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WHY MINORITIES SHOULD PARTICIPATE IN CLINICAL RESEARCH

by Norman M. Goldfarb

Minorities seldom have the opportunity to participate in clinical research studies, with potentially serious health ramifications for their communities. Because of genetic differences, minorities often respond differently than Caucasions to medicines, with potentially-dangerous dosing errors and side-effects. Unless minorities participate in clinical research studies, these health risks may never be known: 77% of drug labels provide no guidance for use by minorities, and less than 1% of new drug labels provide guidance for use by minorities.

Many factors prevent minorities from participating in clinical studies. These factors include socioeconomics, culture, language, and access to physicians who conduct clinical studies. In addition, pharmaceutical companies seldom make a special effort to recruit minorities for clinical studies.

The Food & Drug Administration (FDA) supervises clinical studies of new drugs and approves them for use by the general public. If minorities do not participate in the clinical studies, it may take a long time before safe and effective dosages are determined through trial and error by the general public. If they don't participate, they do not benefit from the free drugs and medical care received by clinical study participants. Most clinical studies even compensate volunteers for their time and transportation costs. In addition, many potentially-life-saving clinical study drugs are not available to the general public because they are not FDA-approved.

The National Institutes of Health (NIH) first published guidelines in 1987 for including more minorities in government-funded clinical studies, but these guidelines do not apply to industry-funded research. Participants in clinical studies in 1999 included only 6% African-Americans, 1% Asians and 1% Hispanics, for a total of 8%, down from 12% in 1995. These three minorities comprise over one-third of our population.

In February 2003, Vaxgen of Brisbane, California, announced that its study of AIDSVAX HIV/AIDS vaccine was unsuccessful. The only bright spot in the study was a favorable indication among African-Americans. However, the number of African-American participants in the study was so small that the data could not be used to obtain FDA approval for use of the vaccine in African-Americans.

According to the FDA, African-Americans overall have lower cancer survival rates than whites, but comparable survival rates in clinical studies. Twenty percent of Americans with Hepatitis C viral infections are African-Americans. However, the standard therapy for Hepatitis C (interferon plus ribavirin) appears to be less effective for African-Americans than for Caucasians. Scientific testing has not been performed to determine if a larger dosage would address the problem. The effectiveness and safety of a new and potentially twice-as-effective therapy using pegylated interferon has not been tested on African-Americans.

Norman M. Goldfarb is Managing Partner of First Clinical Research, a provider of a clinical research best practices consulting, training, implementation and research services.
Website: www.firstclinical.com