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Self Prescribing a Legal Dose or Duped into Deficiency?

Should Dietary Supplements Regulations Be Changed to Avoid Health Adversities?[1]

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Introduction

More than 170 million adults in the United States, or seventy-one percent, take dietary supplements regularly. Generally, consumers take supplements for overall health benefits and to fill nutrient gaps in their diets. While proactivity concerning health is good, consumers are often unaware of the quality of the dietary supplements that they are consuming. Studies have shown that dietary supplements do not always contain ingredients in the quantity that the supplement purports on its label. This inconsistency in potency could cause health adversities, including toxicity or deficiency.

In the past, the government has acted to decrease the potential health adversities that might stem from dietary supplement consumption through regulations. For example, in 1994 Congress enacted the Dietary Supplement Health and Education Act (DSHEA) requiring manufacturers to notify the Food and Drug Administration (FDA) 75 days in advance should the manufacturers use a new dietary ingredient. Unfortunately, many new dietary ingredients are not reviewed before they enter the marketplace. In addition, while the manufacturers have to ensure that dietary supplements are safe, the DSHEA does not require manufacturers to prove safety and efficacy to the FDA. The lack of regulatory oversight over dietary supplements may pose a health threat to American consumers. The question is - can regulations be implemented to ensure that all dietary supplements are safe and effective for consumers?

This article assesses whether new regulations should be enacted to combat potential health adversities related to dietary supplement intake. Part I explains the history, definition, and deregulation of dietary supplements. Part II suggests how current regulations, specifically labeling and manufacturing practices, might lead to adverse health effects in consumers. Part III proposes new regulations as a solution to combat such health adversities. This article advocates that new regulations, requiring proof that dietary supplements are safe and effective, should be enacted because the authors believe that more stringent regulations are in line with the FDA's Mission Statement to protect American consumers.

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Background

The FDA is a public health agency responsible for regulating dietary supplements. This section begins with the evolution of dietary supplements and then delves into the statutory definition of dietary supplements. Lastly, the deregulatory impact of the DSHEA on dietary supplements is explained.

A. HISTORY

The FDA's Mission Statement includes protection of public health through "assuring the safety, efficacy and security of the nation's food supply." Historically, the FDA has carried out its mission by regulating dietary supplements. For much of their regulatory history, laws required the FDA to regulate dietary supplements as a food or a drug. The FDA largely controlled the therapeutic and health-benefits claims for dietary supplements by applying the drug regulatory standards.

While many regulatory changes were implemented during the FDA's history to gain more regulatory power over dietary supplements, the Nutritional Labeling and Education Act (NLEA) provided the FDA with enhanced authority over the labeling of foods, including dietary supplements. Even though the NLEA afforded the FDA authority over labeling requirements for dietary supplements, Congress enacted the Dietary Supplement Health and Education Act of 1994 ("DSHEA") which deregulated dietary supplements. The DSHEA affords the FDA the authority to regulate both finished dietary supplement products and dietary ingredients with a different set of regulations from those covering conventional foods and drug products. Under the DSHEA, dietary supplement manufacturers are responsible for ensuring that a dietary supplement is safe before marketing.

B. DEFINITION

Aside from requiring that manufacturers ensure safety, the DSHEA expanded the definition of dietary supplements. Under the DSHEA, a dietary supplement is defined as a product intended to increase total dietary intake of one of more of its components, which can include vitamins, minerals, herbs or botanicals, amino acids or other substances, as well as concentrations, metabolites, extracts or combinations of these components. In addition, the product (1) must be intended for ingestion; (2) must not be represented as conventional food or sole item of a meal; and (3) must be labeled as dietary supplement. Although this definition excludes tobacco, the statutory definition for dietary supplements is still very broad. For example, vitamin tablets, energy drinks, protein bars, and weight loss supplements can all be classified as dietary supplements.

C. DEREGULATION

Under the DSHEA, the manufacturer is responsible for ensuring that a dietary supplement is safe before marketing. However, the manufacturer is not required to demonstrate safety or efficacy to the FDA before marketing a dietary supplement ingredient that was initially placed on the market before 1994. This differs, for example, from a drug. A drug manufacturer must prove both safety and efficacy of a new drug prior to the drug being sold in commerce.

