

No Blacks Allowed? A Drug Trial Comes Under Fire

April 5, 2006 By Kellee Terrell

Charges of discrimination and bad science are dampening excitement at Schering-Plough this year about a whole new type of drug that might treat hepatitis C virus (HCV) sufferers who don't benefit from the current two-drug regimen. "It is totally unacceptable," says Tracy Swan of the New York-based [Treatment Action Group \(TAG\)](#) about the way the pharmaceutical company purposefully excluded African Americans from the first stages of clinical trials on its new HCV protease inhibitor, SCH 503034. "Could you do that with women? Gays and lesbians? The risks and benefits of participating in research should be divided equally."

Schering-Plough is adamant that its recruiting practices are sound—and FDA-approved. Spokesman Robert J. Cansalvo argues that because black people are known to respond poorly to one of the drugs that SCH 503034 is being tested with, including them as subjects in early, smaller trials would have been unnecessary. "It's a question of timing when to include them," he says, pointing out that African Americans will definitely be in the next round of trials—in large enough numbers to measure any race-related problems or benefits.

Some HCV experts and activists agree that the SCH 503034 trials are proceeding just fine and that Schering-Plough should be left alone on this minor technicality so that this valuable product might move closer to market.

But critics like the [Community HIV/AIDS Mobilization \(CHAMP\)](#) and Hepatitis C Action and Advocacy Coalition (HAAC) see a disservice to both African Americans and research, especially given that HCV is three times more common among them than whites; cure rates are lower for African Americans on the existing meds; and they are more susceptible to complications of HCV infection such as liver cancer, end-stage liver failure, cirrhosis and death.

"We would understand if the exclusion was about safety," says HAAC's James Learned. For instance, he says, he has no problem with Schering's decision not to include HIV positive subjects in these trials for fear that their HIV meds might react with the experimental drugs—even though hepatitis-related liver disease is the leading cause of death for Americans with HIV. "Safety does not seem to be the issue here," he says, but rather "buzz" and "making your group look good."

Cansalvo finds these criticisms "ridiculous." He says, "We are committed to finding help for all African Americans who have hep C." Some activists join Schering-Plough in worrying that CHAMP

and HAAC might have unduly alarmed the African-American community.

Racial questions about prescription drugs and even the origins of some diseases hardly fall on deaf ears. According to a University of Houston [study](#) reported last month in the Journal of Acquired Immune Deficiency Syndromes, 30% of Texas African Americans and 22% of Texas Latinos believe HIV is a government conspiracy to kill minorities.

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