

The Honorable Eric H. Holder, Jr., U.S. Attorney General, Department of Justice
950 Pennsylvania Avenue, NW, Washington, DC 20530-0001

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| The Vitamin D Council | * | Violation of the Fifth |
| Complainant | * | Amendment |
| | * | Violation of Human Rights |
| v. | * | Violation of Equal Protection |
| | * | Inadequate Vitamin D |
| Margaret Hamburg, M.D., | * | Supplementation under |
| In Her Official Capacity as Acting | * | Title 21 of the Code |
| Commissioner Of the United States | * | Federal Regulations |
| Food and Drug Administration | * | |
| (FDA) | * | |
| Defendant. | * | |

COMPLAINT REQUESTING DECLARATORY AND INJUNCTIVE RELIEF

The Complainant, the Vitamin D Council, hereby submits the following Complaint requesting you seek declaratory and mandatory injunctive relief pursuant to 28 U.S.C. §§ 2201-2202 and 5 U.S.C. §§ 701-706 and states:

PRELIMINARY STATEMENT

1. Vitamin D deficiency is associated with over one-hundred health problems, not just osteoporosis.
2. Vitamin D deficiency disparately afflicts African Americans.
3. The FDA knows African Americans consume few milk products.

4. The FDA knows that milk products are the main vehicle for vitamin D fortification. Through a combination of mandated and encouraged practices, the FDA depends upon milk to deliver virtually all supplemental dietary vitamin D to Americans. In fact, under Title 21 of the Code of Federal Regulations, the FDA only mandates that vitamin D be fortified in nonfat fortified milk and evaporated milk.

5. As a result of the FDA's policies, vitamin D deficiency and the diseases associated with this deficiency disparately afflicts African Americans.

JURISDICTION AND VENUE

6. The United States District Court for the District of Columbia would have original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 in that this action arises under the Fifth Amendment of the Constitution of the United States and the regulations of the FDA having the force of laws of the United States. The cause of action would be for declaratory and injunctive relief pursuant to 28 U.S.C. §§ 2201-2202, 5 U.S.C. §§ 701-706, and 21 C.F.R. § 10.45. Venue in this judicial district is proper pursuant to 28 U.S.C. §1391(e).

PARTIES

7. The Complainant is a not for profit corporation whose purpose is to research vitamin D related health issues and to educate the public and the professional

community about the occurrence of diseases and illness caused by vitamin D deficiency and the prevention and treatment of those conditions.

8. The defendant would be Margaret Hamburg, M.D., Acting Commissioner of the FDA, an executive agency. See 21 U.S.C. § 393.

9. The Plaintiff would be Attorney General Eric H. Holder, Jr. of the United States Department of Justice in his capacity as chief law enforcement officer of the Federal Government.

FACTUAL ALLEGATIONS

10. African Americans, as compared to other ethnic or racial groups, bear a greatly increased risk of suffering and dying from numerous diseases, including heart disease, cancer, hypertension, and diabetes. A 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

11. Medical science has identified another condition that shows a striking racial inequity: vitamin D deficiency. 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

12. In 2003, the FDA's own employees warned that vitamin D deficiency is common in the U.S. and "the prevalence of [vitamin D deficiency] in the United States is increasing." ³

13. More importantly, while the epidemic of vitamin D deficiency is problematic for all Americans, its incidence among African Americans is close to universal. African Americans are much more likely to be vitamin D deficient than white Americans. ⁴

14. In 2003, an FDA employee warned the FDA that vitamin D deficiency was “an alarming two to eight times higher among blacks.” ⁵ A year later, the same FDA employee again warned the FDA that African Americans are more likely to be vitamin D deficient than whites. ⁶

15. African American women of childbearing age are ten times more likely to be vitamin D deficient than white women. ⁷ In fact, many African American women of childbearing age have undetectable blood levels of Vitamin D; a startling fact when one considers that Vitamin D is crucial for optimal growth and development of the fetus. ⁸

