Spring 4-8-2021

Corruption in Capsules: How it is Legal for Companies to Put Harmful Ingredients in Vitamins and Dietary Supplements

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Abstract:

The vitamin and supplement industry has increased exponentially in profits as well as potential products on the market since the turn of the century. However, these products are not regulated, nor do they undergo any premarket clinical research or testing. Public health is compromised by vitamins and supplements that are available for American consumption that is disproportionately unregulated to their chemically similar counterparts. This wicked problem is facilitated through the combination of historical legislative definitions that has since been distorted for corrupt administrative gain through the allotment of corporate expenditures. Company disbursements are made to the same policymakers that create the guidelines that would restrict them, which is stimulated by the decision that corporations should have unrestricted limits of free speech.

Keywords:

Corporate First Amendment Rights, Vitamin and Supplements, FDA Vitamin Regulation, Harmful Vitamin Ingredients, Orrin Hatch and DSHEA, Consumer Safety, Regulation of Dietary Supplements, Consumer Product Safety, Public Safety, Manufacturing Bias, Vitamin Labeling

Introduction of a Wicked Problem:

Ralph L. Quinones, business law professor at Loyola Marymount University, characterizes the exponential increase of the vitamin and supplement industry has seen within the turn of the century. In 1994, approximately 4,000 dietary supplement products were available on the market. Now, there are 75,000 different types of dietary supplements that are currently out to be sold in the US, and it is estimated that more than 1,000 new products are introduced every year. The great increase of available products on the market provides immense profits. According to Department of Public Health Analysist, Farin Kamangar (2012), this industry's profits have grown where the total sale of nutritional supplements went from approximately $27 billion in 2009 to over $28 billion (2). For being such a large industry, it is alarming that it has largely been loosely regulated since its foundation; especially since it is reported that approximately one-half of Americans use supplements in some form, and 79% of those users take them daily (1-4).

The supplements that are currently on the market are not FDA regulated and have not undergone any clinical testing before becoming available for American consumption. These products do not receive any pre-market evaluation, and many prove to be detrimental to health. Professors at University of California, Rittel and Weber (1973), coined the phrase "wicked problem" when referring to a complication that is multidimensional in nature. They describe how a wicked problem has no *one* solution because "in order to describe a wicked problem in sufficient detail, one has to develop an exhaustive inventory of all conceivable solutions ahead of time" which poses that these difficulties can only be "re-solved at best" (155). Vitamin and supplement usage can be exemplified as a wicked problem because it has personal, political, and economical factors that are all multifaceted which characteristically define it as a wicked problem.

This wicked problem is rooted in a series of interconnected legislative webs that stem from a company's right to free speech. Through current rulings, supplement corporations are able to express inaccurate suggestive labeling on their products and influence policy by donating large amounts of money to the lawmakers that could create

the regulations that would restrict them. **Corporations first amendment rights should not consist of monetary value to policymakers that is unequal to an average citizen, nor should free speech be extended to the labeling of products that can adversely affect public health.**

Vitamin and Supplement Regulation Background:

According to the Center for Food Safety and Applied Nutrition (2017) the Food and Drug Administration (FDA) is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices (7); however, it should be noted that they only (logically) enforce what is within congressional regulation. Throughout history, the legal definitions of vitamin and supplements play an important role of how they are regulated. Peter Barton Hunt (2005) illustrates the origin jurisdiction through the 1906 Act and the 1938 Act which defines the term “food” broadly to include all articles “used for” food, and the term “drug” to include all articles “intended” for the prevention or treatment of disease and articles (other than food) intended to affect the structure or any function of the human body. Under these definitions, vitamins and supplements should be classified as a drug, and should be regulated as such. However, within the 1938 Act the FDA was also given authority to regulate the labeling of food “for special dietary uses”. Congress intended for this provision to encompass nutrient vitamins and dietary supplements, but this allowed vitamins and supplements to switch between the drug category to the food category based on how the product was labeled. This legislative ambiguity left the choice to manufacturers on how they wanted to label products. If they chose to label them as a drug, they would have to undergo clinical trials, research, testing, and approvals; whereas, they would not have to go through that process if they labeled their products as food.

