National Medical Association

1012 10th St., NW ● Washington, DC 20001
202/347-1895 ● 202/371-1162 (fax)
www.NMAnet.org

Recommendations Regarding Clinical Research

Modern, preventive or therapeutic medical practice is based on evidence gained primarily through controlled clinical trials. It is the National Medical Association's position that African American patient and physician representation in clinical trials is generally inadequate, thus compromising the quality and validity of clinical trial findings used to guide the treatment of African American patients.

The National Medical Association recommends:

1) Product labels should include the demographics of the clinical trial population as a means of guiding physicians in the appropriate interpretation of available clinical data for the use of new drug products in their patients.
2) Since the scientific evidence is not yet supportive, the Food and Drug Administration (FDA) should not condone the use of genomics data as a surrogate for diverse population participation in clinical trials.
3) Priority should be given to the collection of post-marketing clinical trials data on safety and effectiveness in diverse populations as a condition of approval when pre-market data fails to establish product safety and effectiveness in these groups.
4) FDA require minority inclusion in clinical trials of new products to be sufficient to determine safety and efficacy in these population subgroups.

Racial and ethnic minorities are the fastest growing segment of the U.S. population. The National Institutes of Health requires racially diverse representation in government sponsored clinical trials. Although pharmaceuticals are known to be one of the most effective means of healthcare, the evidence publicly available suggests that many pharmaceutical products are approved for marketing in the U.S. without appropriate observations from representative inclusion of minority patients in industry sponsored clinical trials. Industry products may be promoted and prescribed to millions of minority patients without adequate information on safe and effective use. The importance of this issue is heightened by a growing body of knowledge of differences in clinical response as a function of racial and ethnic origin and a growing dependence of foreign clinical data. Phase IV post-marketing trials are typically used to evaluate safety as well as the presence of differences. However, products approved for marketing are made immediately available for use by the entire population without regards to these limitations in data. The overall morbidity and mortality to the African American population that can be attributed to expected, but unproven or diminished safety and effectiveness, or inappropriate dosing, is unclear. However the potential for catastrophe is clearly evident from the observation in 2002 of a significantly higher mortality from the use of the asthma prescription drug, Serevent, in African American patients first reported over 8 years after its market entry and widespread use. The number of patients impacted by this delay in understanding is unknown.

Percent of the Population, by Race and Hispanic Origin: 1990, 2000, 2025, and 2050

(Middle-series projections)