16. Dr. Kathleen Fuller, of the Center for the Study of Race and Ethnicity in Medicine of the University of Kansas School of Medicine, noted that vitamin D deficiency in African American mothers explains the fact that their babies are more than twice as likely to be low-birth-weight as white children. ⁹ Furthermore, unless adequately supplemented, the breast milk of most American women contains insufficient, often undetectable, levels of vitamin D, with African Americans, again, being unequally impacted. Professor Hollis and his colleagues at the Medical University of South Carolina also demonstrated that adequate maternal vitamin D

supplementation can easily correct the vitamin D deficiencies of both the mother and the nursing infant. ¹⁰

17. Eighty-three percent of all American children diagnosed with vitamin D deficient rickets between the years of 1986 and 2003 were African Americans. ¹¹ Furthermore, vitamin D deficiency is now unquestionably associated with diseases that disparately, and prematurely, end the lives of African Americans. All of the major fatal illnesses in the African American community are linked with vitamin D deficiency, including heart disease, cancer, hypertension, kidney disease, and diabetes. ^{12 13 14 15 16}
^{17 18 19}

18. Again, the FDA's own employee has 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]." ²⁰

19. 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. Calcitriol works by

regulating 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. ²¹

20. Unless they specifically avoid the sun, European Americans can easily obtain adequate vitamin D from sunlight. Such is not the case for African Americans who require six to ten times more sun exposure to produce adequate vitamin D. ²²

Therefore, with the average indoor American lifestyle taken into account, 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 do not (or cannot) get vitamin D from the sun, we must get it from supplements or from fortified foods.

21. The FDA oversees and regulates food fortification in the USA through Title 21 of the Code of Federal Regulations (CFR). The FDA mandates that two foods be fortified with vitamin D: fortified nonfat dry milk (21 CFR 131.127) and evaporated milk (21 CFR 131.130). The FDA allows, but does not mandate, other foods to be supplemented with vitamin D, such as other milk products, including whole milk, certain grain products, margarine and 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).

22. 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 milk products.²³ The only two foods mandated by Title 21 to contain vitamin D are milk products. The FDA also knows that the milk industry chooses to supplement virtually all fresh milk with vitamin D. The FDA encourages them to do so through 21 CFR 131.110 and through 21 CFR 101.72. In 21 CFR 101.72, the FDA allows product labeling to "include vitamin D so that, in addition to a claim for calcium and reduced risk of osteoporosis, a claim can be made for calcium and vitamin D and reduced risk of osteoporosis."²⁴ In consequence, the FDA singularly incentivizes the milk industry to fortify their products with vitamin D, full-well knowing that milk is a predominant natural source of high levels of calcium, unlike other foods. Therefore, through a combination of mandated and encouraged practices, the FDA depends upon milk to deliver virtually all supplemental dietary vitamin D to Americans.

23. While the FDA primarily uses milk to deliver vitamin D to Americans, African Americans drink less milk than whites. The National Medical Association (NMA) published an important study on the under-consumption of dairy products in the African American community and called on African Americans to greatly increase their dairy consumption.²⁵ The NMA found disparate milk consumption was especially prominent in childhood. The reasons for this under-consumption are

complex and have to do with a variety of medical and cultural issues. It now appears that previous reports of African Americans being unable to consume milk due to lactose intolerance are incorrect. ^{26 27 28} However, the fact that African Americans consume less milk than whites is well-established. ^{29 30}

24. Concretely, in a study by Dairy Management Inc. in 2010, they found that 38% of lactose tolerant African Americans and 31% lactose intolerant African American drank milk, compared to 61% and 39%, respectively, for the general market. Nine-percent of Caucasian Americans believed themselves to be lactose intolerant, compared to nearly 30% of African Americans. ³¹

25. The FDA knows of these problems. In 2003, an FDA employee warned that vitamin D fortification of foodstuffs in America is not preventing vitamin D deficiency in African Americans. ³² The same employee said, “The racial/ethnicity groups at greatest risk of vitamin D insufficiency consume less milk . . . than do their white counterparts.” Dr. Calvo 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.” ³³

26. 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 efforts to address these specific African Americans’ needs.

