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Food Regulation in the U.S.ANR 811

Food Fortification: For Profit or Health?

I. Introduction

"Should I purchase the Orange Juice with Calcium and Vitamin D, with fiber, or with antioxidants?" Hmmm. This is one of the many questions that a consumer may face when making food purchase decisions. Health awareness is at its peak. Baby boomers are aging and looking for solutions to battle their ailments. As a result, consumers are seeking foods that promise health benefits.[1] Industry is providing just that and more. In the past, food fortification has proven very effective intervention for the prevention of nutritional deficiencies such as goiter, rickets, beriberi, and pellagra.[2] As scientific knowledge regarding micronutrients has increased exponentially, has the government kept up with the industry-initiated pace of fortification? This paper will explore the use and effectiveness of fortification in the United States in the present and past, and the government's role in regulating food fortification.

II. Consumers' Wants

Ninety-five percent of the shoppers surveyed in a survey conducted by Prevention Magazine and the Food Marketing Institute, indicated that their food purchases are influenced by a health concern such as managing fat and cholesterol, reducing risk of a disease, defying the aging process, or following doctor's orders.[3] Of the consumers who are in search of fortified foods, 28% look for vitamin C and 24% look for

Vitamin E fortified products.[4] Based on this statistic, it is easy to see how the food and beverage industry is motivated by profit to develop products that provide consumers with what they want.[5] So, it is evident that there is a consumer desire for fortified products, but is there truly a need?

III. "Emergent Deficiencies"[6]

In the past, food fortification along with nutrition education, and the decrease in food cost relative to income "virtually eliminated" the common nutritional deficiencies. These deficiencies such as goiter, rickets, beriberi, and pellagra have since been replaced with a whole other set of "emergent deficiencies" that were not previously considered a problem (e.g. folate and neural tube defects, zinc and child growth, selenium and cancer, etc). [7] In addition to these, the Dietary Guidelines 2005 from the USDA have identified the following "shortfall" nutrients: for adults, vitamins A, C, E, calcium, magnesium, potassium, and fiber and for children vitamin E, calcium, magnesium, potassium, and fiber. These nutrients are of concern due to low consumption by the average American.[8] Many complex diseases with multiple causes such as atherosclerosis, diabetes, cancer, and obesity have also emerged. [9] These are not simply deficiency diseases, but rather conditions that are present in a relatively well-nourished society. Although fortification has proven effective in treating nutritional deficiencies in the past, "food fortification should support dietary improvement strategies and not be seen as an alternative strategy."[10] In light of this, the government is faced with policy decisions that they weren't faced with previously. [11]

IV. Success of Fortification in the Past

In order to understand the present situation regarding food fortification, the past record and its effect on public health should be reviewed. “Food fortification is a public health initiative with a long history of being used effectively to remedy nutritional deficiencies that were causing widespread national public health problems.” [12] In the early 1920’s, medical researchers announced that iodine could prevent goiter, which was widespread at that time. Through the efforts of public health officials, private industry, public education, implementation (in salt), and epidemiological evaluation, this was a successful fortification program, which decreased goiter incidence by 74-90% in the areas surveyed. Thereafter in 1932, milk was fortified with Vitamin D, and again, this was heavily supported by the medical community due to the prevalence of rickets in children. This was followed by the 1941 fortification of flour and bread with the B vitamins, which was “presented as insurance against nutritional deficiencies” when B vitamin deficiencies were highly prevalent in the United States.[13] And currently, the required enrichment of cereal grain-based foods with folate reduced the annual incidence of neural tube birth defects by 25%.[14] One common thread amongst all of these fortification programs is that there was great cooperation between the private (industry) and public sectors (government, consumers, health officials) and that the public health needs were addressed. That said, are the products that are currently on the market serving the nutritional needs of the population?

V. Fortification Today

Food and beverage companies spend $10 billion to $12 billion a year in advertising with the intent to reach America's youth. Astonishingly, half of this money is budgeted to the marketing of foods and beverages such as candy, fast food, snack foods, soft drinks and sweetened breakfast cereals. These are foods that are high in calories and/or fat, but low in other essential nutrients.[15] In perusing the grocery store, it is easy to see that fortified Jell-O® Sundae Toppers (Now Calci-Yum!), Honey Teddy Grahams®, Nestle Nesquik® (Helps Build Strong Bones), Koolaid® Jammers, Fruit Jammers Gummy Bears, and Eggo® Mini Rolls Toaster Swirlz,, amongst countless other food items, are not necessarily fulfilling the nutritional needs of the U.S. population. The Institute of Medicine Report (2004) on strategies to tackle childhood obesity indicated that at least 30% of the calories consumed by the average American are from foods that are high in calories, but low in nutrients. [16] With the onset of calcium fortification in the 1980's, the industry-driven fortification of nonstaple food items has taken off, and most importantly, does not reach the people who are actually at risk for nutritional deficiency. From past success with fortification, the key ingredients are health official, government and industry cooperation; public education; and epidemiological evaluation to assess the program. From these examples, it is clear that consumers and industry are so at ease with the concept of fortified foods that they no longer require the "public health campaign" in order to market and purchase fortified foods. [17]

