Acceptance of Alternative Test Methods'' planned for October 30–November 1, 1995 are examples of how this recommendation will be acted upon. The NTP plans to continue these types of activities in the future.

Current BRC Criteria

For the purpose of the BRC, the degrees of evidence are as follows:

1. *Known To Be Carcinogens*

There is sufficient evidence of carcinogenicity from studies in humans that indicates a causal relationship between the agent and human cancer.

2. *Reasonably Anticipated To Be Carcinogens*

a. There is limited evidence of carcinogenicity from studies in humans, which indicates that causal interpretation is credible, but that alternative explanations, such as chance, bias or confounding, could not adequately be excluded, or

b. There is sufficient evidence of carcinogenicity from studies in experimental animals that indicates that there is an increased incidence of malignant tumors: (a) in multiple species or strains, or (b) in multiple experiments (preferably with different routes of administration or using different dose levels), or (c) to an unusual degree with regard to incidence, site or type of tumor, or age at onset. Additional evidence may be provided by data concerning dose-response effects, as well as information on mutagenicity or chemical structure.

Proposed Revised BRC Criteria

For the purpose of the BRC, the degrees of evidence are as follows:

1. *Known To Be Human Carcinogens*

There is sufficient evidence of carcinogenicity from studies in humans that indicates a causal relationship between the substance and human cancer.

2. *Reasonably Anticipated To Be Human Carcinogens*

a. There is limited evidence of carcinogenicity from studies in humans which indicate that causal interpretation is credible but that alternative explanations such as chance, bias or confounding could not adequately be excluded, or

b. There is sufficient evidence of carcinogenicity from studies in experimental animals that indicates there is an increased incidence of malignant and/or combined benign and malignant tumors: (1) in multiple species or at multiple tissue sites, or (2) by multiple routes of exposure, or (3) to an unusual degree with regard to incidence, site or type of tumor or age at onset.

Conclusions regarding carcinogenicity in humans or experimental animals should be based on scientific judgment. Consideration may be given to relevant information on dose response, route of exposure, chemical structure, sensitive sub populations, genetic effects or other data relating to mechanism of action, and/or factors that may be unique to a given substance. There may be substances for which there is less than sufficient