

6/3/05

Perry W. Payne, Jr., MD/JD/MPP  
Project Manager/Co-Investigator  
CEER Planning Grant for Center on Genomics and Social Identity in the  
African Diaspora  
National Human Genome Center, Howard University  
2216 6th Street, NW - Suite 207  
Washington, DC 20059  
Phone - 202-806-4434  
Fax - 202-265-1434  
[ppayne@genomecenter.howard.edu](mailto:ppayne@genomecenter.howard.edu)

Cathy Groupe  
FDA Advisors and Consultants Staff  
5630 Fishers Lane, HFD-21  
Rockville, MD 20857

Dear Cathy Groupe/ Cardiovascular and Renal Drugs Advisory Committee:

This letter is written to provide a brief sociological/bioethical analysis of the use of the Census category "Black or African American" as an indication for the drug Bidil (isorbide dinitrate and hydralazine) and other drugs reviewed by the FDA in the future with a similar potential use. This letter is also meant to provide meaningful analysis with regard to the present or future use of *any* US Census Bureau racial/ethnic category as an indication for a drug. There is one major question which must be addressed to understand the potential benefits and dangers of using Black or African American as an indication for Bidil or any other prescription drug. The question is: Who does the Census category "African American" represent? The answer to this question is a model for analyses related to the use of other Census

categories, including White, Asian, Hispanic, and American Indian as indications for prescription drugs.

### Who does the Census category "African American" represent?

The US Census Bureau defines Black or African American as:

"a person having origins in any of the Black racial groups of Africa. It includes people who label themselves as 'Black, African Am., or Negro,' or provide written entries such as African American, Afro American, Kenyan, Nigerian, or Haitian."<sup>1</sup>

Unfortunately, the Census Bureau does not provide a definition of "Black racial group." There is no discussion in any of their methodology materials of what physical or cultural traits one must have to be considered "Black." Hence, the definition of Black or African American contains ambiguities and open questions making the labeling of a person from this group highly subjective and not evidence-based. This same subjective quality exists for other Census categories for race/ethnicity. Using such subjective information as an indication for prescribing a drug with known harmful effects runs counter to the principles of evidence-based medicine, and is inappropriate medical practice given the current state of medical and sociological knowledge that exists today.<sup>2</sup> Such medical practice would likely receive little favor in the US court system.

---

<sup>1</sup> Race [definitions], US Census Bureau, available at [http://quickfacts.census.gov/qfd/meta/long\\_68176.htm](http://quickfacts.census.gov/qfd/meta/long_68176.htm).

<sup>2</sup> Evidence based medicine has been defined as: "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." David

Strangely, the definition for Black or African American excludes North Africans who are actually labeled as “White” for the purposes of the US Census Bureau.<sup>3</sup> There are two problems with this approach. First, the Census Bureau’s categorization of North Africans actually runs counter to how North Africans identify themselves. **Chart 1** of this document provides the reported ethnic composition of North African countries at the present time. The data from the chart comes from one of the best sources of data on populations internationally, the US Central Intelligence Agency. In many cases, North Africans classify themselves as “black.” Hence, the Census categories have an inherent problem in which some people automatically fit in the black and white category. Hence, scientists seeking to use these categories would need some way to actually distinguish the differences between the “black” and “white” components of such individuals, in order to truly assign medical characteristics to them. Of course, the preposterous nature of this idea, leads a reasonable researcher to understand that Census categories convey little objective information for evidence-based medicine in the 21<sup>st</sup> century. Secondly, the definition of North Africa is not clearly defined by the Census Bureau, thereby increasing the subjective nature of the label “White” and “Black/African

---

Sackett, et al. "Evidence Based Medicine: What It Is and What It Isn't," *BMJ* 312, no.7023 (1996).

<sup>3</sup> Race [definitions], US Census Bureau, available at [http://quickfacts.census.gov/qfd/meta/long\\_68176.htm](http://quickfacts.census.gov/qfd/meta/long_68176.htm).

American.” Encyclopedia Britannica indicates that the definition of North Africa is itself a question:

“The geographic entity North Africa has no single accepted definition. It has been regarded by some as stretching from the Atlantic shores of Morocco in the west to the Suez Canal and the Red Sea in the east, though this is more commonly referred to as northern Africa.”<sup>4</sup>

In addition, according to Encyclopedia Britannica, the original peoples of North Africa were Berbers, not “whites.”<sup>5</sup> Berbers, today, are composed of people with various skin tones and cultural backgrounds. This evidence further supports the highly subjective nature of Census categories with regard to race/ethnicity.

People who may consider themselves Arabs are also labeled White by the Census Bureau. Given the history of Arab migration through Africa prior to the Middle Passage and TransAtlantic Slave Trade, a substantial number of “Black or African American” people are descendants of Arabs and Africans whether or not they are aware of this ancestry. Thus, this is another situation where numerous individuals who label themselves Black or African American are also White American according to the Census Bureau. Many individuals who label themselves Black or African American also have

---

<sup>4</sup> Encyclopedia Britannica Online, <http://www.britannica.com/eb/article?tocId=9110706>.

