There Is No Scientific Rationale for Race-Based Research

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For centuries, the colonial governments used a combination of race and ethnic characteristics to subjugate and control people of color, and scientists of the day provided evidence of the "natural order of things" to support national policies of domination, segregation and control. There have been many examples of events in the past 70 years to suggest that achievements by ethnic peoples are not genetically determined and that race and ethnicity are merely terms to describe external features, language, culture, social mores and folklore. BiDil® was the first drug in this country approved by the FDA for use in a single "race" after a clinical trial that enrolled only members of that race. Thus arose the question of the efficacy of doing race-based research in humans. In order for this kind of research to have any scientific basis, each individually defined or self-declared race would have to have a 100% pure gene pool, and the data show that the gene pool among whites, blacks and Hispanics in America is very heterogeneous. This makes for far greater similarities among U.S. citizens than any perceived differences, and genomic science has failed to support the concept of racial categories in medicine. Scientists involved with the first mapping of the human genome have noted that there is no basis in the genetic code for race. That being the case, there appears to be no justification for race-based research among human beings.

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Although the United States has experienced enormous improvements in its healthcare system over the past half-century, there are still widening disparities in most disease processes between whites and blacks/Hispanics.[1] There has been much debate as to how these disparities can be eliminated, but simple, logical programs that could be tailored to specific minority communities in different geographical locations have not proven to be practical for a variety of reasons. To be sure, disparities in healthcare, like anything else, are a function of a variety of factors, including education, environment, income and culture, among others. Race and ethnicity are important determinants of some of these functions, thus raising the question as to whether these parameters may, in fact, be determinants of outcome in some of these disease processes based upon genetics as well as the aforementioned risk factors.

Such may be the case with the drug, BiDil, which was the first drug in this country to be approved by the Food and Drug Administration for a single ethnic-racial group as a result of clinical trials that were conducted solely within that one race for the treatment of congestive heart failure and, thus, the efficacy of the drug in other race and ethnic groups is unknown.[2] My colleague, Dr. Robert Sade, has done an excellent job of recounting the various clinical trials that led to the development of BiDil in his accompanying "pro" editorial, and I will not restate them here. Suffice it to say that an analysis of an earlier clinical trial, the second Vasodilator-Heart Failure Trial, suggested that whites had disproportionate benefit from enalapril, whereas blacks benefited more from isosorbide-hydralazine therapy, and the commercial firm, NitroMed, tested the hypothesis that this combination added to a program that already included an angiotensin-converting enzyme (ACE) inhibitor might prove to be efficacious in blacks with congestive heart failure.[3] Therefore, BiDil is not a new drug, just the result of a successful marketing strategy resulting in a product that costs up to seven times that of its two generic components. This obviously has created considerable controversy and, thus, it becomes necessary to explore how race and ethnicity are applied to scientific research.

In its most elemental form, ethnicity is an expression of language, culture, social mores and folklore, while race is determined by external features—the most important of which are skin color, facial features and hair texture. In the 19th century, scientists ascribed intelligence to the size of the cranial cavity, the brain and the shape of the skull, and over time, society used this bogus information to formulate and justify colonialism, slavery, social standing and national policies about the

exclusion of populations and certainly integration and immigration policies and procedures.[4] However, the discovery of the Neanderthal man across the whole of Europe extending eastward to the foothills of the Himalayas, and the fact that his brain and cranial vault was larger than that of subsequent homo sapiens negates this theory out of hand.

Nevertheless, such train of thought set the standards for biological research for centuries based upon the supposition that the "natural order of things" was determined by biology and by extrapolation as scientific knowledge progressed to include genetics. As recently as World War II, U.S. military officials were firmly convinced that the Japanese as a race had poor night vision because of the contour of their eyes, suggesting that they had to "squint just to see in the daylight hours," thus rendering them less effective in night combat until the Japanese came storming ashore at 10 p.m. on the night of December 13, 1941, when they began their assault on Hong Kong and when American troops encountered the infamous night time "banzai attacks" in the Pacific theater.[5] Some 20 years later, the nation's premier athletic coaches and managers were absolutely convinced that black athletes did not have the mental capacity to master the nuances and intricacies of basketball or baseball, and their opinions about a black being able to play the quarterback position at a white college or the professional football leagues were simply unfathomable. These opinions were formulated despite the fact that there was evidence to the contrary throughout the land at the time, especially in the Negro Baseball League.