VI. Fortification Policy

Despite the FDA's attempts to regulate food fortification, the 1980 *guidelines* are the most recent regulations to date. As stated in the Fortification Policy Statement of Purpose CFR §104.20:

> "The Food and Drug Administration does not encourage the indiscriminate addition of nutrients to food, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages. To preserve a balance of nutrients in the diet, manufacturers who elect to fortify foods are urged to utilize these principles when adding nutrients to food." According to the policy, a "nutrient…may appropriately be added to a food":
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> 1) "to correct a dietary insufficiency", as long there is "sufficient information …to identify the nutritional problem and the affected population groups, and the food is suitable to act as a vehicle for the added nutrients."
> 2) "to restore such nutrient(s) to a level(s) representative of the food prior to storage, handling and processing…"
> 3) "to balance the vitamin, mineral, and protein content…" (goes further to explain criteria)
> 4) "to avoid nutritional inferiority" when replacing a traditional food[18]

Prior to these guidelines, in 1976, the Vitamin and Minerals Amendments were passed. The law stated that "the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the secretary determines is nutritionally rational or useful." [19] This was a step backward for the FDA who had attempted a number of times to tighten its regulatory grip on food fortification.[20] And later, in 1990, the Nutrition Labeling Education Act [21], which provides the FDA with the authority to regulate nutrient content and health claims, and in 1994, the Dietary Supplement Health Education Act (DSHEA)[22], which further restricted the FDA power by allowing industry to make health claims without pre-market approval.

VII. Industry-Driven Fortification and Policy: The Net Effect

The net effect of industry's increasing ability to fortify and to make nutrient and health claims coupled with government's reduced role in regulating fortification has resulted in market-driven development of fortified foods. From the 1980's "calcium craze" to the present, profitability rather than the actual prevention of disease seems to control policy.[23] According to Reuters 2001, consumers may be consuming too much folate and iron from fortified cereal. Too much iron in males is associated with increased risk for cancer and heart disease, and too much folate can actually precipitate Vitamin B12 deficiency. An individual could readily consume 400% of the recommended level for both these nutrients, given the fact that an individual typically consumes more than a serving, and that these products typically contain more nutrient than they claim. [24] Some studies show that increased Vitamin E intake can have a potentially detrimental effect on HDL cholesterol , and the incidence of autoimmune diseases. Nutrient toxicity is usually associated with high doses of single nutrients, but has rarely occurred from eating foods that are naturally rich in nutrients.[25] Fortification may increase the nutrient quality of our food supply, but may have little to no effect on public health. [26] Unfortunately, few researchers have examined the effect of fortification driven by industry on the national nutrient supply. These studies, conducted in the early 1990's, focused on certain populations (women in NY, children) or certain food types (ready-to-eat cereals).[27]

VIII. "Reductionist Approach"[28]

It must be determined how to provide the nutrients to those people who need the intervention while avoiding imbalanced or excessive intakes for other groups. [29] This is a risk and benefit calculation that is dependent on the distribution of nutritional requirements and susceptibility to toxicity, neither which has been determined for many nutrients. [30] One of the intentions in the Dietary Guidelines for Americans 2005 is to condense the knowledge in regard to nutrients in order to recommend "a *pattern* of eating that can be adopted by the public". [31] It has been concluded that *dietary patterns* can be associated with reduced risk of certain chronic diseases (e.g. diet high in fruits and vegetables and decreased risk of cardiovascular disease); however, many intervention trials have focused on individual nutrients or combinations of nutrients rather than dietary patterns to assess disease risk, and have had mixed results. [32] This is a "reductionist approach", which characterizes the relationships of single nutrients and disease, but is an oversimplification of the complex relationship between diet and disease, and does not account for food synergies.[33]

IX. Future

It is evident that nutritional fortification of foods has been very effective in the past in eliminating widespread nutritional deficiencies. As consumer health awareness and scientific knowledge both increase, there is a great need for the 1980 Fortification Policy to be reevaluated. It is a different world than it was 25 years

ago. What began in the 1920's as a cooperative response to a public health need has escalated into an industry-driven fortification with no longer a need for a public health campaign. Yes, consumers are seeking food with health benefits in an era of complex diseases. But, it should not be left to the food and beverage industry to decide what those health benefits will be. There is a conflict of interest. "Today, federal regulation of food fortification has nearly returned to the pre-1938 situation."[34]

Endnotes

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[12] L’abbé, Mary R., Cockell, Kevin A. and Nora S. Lee. “Micronutrient Supplementation: when is best and why?.” *Proceedings of the Nutrition Society*, 62, No.2 (May 2003): 413-420.Ingenta connect. http://www.ingentaconnect.com/search?title=micronutrient+supplementation&title_type=tka&author=L%27abbe&journal=Proceedings+&journal_type=words&volume=62&issue=2&database=1&year_from=2001&year_to=2006&pageSize=20&x=43&y=11&form_name=ADVANCED (accessed 10/13/2006)

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[16] Ibid.

[17] Bishai and Nalubola. " History," 51.

[18] 21 CFR § 104.20

[19] 21 U.S.C. § 350(1) (2005)

[20] Backstrand, "History", 2.

[21] Nutrition Labeling and Education Act (NLEA) of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified in 21 U.S.C. § 343-1.

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