# Vitamin D and the FDA

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## Abstract

The Food and Drug Administration (FDA) knows that vitamin D deficiency is much more common among African Americans than white Americans. The FDA knows that vitamin D deficiency is associated with numerous health problems in the African American community. The FDA knows that many African Americans do not, and perhaps cannot, consume lactose containing milk products due to lactose intolerance. In spite of these facts, the FDA uses milk to deliver supplementary vitamin D to Americans. In fact, virtually all the foods the FDA mandates to contain vitamin D are lactose containing milk products—the one food most African Americans do not consume. The FDA could easily mandate other foods contain vitamin D, such as cheese, yogurt or cereal grains—foods African Americans do consume. (© Copyright 2005, Pearblossom Private School, Inc.–All rights reserved.

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#### 1. Discussion

Compared to Whites, African Americans bear a greatly increased risk of suffering and dying from numerous diseases, including the major killers: heart disease, cancer, hypertension and diabetes. A recent review by Professor Lundy Braun of Brown University concluded, "Over the past decade, numerous studies have documented profound racial and ethnic disparities in disease in the United States [1]."

Medical science has recently identified another condition that shows a striking racial inequity, vitamin D deficiency. Last year, the world's best known authority on vitamin D, Professor Michael Holick of Boston University, wrote, "Vitamin D deficiency is an unrecognized epidemic among both children and adults in the United States [2]." Furthermore, in 2003, the FDA's own employee warned the FDA that vitamin D deficiency is common in the U.S. and "the prevalence of [vitamin D deficiency] in the United States is increasing [3]."

While the epidemic of vitamin D deficiency is problematic for all Americans, its incidence among African Americans is close to universal. Blacks are about three times as likely to be vitamin D deficient as whites [4]. Two years ago, the same FDA employee warned the FDA that vitamin D deficiency was "an alarming two to eight times higher among blacks [3]." Last year, the same employee again warned the FDA that African Americans are more likely to be vitamin D deficient than whites [5].

The unkindest cut of all befalls African American infants. African American women of childbearing age are ten times more likely to be vitamin D deficient than white women [6]. In fact, many African American women of childbearing age have undetectable blood levels, a startling fact when one considers this substance appears to be crucial for optimal growth and development of the fetus [7].

Dr. Kathleen Fuller, of the Center for the Study of Race and Ethnicity in Medicine of the University of Kansas School of Medicine, noted vitamin D deficiency in African American mothers explains the fact that black babies are more than twice as likely to be low-birth-weight as white children [8]. Furthermore, unless adequately supplemented, the breast milk of most American women contains insufficient, often undetectable, levels of vitamin D, with African Americans, again, being unfairly impacted. These problems are easily prevented with adequate maternal supplementation. Professor Hollis and his colleagues at the Medical University of South Carolina recently demonstrated that supplementing lactating mothers with 4,000 units of vitamin D a day turns breast milk into a rich source of vitamin D and fully corrects vitamin D deficiencies of both the mother and the nursing infant [9].

Eighty-three percent of all American children diagnosed with vitamin D deficient rickets in the last 17 years were African Americans [10]. Furthermore, vitamin D deficiency is now unquestionably associated with the diseases that disparately, and prematurely, kill African Americans. All of the major killers in the African American community are linked with vitamin D deficiency, including heart disease, cancer, hypertension, kidney disease, and diabetes [11-18]. It is quite possible that vitamin D deficiency explains a significant part of the reason African Americans die younger than whites.

Once again, the FDA's own employee warned the FDA about the alarming associations of vitamin D deficiency with chronic disease in the African American community. Writing in 2003, Dr. Mona Calvo said, "In sharp contrast to their white counterparts, blacks have a much higher incidence and mortality of certain types of aggressive cancers and autoimmune diseases, including diabetes, that cannot be attributed entirely to socioeconomic differences or disparities in health care. The strong association between vitamin D insufficiency and risk of chronic diseases should raise concern about the current mechanisms in place to prevent [vitamin D deficiency] [3]."