Why don't dietary supplements have to prove safety or efficacy? The DSHEA was an attempt by Congress to find a balance between the requirements of: (1) individuals that believe supplements are useless until proven effective and (2) individuals that believe people should have access to dietary supplements even if they have not been proven effective. The DSHEA worked to prevent the federal government from interfering with the supplement industry in four ways. The first was the expansion of the definition of a dietary supplement. Prior to the DSHEA, dietary supplements were defined as vitamins and minerals. The DSHEA expanded the statutory definition to include herbal, botanical, and diet products. The second means by which the DSHEA prevented federal intervention was that manufacturers did not need to prove that their product was safe prior to manufacture. Thirdly, the DSHEA grandfathered in the safety of supplements that were marketed in the United States prior to October 15, 1994, and lastly, it allowed supplement manufacturers to label their products with statements of nutritional support.

In conclusion, the FDA's current regulatory scheme places great trust in the dietary supplement manufacturers. The DSHEA requires manufacturers to ensure that their products are safe, but the manufacturers are not required to prove safety and efficacy to the FDA. Since manufacturers are not required to prove safety and efficacy, the authors suggest that the DSHEA does not protect consumers from manufacturers who behave irresponsibly.

Analysis

The DSHEA may not protect consumers from any potential labeling and manufacturing errors that might affect dietary supplements, meaning that the current regulatory scheme might lead to health adversities, including toxicity or deficiency in some instances. This section explains why lack of regulations over dietary supplements could cause this to happen, and why toxicity and deficiency could pose health risks to patients. Lastly, due to the health adversities that could stem from labeling and manufacturing errors, the merits of a national certification system designed to ensure consistency of dietary supplements are discussed.

A. TOXICITY

In the United States, cases of vitamin D intoxication due to significant errors in the manufacture and labeling of dietary supplements have occurred, which have caused patients to consume, in some instances, thousands times more than the recommended dose of vitamin D3. For example, a 58-year-old man complaining of fatigue, excessive thirst, polyuria, and poor mentation was taking a vitamin D supplement in tablet form. The label stated that the tablets contained 1600 IU of vitamin D3. However, analysis revealed that the tablets contained 186 400 IU of vitamin D3. In addition to this error, the label recommended that a consumer should take 10 capsules each day. As a result, the man consumed 1 864 000 IU of vitamin D3 daily for two months and was diagnosed with vitamin D toxicity.

Another example of toxicity from vitamin D occurred in a 40-year-old man. The man stated that he had been taking multiple dietary supplements, one of which was claimed to contain 1000 IU vitamin D3. Analysis revealed that some of the product contained 970 000 IU of vitamin D3, almost 1000 times the amount stated on the label.

The two case studies described above demonstrate how manufacturing and labeling errors can cause vitamin toxicity. Generally, the main consequence of vitamin D toxicity is hypercalcemia, which can cause poor appetite, nausea, and vomiting, as well as weakness, frequent urination and kidney problems. Because vitamin D is a fat-soluble vitamin, it takes weeks to months for the toxicity issues to normalize and the health adversities listed above to dissipate.

B. DEFICIENCY

In the United States, vitamin and mineral deficiency cases due to manufacturing and labeling errors have been reported. While executing an exact micronutrient level in a dietary supplement may be challenging due to processing variations or changes during storage, substantial deviations from amounts stated on the labels should always be avoided. A pilot study found that supplements purporting to contain 10µg of vitamin D contained anywhere from 0.8 to 18 µg per daily advised dosage. Vitamin D deficiencies are prevalent in the modern era. In fact, ten percent of the United States population is deficient in vitamin D and twenty-five percent is marginally deficient. Dietary supplements containing less than the purported amount of vitamin D may lead to adverse health effects in consumers.

