

## Testimony Before the Committee on Oversight and Government Reform United States House of Representatives

## Vitamin B12-State of the Science

Statement of

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For Release on Delivery Expected at 10:00 a.m. February 12, 2008 Mr. Chairman and members of the Committee, thank you for the opportunity to appear before you in my capacity as Deputy Director of the National Heart, Lung, and Blood Institute, part of the National Institutes of Health, an agency of the Department of Health and Human Services. I am here today to discuss the current state of the science of vitamin B12 and to briefly outline what we know about B12 deficiency and administration of vitamin B12 to healthy persons.

A vitamin is a chemical substance that is required for a particular chemical reaction to occur in the body, but is not synthesized by the body, and therefore needs to be included in the diet. The dietary requirements for normal function are usually relatively small. Most vitamins that are known today were discovered because their deficiency causes recognizable diseases. Examples are scurvy, caused by a deficiency of vitamin C, which ultimately motivated British sailors to carry limes onboard ship, and beriberi, caused by a deficiency of thiamin, or vitamin B1.

Supplemental vitamins are usually not required by people who have varied, well-balanced diets and normal metabolism. However, supplements are often advisable for people with limited diets or increased requirements for vitamins, such as pregnant women and growing children. Moreover, a number of gastrointestinal diseases can interfere with absorption of vitamins and cause deficiencies even in persons who have adequate dietary supplies.

Vitamin B12 is required for a number of vital biological reactions. Two of its most important roles are in the production of components of DNA and the proper functioning of different parts of the neurological system. Tissues in which cells are constantly dividing, such as bone marrow and the lining of the entire gastrointestinal and respiratory tracts, require a constant supply of vitamin B12. Normal function of cells throughout the nervous system and spinal cord also requires vitamin B12.

Vitamin B12 comes from animal products and bacteria. The stomach produces a factor that binds to the vitamin in food and allows it to be absorbed in the small intestine. Therefore, the primary causes of vitamin B12 deficiency are dietary deficiency and malabsorption.

Diets that lack foods from animal sources tend to be low in vitamin B12; strict vegans, for instance, need a source of B12. However, it can take five years for someone with adequate stores of vitamin B12 to develop a deficiency after a major change in diet.

Diseases of the stomach and small intestine can cause problems with absorption and consequent vitamin B12 deficiency. Some people make antibodies to the cells that produce the stomach factor necessary for absorption of B12, and therefore cannot produce the factor. As a result, they develop a condition called "pernicious anemia", which can cause a decrease in the number of blood cells. Extensive bowel resections, removal of much of the stomach, or inflammatory bowel disease can also cause vitamin B12 deficiency. All of these conditions need to be treated with monthly vitamin B12 injections since the vitamin cannot be absorbed from food or pills without the stomach factor.

Vitamin B12 deficiency has several major manifestations. A very characteristic anemia, in which the red blood cells are larger than normal, may progress to include low numbers of white blood cells and platelets as well. The symptoms of anemia include fatigue and shortness of breath on exertion. The lining of the mouth and gastrointestinal tract can be thin and abnormal. The neurologic symptoms are particularly serious and often hard to recognize. Difficulty with position sense, nerve damage, depression, memory loss, and dementia are seen with vitamin B12 deficiency even when the hematologic manifestations are not obvious. Recent studies have highlighted the value

of screening for B12 deficiency in older people with mild dementia. B12 deficiency in older individuals is probably related to changes in the gastrointestinal tract with aging and fairly limited diets, both problems that appear to be more common with advancing age. Pernicious anemia is most common in older women. For this reason, the 2005 Dietary Guidelines for Americans recommends that people over age 50 consume vitamin B12 in its crystalline form (i.e., fortified foods or supplement pills).

Diagnosing mild cases of vitamin B12 deficiency can be difficult. While looking for low B12 levels can be useful for diagnosis of severe deficiency, serum levels of folate, homocysteine, methylmalonic acid, 2-methylcitric acid, and cystathionine can help make the diagnosis in milder cases.

The only medical indications for administration of vitamin B12 are deficiency of the vitamin or risk factors for developing such deficiency, such as stomach or bowel disease or a limited diet.

Under the Federal Food, Drug, and Cosmetic Act, the Food and Drug

Administration regulates most vitamin products as dietary supplements. Although

manufacturers and distributors of dietary supplements must have substantiation for the

claims they make for their products, there is no pre-market approval requirement for

dietary supplements or many of the claims they make, such as claims related to classical

nutrient deficiency diseases or claims related to the structure or function of the body.

Claims are made that vitamin B12 administration will improve energy levels, memory,

concentration and mood. All of these are true when persons deficient in vitamin B12 are

treated; however, there is no evidence at all of those clinical benefits when the vitamin is

given to persons who are not deficient. Vitamin B12 is not toxic when given to non
deficient persons C it is simply excreted in the urine. Administration of vitamin B12 does

not enhance the physical or cognitive function of persons who are not Vitamin B12 deficient.

Thank you for the opportunity to provide information on this topic. I would be pleased to answer any questions the committee may have.