Although named a vitamin, Vitamin D is unlike any other vitamin. It is a prehormone normally made in the skin by ultraviolet radiation from the sun. Vitamin D is the body's only source of a potent steroid hormone, calcitriol. In fact, calcitriol is the most potent steroid hormone in the human body, being active in picogram quantities. Like all steroid hormones, calcitriol works by demasking the genome; that is, it regulates the genetic production of hundreds of proteins and enzymes in the human body. Through its potent actions on the human genome, calcitriol is intimately involved with numerous and disparate biochemical and physiological processes, and thus with a multitude of diseases. For a review of the physiology of vitamin D, and a growing list of diseases associated with vitamin D deficiency, see Holick [2].

Unless they expressly avoid the sun, European Americans can easily obtain adequate vitamin D from sunlight. Such is not the case with African Americans. African American skin is designed for Africa. White skin manufactures vitamin D very quickly; black skin requires up to ten times more sun exposure to make the same quantity of vitamin D [19]. Therefore, supplementation through diet is crucial to the health of African Americans. Furthermore, with the exception of some fish, significant amounts of vitamin D do not exist in the foods humans normally consume—unless it is added through fortification. That is, if we don't (or can't) get vitamin D from the sun, we must get it from supplements or from fortified foods.

The FDA oversees and regulates food fortification in the USA through Title 21 of the Code of Federal Regulations (CFR). The FDA only mandates that one food be fortified with vitamin D: evaporated milk (21 CFR 131.130), which contains lactose, or milk sugar. The FDA allows, but does not mandate, other foods to be supplemented with vitamin D, such as other fortified milk products, certain grain products, margarine and calcium fortified fruit drinks (see 21 CFR 137.305; 137.350; 137.260; 139.155; 139.115; 131.110; 131.111; 131.112; 131.115; 131.147; 131.200; 131.203; 131.206; 166.110 and 172.380).

As pointed out by the FDA's own employee, the vast majority of all the vitamin D consumed in fortified foods is consumed in the form of lactose containing milk products [20]. The only food mandated by Title 21 to contain vitamin D are lactose containing milk products. The FDA also knows that the milk industry chooses to supplement virtually all fresh milk, which also contains lactose, with vitamin D. The FDA encourages them to do so through 21 CFR 131.110. Therefore, through a combination of mandated and encouraged practices, the FDA uses lactose containing milk products to deliver virtually all supplemental dietary vitamin D to Americans.

While the FDA uses lactose containing milk products to deliver vitamin D, most African Americans do not drink much milk. More than 75% of African Americans suffer from some degree of lactase deficiency (they lack sufficient lactase enzyme in the intestine to fully digest lactose and thus have some degree of milk intolerance) [21,22]. A recent study demonstrated that lactose intolerance does not persist in humans who regularly drink milk, as intestinal bacteria develop the ability to digest lactose. Furthermore, avoidance of lactose may be as much cultural as it is medical [23]. What no one debates, however, is the fact that most African Americans drink very little milk [20,24].

Again, the FDA knows of these problems. In 2003, Dr. Calvo warned the FDA that vitamin D fortification of foodstuffs in America is not preventing vitamin D deficiency in African Americans [3]. Last year, she said, "The racial/ethnicity groups at greatest risk of vitamin D insufficiency consume less milk ... than do their white counterparts." She went on to say, "African Americans, with the greatest physiological need for dietary sources of vitamin D, have the lowest intake from food alone and food plus supplements [20]." In spite of this, the FDA continues to rely mainly on lactose containing foods to deliver supplementary vitamin D, knowing African Americans consume few such products.

The FDA recently changed regulations to allow voluntary supplementation of fruit juice with vitamin D. Although a step in the right direction, such voluntary supplementation is unlikely to make much impact on endemic vitamin D deficiency in the African American community.

Certainly, once the FDA undertook an effort to address vitamin D deficiency, and they have done just that by mandating certain milk products contain vitamin D, they assumed the obligation to address that problem equitably. African Americans deserve equal protection against vitamin D deficiency. Furthermore, the FDA knows African Americans are more likely to suffer from vitamin D deficiency but chooses to make no special efforts to address African Americans' special needs. Instead, they mandate fortification of food which helps whites but not blacks.

