Targeting Groups for New Drugs Questioned

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WASHINGTON — Drugs like BiDil that target a particular racial or ethnic group do not represent the best approach for looking at health disparities, Dr. Francis S. Collins said at a meeting sponsored by the Department of Health and Human Services and the Office of Minority Health.

"It is a good thing that we have a drug that treats individuals with congestive heart failure and clearly improves their survival," said Dr. Collins, director of the National Human Genome Research Institute, in Bethesda, Md. "But are we sure that this came about in a way that actually makes the most sense? Are we sure this drug would not have benefited other groups?"

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Although the original clinical trial for BiDil (fixed-dose isosorbide dinitrate and hydralazine) appeared to show that only African Americans clearly benefited from the drug, "it was a relatively modest-sized study, and there could very well have been some benefit in others," Dr. Collins said. "Are we sure that this has anything to do with being African American, or could it be that since African Americans tend to have heart failure on the basis of hypertension, that this [study] says this drug works for hypertensive heart failure and not as well for heart failure from coronary artery disease, which is perhaps more common in other groups?"

By lumping the responders into the category of a racial group, "there's a real risk that this will be interpreted as, 'Oh, well, that means black people really are biologically different. After all, there is this drug that only works for them,' " said Dr. Collins. "That is unjustified by the science that's been done here."

More drugs like BiDil may be coming, but "I don't think this is where we want to go," he said. "I think we want to go in the direction of figuring out, 'Okay, if this drug works for some people and not others, why is that? What specific DNA variants are responsible for the variation in response?' Let's check the individuals and find out whether they're likely to respond to the drug or not, and not use this very murky and potentially misleading and damaging proxy called race, and pretend that we're practicing really upscale medicine. We can do better than that."

Part of the problem with using racial groups to explain health disparities is that race is hard to define, Dr. Collins noted.

"First you have to decide exactly what you mean by race. Race has so much baggage; it carries with it connotations of history and discrimination, culture and society, and dietary practices. It carries a little bit of ancestral geography, of course, but that is probably in the minority of what most people are actually thinking of when the term race appears in the census," he said.

Another problem with separating people into races is that the genetic makeup of all humans is actually quite similar, said Dr. Collins, who leads the Human Genome Project. He noted that people are 99.9% the same, genetically speaking.

"We are much more alike … than most other species on the planet. There's more diversity in a small group of chimpanzees living on one hillside than there is in the entire human race, because we're so new on the scene."

Now that the Human Genome Project and other private groups have decoded the human genome, researchers are focusing on the 0.1% of the genome that varies among individuals. Dr. Collins is currently managing the International HapMap Project, a cooperative effort among researchers in six countries to build a catalog of human genetic variation.

"In the space of just 3 years, the HapMap has delivered this remarkable picture of how DNA variation has occurred across all chromosomes," he said. "This has been a gold mine of information for people trying to unravel the genetic contributions of diabetes, heart disease, mental illness, blindness, and a whole host of conditions that fill up our hospitals and our clinics." ■

Information on the International HapMap Project can be found online at www.hapmap.org.