27. In the past, and under similar circumstances, the federal government has acted to assure those 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 reluctantly 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.”³⁴

28. Foods other than milk, such as fruit juice and cereal grains, could be mandated to contain vitamin D. Experts have called upon the FDA to mandate enrichment of cereal grain products with both vitamin D and calcium.³⁵ Such a mandated enrichment program would safely, and cheaply, provide more vitamin D and calcium (required for many of Vitamin D’s functions) to African Americans. The failure of the FDA to mandate fortification of foods other than milk products with vitamin D and calcium ensures that most African Americans ingest deficient diets.^{36 37}

29. 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 equatorial African zones. ³⁸

30. The FDA chooses to fortify a food with vitamin D that many African Americans do not consume. Caucasian Americans do consume vitamin D enriched milk but are less likely to need the vitamin D in the first place -- due to their light skin sufficiently making vitamin D from sunlight. The FDA's policies and practices actually assure that African Americans, 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.

31. The Universal Declaration of Human Rights, adopted by the United Nations on December 10, 1948, to which the United States is a signatory, provides:

32. Article 3. Everyone has the right to life, liberty, and security of person.

33. Article 7. All are equal before the law and are entitled without any discrimination to equal protection of the law. All are entitled to equal protection against any discrimination in violation of this Declaration and against any incitement to such discrimination.

34. In addition, the right to due process embodied in the Fifth Amendment to the Constitution of the United States has been interpreted (*Bolling v. Sharpe*, 347 U.S. 497 (1954) to prohibit the Federal government from denying its citizens the equal protection of the laws.

35. In the words of Justice Louis Brandeis: "Decency, security and liberty alike demand that government officials shall be subjected to the rules of conduct that are commands to the citizen. In a government of laws, existence of the government will be imperiled if it fails to observe the law scrupulously. Our government is the potent, omnipresent teacher. For good or for ill, it teaches the whole people by its example." [United States v. Olmstead, 277 U.S. 438 (1928)].

36. African Americans have the right to expect that the FDA's food fortification policies treat African Americans fairly and equitably under the law. Currently, 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 African Americans consume in similar quantities.

37. As a result, the FDA's actions create unreasonable classifications based on race and fail to address the health problems of African Americans on an equal basis with those of other citizens.

38. The FDA's current policies are therefore in violation of the Fifth Amendment to the Constitution of the United States and the Universal Declaration of Human Rights as cited above.

39. While the FDA's policies and procedures, as set forth in Title 21, are matters of record, some may dispute our other contentions. If there is a question that (1) African Americans have a higher incidence of vitamin D deficiency, or (2) that the

majority of African Americans drink less milk than Caucasian Americans, we recommend that the National Academy of Sciences settle the matter. The Complainant asserts that to its knowledge, all the scientific studies in the medical literature support these two assertions, as do the FDA's own employee.

40. However, Professor Heaney's warning that vitamin D deficiency may be causing "massive" disease is suspected by many to be true but not yet proved. While we wait the needed decades for science to answer the question, it is only equitable and fair that African Americans and Caucasian Americans await that answer with similar vitamin D levels.

41. The Vitamin D Council respectfully asks you to investigate this matter. Please contact any of the vitamin D experts listed below. They can substantiate, and add to, the concerns we raise with you today about vitamin D. Once you assure yourself of the facts in this case, we ask that you ensure the FDA begins treating African Americans equally under the law by taking the following steps:

- A. 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.
- B. 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.
- C. 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.

- D. 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.
- E. Although it may not be required under the law, 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.
- F. 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.

Respectfully submitted,
The Vitamin D Council

By: _____
John J. Cannell, M.D., Executive Director

SUBSCRIBED AND SWORN TO BEFORE ME, the
undersigned authority, on this the ____ day of July
2011.

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