In the past, and under similar circumstances, the federal government has acted to assure that food fortification policies address known health needs. For example, in 1943, the government mandated that flour be enriched with niacin to prevent pellagra. More recently, the FDA began a policy of enriching cereal grain products with folic acid to prevent birth defects in infants. The ill effects of vitamin D deficiency may dwarf these other two problems. In the words of Professor Robert Heaney, another world class expert on vitamin D, "the cost of vitamin D deficiency, while yet to be fully reckoned, may well be massive [25]."

Foods other than milk could be supplemented with vitamin D, such as cheese, yogurt, or cereal grains; all of which are consumed by blacks. Experts have recently called upon the FDA to mandate enrichment of cereal grain products with both vitamin D and calcium [26]. Such a mandated enrichment program would safely, and cheaply, provide more vitamin D and calcium to African Americans. Furthermore, Black's inability to drink milk, combined with the failure of the FDA to mandate fortification of cereal grain products with vitamin D and calcium (calcium is required for many of vitamin D's functions) also ensures that many African Americans ingest calcium deficient diets [27,28].

The FDA's policies are even more egregious when one remembers that African Americans were forced to live at North American latitudes, against their will, via the slave trade. Now, they find themselves a class of Americans at risk for a serious medical condition, vitamin D deficiency, which is a direct result of the fact their skin pigmentation is designed for equatorial latitudes, not North American latitudes. The USA gets 20 times less vitamin D producing ultraviolet light every year than does equatorial African zones [29].

The FDA did not choose to fortify milk with vitamin D to deliberately hurt African Americans. The decision to use milk to deliver supplementary was made many years ago, before it was known that African Americans consume little milk. Now, it is well-known that blacks do not consume much milk. Whites can and do drink milk but are less likely to need it in the first place—due to their light skin making vitamin D from sunlight. Therefore, the FDA's current policies and practices are specifically helping whites but not blacks. The FDA's policies and practices actually assure that blacks, who get very little vitamin D from the sun, will get little in their diet. That is, the FDA's policies help the class of people who need the least help and hurt the class of people who need the most help. The fact that most African Americans consume little milk means that the FDA's policy ensures that vitamin D deficiency is widespread in the African American community.

African Americans have the right to expect that the FDA's food fortification policies treat African Americans fairly and equitably under the law. In fact, the FDA's policy fails to treat African Americans fairly and equitably because the FDA mandates fortification of a food white Americans consume but fails to mandate vitamin D fortification of foods that blacks consume. The FDA's action, codified in Title 21 of the Code of Federal Regulations, has the force of federal law and thus appears to be a violation of equal protection clauses of the U.S. Constitution. The FDA is denying a class of persons "within its jurisdiction the equal protection of the laws."

## 2. Conclusions

The FDA should take the following steps:

- 1. The FDA should immediately consult with experts in the African American medical and scientific community, such as the National Medical Association, to compile a list of foods frequently consumed by African Americans and make recommendations on more equitable food fortification.
- 2. After appropriate consultation, the FDA should revise its food fortification policies to assure that African Americans are receiving adequate amounts of vitamin D and calcium in fortified foods. Their future food fortification policies should make a good faith effort to correct the disparate and inequitable rate of vitamin D deficiency in the African American community.
- 3. The FDA should take steps to see that those subgroups of African Americans with the highest rate of vitamin D deficiency, such as pregnant African Americans, African American infants, and African American women of childbearing age are further supplemented with vitamin D.
- 4. The FDA should also revise its recommendations concerning vitamin D supplementation during lactation to assure that African American breast milk becomes an adequate source of vitamin D.
- 5. Although it may not be required under the Fourteenth Amendment, the FDA should consider undertaking further food fortification policy revisions in an attempt to assure that no American, of any color, suffers from vitamin D deficiency.

6. The FDA should undertake a public education effort to warn all Americans about vitamin D deficiency and take extra steps to target African Americans with that message.

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