More Minorities Called for in Clinical Drug Trials

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WASHINGTON — More needs to be done to encourage minority patients and providers to participate in clinical drug trials, several speakers said at a meeting sponsored by the Alliance of Minority Medical Associations, the National Association for Equal Opportunity in Higher Education, and the Department of Health and Human Services.

"If you go to the package insert of a lot of drugs currently on the market and look for information on minority participation in clinical trials, what you frequently will see is the phrase, 'No data available,' " said Basil Halliday, founder of BDH Clinical Research Services, a clinical trial consulting firm in Ridgemont, N.C. "It's high time we get rid of that phrase in the package insert."

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One of the most important changes would be a federal mandate to include minority patients in clinical trials as a condition of approval by the Food and Drug Administration. "We also need specific guidance on the degree of representation," Mr. Halliday said. "I don't want to hear you say that you 'encourage it,' 'support it,' or 'want to see more of it.' You need to give specific numbers because that's the only time the industry will respond. I say mandate, mandate, mandate."

B. Waine Kong, Ph.D., CEO of the Association of Black Cardiologists, suggested that the FDA establish an Office of Minority Affairs to address issues relating to minorities, including increasing their participation in clinical trials.

Several barriers impede minority participation in trials, among them a lack of minority physicians, who are six times more likely to treat minority patients, compared with white physicians, Mr. Halliday said. "As for African American physicians doing clinical trials, it's almost nonexistent."

Mr. Halliday's company has started the Clinical Research Investigator Support Program to encourage more minority physician participation. "We need to do a better job of creating a pipeline of future physicians, minority scientists, and researchers who are culturally competent and culturally sensitive to the people they're six times more likely to treat," he said. "We need to involve those people in the process early."

Minority physicians have a lot of reservations about participating in clinical trials, he continued. "A lot of physicians I have talked to over the years don't know that the pharmaceutical industry had nothing to do with Tuskegee," Mr. Halliday said, referring to an experiment conducted by the U.S. Public Health Service in which African American men were deliberately left untreated for syphilis, even after penicillin became known as a cure for the disease.

Dr. Kong noted that minority physicians also face a variety of entry barriers to clinical trials, such as complex, technical forms to fill out and the need for capital investment, including hiring someone to help run the trial. Further, many minority physicians are reticent to refer patients to trials being run by other physicians "because of a belief that if they send that patient to another doctor, they may lose that patient. That's not necessarily true."

On the patient side, minority patients need to be better educated about the benefits of trial participation, such as free, state-of-the-art medical care and better outcomes due to more frequent physician visits, Mr. Halliday said.

He said that his company also has started a minority community outreach and education program with institutional review boards. "It doesn't make sense that the folks sitting on the IRB and approving protocols don't accurately reflect the communities in which they live," he said. He complimented one board, Essex IRB in Lebanon, N.J., for changing its board makeup to allow for more minority participation.

Mr. Halliday urged the National Institutes of Health to start grant reviewer education programs about minority inclusion in clinical trials. "The same folks, year after year, get money from NIH, but there's no demand on those people to change. We need to hold them accountable for putting minorities in the clinical trial process." ■