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NIH Revitalization?

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On June 10, 1993, the National Institutes of Health (NIH) Revitalization Act of 1993 (Public Law 103-43) was enacted. Its provisions have been circulated to all clinical investigators as an NIH "Guideline" (*Federal Register,* March 28, 1994). The subtitle of this law is Clinical Research Equity Regarding Women and Minorities. This law mandates that the Director of the NIH "shall conduct or support outreach programs for recruitment of women and members of minority groups in projects of clinical research in a manner sufficient to provide a valid analysis of whether the variables being studied in the trial affect women or members of minority groups differently than other subjects in the trial."

If present trends in the United States continue, the largest proportionate increase in the population in the next few years will be among minority groups. These racial and ethnic minority groups are diverse in culture and socioeconomic status, but make up an integral part of the national fabric. The National Cancer Institute has set forth the goal of decreasing the cancer mortality rate by 50 percent by the year 2000. Efforts to achieve this goal must address the cultural heterogeneities that exist, then develop interventions sensitive to the lifestyles, beliefs, and behaviors of each minority group. African Americans make up the largest minority group in the United States, and they experience some of the highest cancer incidence and mortality rates of all U.S. populations. Historically, African Americans have been disproportionately underrepresented in clinical trials.

It has been suggested that the greatest potential for reducing cancer mortality may be through increasing participation in investigational cancer protocols. One of the major hindrances to recruitment is that the majority of the African-American community is not aware of the opportunities and benefits of participating in clinical trials.

The issue of gender in cancer clinical trials is frequently dictated by the disease (i.e., breast cancer, prostate cancer, testicular cancer, and ovarian cancer). As the number of women with lung cancer has increased, the number of women entered onto cancer clinical trials to treat this disease has increased proportionately. Possible gender differences in responses to colon and rectal cancer have recently been observed, and new clinical trials are being mounted to try to verify these potential differences. Overall, cancer clinical trials have not shown partiality with reference to gender, and women have been enrolled in equal numbers when appropriate.

So, what is the problem? Women and men may react differently to drugs. In addition, women of reproductive age have often been excluded from clinical trials. But what are the merits of requiring that women and minorities be included in clinical trials in numbers large enough to determine if differences in response exist? And more significantly, is there a biologically plausible reason to expect that true clinically significant differences will be found?

Is it not backwards that the new law mandates that inclusion of women and minorities is not required if there is substantial scientific data that no significant differences exist? Would it not be infinitely more reasonable to attempt to identify these differences in the laboratory rather than in large-scale clinical trials? If biological or pharmacological clues are to be found in the laboratory, clinical trials could then be specifically designed to confirm or exploit the differences identified.

To blindly mandate inclusion of large numbers of women and minorities in clinical trials to try to confirm differences where no differences may exist will greatly increase costs, as well as limit the number of clinical trials that can be completed in a reasonable time frame. This could result in a backlash against the inclusion of these groups in specific trials designed to confirm or deny true biological differences.

The mandate to revitalize the NIH will greatly increase the cost of clinical trials, but guess what...there is no increase in funding to the NIH or to the National Cancer Institute to help cover the cost of achieving balance in numbers of women and minorities. There is no reason to think that balance per se will improve our ability to treat cancer or any other major health problem. Clinical trials need to be based on reason and scientific data, not quotas.

Clinical trials in the United States are currently in jeopardy for several reasons. These include problems with third-party reimbursement for patient care costs related to clinical trials, as well as increasing government regulation. The community oncologist/physician/investigator is being bombarded with never-ending paperwork that makes clinical trials an increasing chore rather than intellectual stimulation. The community physician/clinical investigator is becoming an endangered species.

The community is a major resource for cancer clinical trials. The continued success of cancer clinical trials in the United States is dependent upon the participation of the community oncologist. Governmental mandates such as the NIH Revitalization Act of 1993, no matter how well intentioned, are increasing barriers to the successful conduct of meaningful clinical research within the community.