<sup>5</sup> According to Encyclopedia Britannica Online:

**Berber**-speakers were the original inhabitants of North Africa, though many regions succumbed to colonization by the Roman Republic and Empire and later (from the 7th century AD) to conquest by the Arabs. Berbers gradually accepted Islam, and many switched to Arabic or became bilingual. Berber languages are still spoken in some rural and mountain areas of Morocco and Algeria and by some inhabitants of Tunisia and Libya. Since the 1990s Berber intellectuals have sought to revive interest in the language. The Berber-speaking Almoravid and Almohad dynasties built empires in North Africa and Spain in the 11th–13th centuries.” Available at <http://www.britannica.com/ebc/article?tocId=9357056&query=berber&ct=>

European heritage which they may choose not to recognize for political reasons or are not aware of because of gaps in their family history due to slavery and Jim Crow, oppressive systems which prevented stable family development numerous Americans. This ancestry is reflected in the growing “multi-racial” grouping of the Census. Also, given that a person can marry whomever they choose today without any repercussions, people of all types marry each other and have children. Their children decide which political grouping they want to associate with based on personal preference, not an objective evaluation of their ancestry. Their choice may be completely different from their true geographic genetic ancestry<sup>6</sup>, but the choice is theirs. For example, a “White” South African child with European geographic ancestral heritage may label themselves African American, because of their families lineage in South Africa for three or four generations. Although this child may fit the traditional “skin color-centric” understanding of Black or African American in the United States, he can choose this category and feel quite comfortable with it, given his African heritage and culture. However, a physician should not assume that being African American will convey some medical information about this person based on the label he/she chooses on a US Census form. Similarly a person who with Indian geographic heritage living in South African for multiple generations or Tiger Woods, a person with multiple geographic ancestries, can also mark African American on a form. The subjective nature of the category allows any person to self-report

---

<sup>6</sup> I am using the term “geographic genetic ancestry” to refer to any genetic ancestral markers individuals may possess which provide clues regarding the migration of their ancestors from one physical geographic point on the earth to another.

themselves as Black or African American. This is a far cry from objective groupings needed to compare medical treatment methodologies.

At best African American has some political meaning to individuals. The meaning springs from a history of racism during the US apartheid/Jim Crow era during which people were categorized as inferior due to their dark skin color. Although this political group has always contained members who have a wide variety of skin colors, the political use of this term links these individuals and their geographic ancestral heritage and culture. Such political uniting helped develop the Civil Rights Movement and provide numbers for various social struggles. However, this labeling, as shown above, is quite ambiguous for classifying people and has no objectively defined meaning for labeling populations in medical research studies.

I ask that the committee takes the subjective nature of the Census category "Black or African American" into account when assessing any prescription drugs which claim to work better in this highly subjective population grouping as compared with other highly subjective population groupings. This analysis should also be used with regard to claims that prescription drugs are more effective for other highly subjective Census category groupings such as White, Asian, Hispanic, and American Indian. I ask that the committee also work with scientists to develop protocols that allow them to recruit patients with diverse physical geographic ancestries based on family history and/or genetic ancestry testing. Such groupings are much more meaningful and move medical research closer to finding out information that will be helpful in curing disease. Thank you for taking time to read this statement.

Respectfully,

Perry W. Payne, Jr., MD/JD/MPP

## CHART ONE - Ethnic Groups<sup>7</sup> of North Africa<sup>8</sup>

Country	Ethnic Groups
Algeria – Ethnic Groups -	<p>Arab-Berber 99%, European less than 1%</p> <p><i>note:</i> almost all Algerians are Berber in origin, not Arab; the minority who identify themselves as Berber live mostly in the mountainous region of Kabylie east of Algiers; the Berbers are also Muslim but identify with their Berber rather than Arab cultural heritage; Berbers have long agitated, sometimes violently, for autonomy; the government is unlikely to grant autonomy but has offered to begin sponsoring teaching Berber language in schools</p>

<sup>7</sup> Data taken from the US Central Intelligence Agency Factbook, <http://www.cia.gov/cia/publications/factbook/index.html>

<sup>8</sup> Although the concept of North Africa is ill-defined as stated earlier in the document, a popular online reference indicates that North Africa is generally considered to include: 1) Algeria; 2) Egypt; 3) Libya; 4) Mauritania; 5) Morocco; 6) Sudan; 7) Tunisia; and 8) Western Sahara. Available at [http://en.wikipedia.org/wiki/North\\_Africa](http://en.wikipedia.org/wiki/North_Africa).

Egypt	Eastern Hamitic stock (Egyptians, Bedouins, and Berbers <sup>9</sup> ) 99%, Greek, Nubian, Armenian, other European (primarily Italian and French) 1%
Libya	Berber and Arab 97%, Greeks, Maltese, Italians, Egyptians, Pakistanis, Turks, Indians, Tunisians
Mauritania	<b>mixed Maur/black 40%</b> , Moor 30%, <b>black 30%</b>
Morocco	Arab-Berber 99.1%, other 0.7%, Jewish 0.2%
Sudan	- <b>black 52%</b> , Arab 39%, Beja 6%, foreigners 2%, other 1%
Tunisia	Arab 98%, European 1%, Jewish and other 1%
Western Sahara	Arab, Berber

<sup>9</sup> Berbers range in skin color and phenotypic features. Some would classify themselves as dark skinned and others as light skinned. Many would be consider "Black" by American skin color standards of being darker than certain individuals with only European ancestry. However, others would be considered "White." Such ambiguities point to the major problem of using a political category, like White American, for a drug indication.