One adverse health affect associated with vitamin D deficiency is rickets. Rickets is a worldwide disease and affects infants and adolescents having inadequate sunlight exposure with low intake of vitamin D. It starts with pain or tenderness of the bones and teeth and progresses to visible deformities and stunted growth. Vitamin D deficiencies exist in other stages of life as well. For example, deficiency in later life typically manifests itself as osteoporosis, a condition in which bone mineral density is reduced.

C. UNITED STATES PHARMACOPEIA

A national certification system designed for dietary supplements could be a means to ensure product consistency across multiple manufacturers. Certification is currently available for dietary supplements on a voluntary basis. In the US, drugs are required to meet United States Pharmacopeia (USP) standards. However, USP standards are voluntary for dietary supplements. If manufacturers meet the necessary requirements under USP standards, then they are permitted to place a USP certification mark on their product labels. This system is an effective means to ensure product consistency and consumer safety. However, it has limited capability to protect consumers because of its voluntary nature. In addition, this system does not address health claims or safety issues, and the USP cannot enforce adherence to USP standards. While the USP certification system is a means to ensure product consistency across multiple manufacturers, new regulations requiring proof that dietary supplements are safe and effective could address health claims and safety issues, and the FDA could enforce adherence to these regulations.

Solution

To ensure that manufacturing and labeling errors do not continue, new regulations for dietary supplements could be enacted. The regulations should be sufficiently stringent to ensure that they are in line with the FDA's Mission Statement. The United States could modify its current dietary supplements regulations to make them similar to those in Canada, which require evidence of safety and efficacy.

In Canada, supplements are classified as natural health products, which are limited to products that meet the following definition:

> Natural health product means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in: (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; (b) restoring or correcting organic functions in humans; or (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health. However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

If a product meets the definition provided above, the manufacturer must prove its safety and efficacy and health claims must be supported by proper evidence so that consumers and Health Canada know the products are safe and effective. Evidence may include clinical trial data or references to published studies, journals, pharmacopoeias, or other traditional resources. The type and amount of supporting evidence required depends on the proposed health claim for the product and the product's overall risks.

Canada's natural health products present less risk compared to the dietary supplements that are sold in the United States. However, natural health products still pose some risks to Canadians. These risks include: manufacturing problems; unproven claims, which can lead people to use the wrong products for serious conditions or to delay proper treatment; not enough information for people to make an informed choice; interaction with prescription drugs or other natural health products; and unwanted side effects, such as allergic reactions. Twelve percent of Canadians who use Natural Health Products report unwanted side effects.

It can be argued that the risks associated with natural health products in Canada emphasize the importance of both safety and efficacy. Many legal practitioners argue that safety, without efficacy, is sufficient, whereas others believe that dietary supplements must be effective to ensure safety. As stated, dietary supplements are taken to fill nutritional gaps in the diet and consumers expect them to produce the desired result. If they are not effective, consumers could still be subject to deficiency or toxicity adversities. Therefore, regulations concerning dietary supplements should be changed to account for both safety and efficacy.

Many upstanding dietary supplement manufactures in the United States participate in USP standards for dietary supplements, but these standards are voluntary and allow for no enforcement. Manufacturers are likely to argue that modifying the regulations in the United States in line with those in Canada will be too costly and result in too much similarity to the current drug regulations in the United States. Modifying the regulations will cause manufacturers to incur costs associated with clinical trials and the dietary supplements will not get onto the market as quickly. However, manufacturers could charge consumers more for their products to cover increases in costs. Also, these increases in costs may deter many consumers from self-prescribing and over-use of dietary supplements.

Conclusion

The lack of regulatory oversight over dietary supplements poses a potential health threat to consumers in the United States. Manufacturing and labeling errors could cause health adversities, specifically problems associated with toxicity and deficiency of vitamins or minerals. The issue is whether new regulations for dietary supplements should be implemented to ensure that dietary supplements are safe and effective for consumers?

The authors believe that the answer to this question is “yes”. If the United States were to adopt more stringent regulations for dietary supplements, similar to Canada’s regulations concerning natural health products, requiring proof that supplements are safe and effective, manufacturing and labeling errors would be minimized. This would ensure that dietary supplements are safe and effective, and that consumers are protected from adversity, in line with the FDA’s mission statement.

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