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Consensus Panel Recommendations

The following statements, recommended by the members of the Clinical Trials Consensus Panel, will be debated for adoption as official NMA policy at the NMA Annual Meeting in August 1999.

The Clinical Trials Consensus Panel states:

Medical practice (i.e., pharmacotherapy, procedures, and products) is increasingly based on evidence gained through controlled clinical trials. The basis of the panel's deliberations was that African-American patient and physician representation in clinical trials is generally inadequate, compromising the quality of clinical trial findings applicable to the treatment of African-American patients.

The objective of this panel was to recommend policies and programs that the National Medical Association should consider to improve African-American participation. Although not an exclusive list, the panel felt that the following issues were major contributors to low participation of African-Americans in biomedical research:

- The African-American community generally distrusts the medical community
- There are insufficient numbers of African-American physicians engaged in biomedical and clinical research
- The inadequate representation of African-Americans in biomedical and clinical research has a negative impact on the quality of medical care

On the basis of these issues, the panel recommends the following steps:

The African-American community generally distrusts the medical community:

The National Medical Association should:

- Advocate for maximal effectiveness of human subject protection through oversight agencies such as the NIH, FDA, and CDC, as well as IRBs.
- Strongly advocate for the increased participation of African-Americans in human-subject oversight protection programs.
- Advocate for the implementation of a system of periodic certification or accreditation of IRBs by an independent body to ensure:
 - Adequate training of personnel.
 - Appropriate implementation of oversight policies.
 - An understanding of cultural issues in the research process.
- In concert with other organizations such as pharmaceutical companies, the NMA should develop a "Code of Investigator Conduct" and a "Trials Participant Bill of Rights."
- Develop resources to determine that all pre-trial expectations have been met.

- Develop educational materials that should be culturally and linguistically concordant.
- Encourage research sponsors to share study results with subjects.
- Encourage research sponsors to increase the use of community-based physicians with whom long-term patient relationships have been established.

There are insufficient numbers of African-American physicians engaged in biomedical and clinical research

The National Medical Association should:

- Encourage current and future African-American physicians engaged in community or private practice towards careers in biomedical research.
- Seek to involve the historically black medical schools in NMA research education programs to increase the number of researchers/academicians.
- Provide African-American students and post-graduate trainees with information and support to facilitate their entry into careers in biomedical research.
- Establish an individual recognition program throughout the various disciplines and stages of training/practice, to heighten perceived value and increase awareness of biomedical research.

The inadequate representation of African-Americans in biomedical and clinical research has a negative impact on the quality of medical care

The National Medical Association should:

- Encourage efforts to quantitate disease specific morbidity and mortality disparities and consequences of inadequate African-American participation in clinical trials.
- Strongly recommend that clinical trials be adequately designed and powered to demonstrate safety and efficacy in African-Americans. Proportional population representation is an inadequate method of assessing safety and efficacy in a specific patient population.
- Recommend that race and ethnicity be a retrievable query in all health-related databases.
- Advocate for a more clear definition of disease characteristics in African-Americans, through basic science and clinical studies, as well as studies of diseases that have an important impact on African-American public health.

In addition, Consensus Panel members presented several recommendations related to infrastructure changes within the NMA. Panel members voiced their agreement on the following issues:

- Implementation of a Council for Health-Related Research
- Development of a physician investigator's research network
- Serve as a channel for recruitment of African-American patients into biomedical research
- Development of an Administrative Unit for Research within the national office of the NMA
- Provide a model for NMA involvement in clinical trials
 - NMA would solicit training support for clinical trial investigators
 - Establish a Council of Advisors to review trial protocols to ensure:
 - The ethical treatment of patients
 - That trials meet with basic criteria/regulations
 - The interests of the African-American community and satisfaction of NMA goals
- Provide review protocols related to the network of NMA physicians