Even today, a large number of white America is probably unaware of the outstanding contributions blacks have made to the world, including inventing the traffic light, refrigerator, the elevator, air conditioning, the refrigeration unit for tractor-trailer trucks, the incandescent light bulb, the golf tee, air brakes for trains; or that 1,000 patents that were issued to blacks in the year 1913 alone; or the fact that a black scientist, Nortover, discovered the process of passing light through spools of glassfibre, thus making way for the present-day fiberoptic industry; nor the fact that the original Duke University campus was designed by an African-American architect, Julian Francis Abele; or the contribution to the advancement of cardiac surgery by Vivian Thomas at Vanderbilt and Johns Hopkins Hospital.[6-8]

While it is certainly true that American plantation owners bred their slaves just as they did their livestock, that same biological racism still lingers now that major league and college sports are now disproportionately populated by black athletes. In other words, "their genetic make-up" has been suggested as being accountable for their prowess in these areas. Thus, one must counter this question or argument as to what is the genetic basis explaining the disproportionate numbers of blacks and Hispanics serving as "boots on the ground" in the Middle East: is patriotism genetically determined?

Modern-day science has amassed enough evidence to suggest that there is very little biological difference between the various races.[9] In order for race-based research to have any scientific basis, each individually defined or self-declared race would have to have a 100% pure and homogenous gene pool. Some racial and ethnic groups have a very heterogeneous gene pool, such as whites and Hispanics.[9] The same scientific data show that approximately 80% of American blacks have some degree of white ancestry, and although not so nearly well publicized is the fact that many whites also have black and Hispanic ancestry.[10] This would make for far greater similarities in the U.S. black/white gene pool than any perceived differences, and genomic science has failed to support the concept of racial categories in medicine and further purports that there is more genetic diversity within a "racial cohort" than any differences between two such cohorts.[11] Craig Venter, who helped produce the first map of the human genome, noted that there is no basis in the genetic code for race.[12] That being the case, race then becomes rather meaningless in scientific research. This would obviously include race-based pharmaceutical research that resulted in the drug BiDil. This is not to be confused with the fact that race indeed affects both access and outcomes in our healthcare system, as it most certainly does. Even black medical professionals do not enjoy the same access to highly specialized services as their white counterparts, such as coronary artery bypass grafting, but the basis is not biological and by extension, not genetically determined.

One's environment over time tempers adaptability, thus facilitating or ensuring survival. We can be sure that he first rendition of the camel could not have survived life in the desert as does the current model. So there are, perhaps, some areas in which the gene pool is pure enough to lend itself to race-based research. Examples might include the Ashkenazi Jews and breast cancer, sub-Saharan populations that developed the sickle cell blood disorder in order to ward off malaria and perhaps other tropical diseases. Even the diseases in these special populations could probably be bred out over time. After all, this was the intent of the program in western Australia depicted in the movie "Rabbit Proof Fence" in which half-caste offspring of white Australians and Aborigine women were forceably removed form their homes and taken thousands of miles away to government-run camps in a form of indentured servitude to be trained as domestic workers and integrated into white society by continuously breeding the "Aborigine" gene pool out of them.[13] Cows are a good example of what selective breeding can accomplish over time, as the aggression has been completely bred out of these now-docile, domesticated animals. I often wondered by the Africans never domesticated zebras as beasts of burden as the rest of the world did the horse. Apparently, there were many

such attempts, but too few were successful. Apparently, a group of American cowboys traveled to Africa to do just that only to discover that zebras have such excellent peripheral vision and reflexes that they can almost always avoid being lassoed. And if you did manage to lasso one, you would soon wish that you had not because of the ferocity of their kicking and biting. A Cape Town guidebook noted in 1819 that "the zebra is said to be wholly beyond the government of man."[14,15] But who is to say that 200 years from now some enterprising African entrepreneurs might not have captured some baby zebras and bred this aggression out of them and trained them in captivity, thus producing a brand for show, pleasure and work. Mother Nature has a pretty good way of deciding biological equivalency. If you look beyond the offspring of a horse and a jackass, i.e., a mule, mating between biologically incompatible animals will not produce an offspring. One can surmise that biological systems are reasonably equivalent for any animals whose mating will produce a like offspring so the physiology, biochemistry and pathology of the parents should be pretty much the same. So again, race-based research does not appear to have a place in medical research.

In conclusion, while scientists may have "stumbled" upon Bidil as a success story involving race-based research, the data would suggest that to have this concept be the linchpin of all future medical research has no merit, at least in a population as heterogeneous as that of the United States, and the buyer should beware. Nevertheless, it is still important that all such clinical trials include blacks, Hispanics and females as is currently mandated by the National Institutes of Health. For the many years that I served on various NIH panels and study sections, one of my assignments always was to address the issue of the inclusion of women and minorities in the study, and many times the investigators had done a yeoman's job in attempting to reach minority and women patients through various professional associations without much success. Perhaps this is an area that the National Medical Association and the National Association of Hispanic Physicians and others can be of assistance to investigators through education and recruitment of minority physicians and patients. However, in doing so, we must be ever vigilant about interpreting the actions of the FDA arm of the federal government as justification for the government to use race as a biological marker. Examples of the extremes of such thinking abound throughout the world today.

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