The current enactment, the Dietary Supplement Health and Education Act of 1994 (DSHEA), was enacted to resolve debates by consumers and supplement makers who argued for more market autonomy and self-determination. This policy also represents

an attempt to resolve debates about First Amendment rights and labeling limitations on supplements that manufactures deemed too restrictive. In the *Journal of Consumer Affairs* (2013), Ralph Quinones also enlightens that under this new regulatory framework, products are not required to undergo premarket government testing, but Section 402(a)(1) prohibits from food to have any poisonous or deleterious substance which may render it injurious to health (159).

Through DSHEA, the products that are released to public consumption are considered safe unless proven otherwise. DSHEA poses to be a reactive way for regulation and seemingly unattainable since The Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2007 (DSNDCPA) defines “serious adverse events” regarding dietary supplements and nonprescription drug usage as one that “results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect” (9). DSHEA allows vitamin and supplement to be produced and sold without any evaluations or approvals and will stay on the market until it has sufficient evidence that it causes such serious adverse events. This proves to be problematic because it provides little improvement in the capacity of what the FDA can govern, nor does it authorize the FDA to prosecute against manufacturers who fail to report these events.

Problematic Vitamin and Supplement Advertising and Efficacy in the US:

Based on the legal provisions under DSHEA, vitamin and supplement advertising involve heavy advocacy despite scientific evidence providing their claims. In the *American Journal of Law and Medicine* (2005) Michael McCann describes the several ways companies capitalize on the value that is given to the reputation of supplements and how companies advertise strategically to manipulate consumers. Companies market certain supplements as medicine rather than food products, even though they are regulated as food products. The misleading product name “Herbrozac” claimed to treat clinical depression among children, sounds much like the antidepressant drug, Prozac, that treats for the same symptoms. Similarly, the supplement “herbal fen-phen”

is produced which is the same nickname given to the clinical diet drug combination of fenfluramine and phentermine. With such similar names, it entices costumers to purchase the cheaper supplement instead of the pharmaceutical version (217-220). This is concerning considering that individuals without access to sufficient health care often rely on vitamins or supplements. According to a study released by the non-partisan Center for Studying Health System Change, consumers who select supplements opposed to conventional treatments are almost twice as likely to earn incomes below the poverty line, significantly more likely to report poorer health status, and four times more likely to be uninsured. It is also reported that the most popular supplements among low-income people are known to cause serious side effects, such as St. John's Wort and Kava. These supplements cause autoimmune suppressant interactions which can cause increase the risk of infection along with the potential treatment failure (224).

In McCann's article he reports that approximately 80% of supplement consumers prefer to purchase dietary supplements instead of prescription drugs. The two most cited reasons these customers provide as their explanation on why they take these supplements were to "feel better" and "to help prevent getting sick" (219). Companies capitalize on the individualistic or traditional approach to health by creating an impression that supplements are a holistic or natural way to independently control health. Manufacturers advertise around this fabricated idea to mislead consumers to believe that "natural" equates to "harmless".

This equally alarming because according to The Selenium and Vitamin E Cancer Prevention Trial in the report by Kamangar (2012) results show that vitamin E supplements increases the risk of prostate cancer among healthy men by 17%. In conjunction, an analysis of the Women's Health Initiative concluded that calcium supplements (with or without vitamin D) increases the risk of cardiovascular events, particularly heart attacks (224). Many consumers are in favor of taking their personal health through self-medication through supplements, but unknowingly hold the risk of making themselves sick. Labels on vitamin and supplements also do not caution for

adverse effects if taking certain medications which jeopardizes consumer health since it is uncertain how these products will interact with other prescriptions.

Consumer Lab is a third-party company that tests various vitamins and supplements and report their findings on whether they would approve of public consumption. In one of their studies, they focused on the supplement ginkgo biloba which is used as an antioxidant along with suggested improvement in memory retention. They studied 30 different brands and discovered that one-quarter of the 30 brands of ginkgo biloba the levels of the active ingredients were less than indicated on the labels. Similarly, Henry Miller (2000) recounts the finding from Chemists at the Good Housekeeping Institute where they analyzed eight brands of SAMe, advertised as a natural Prozac, which was described earlier to relieve symptoms of depression. It was found that two had only half the promised levels of the active ingredient, while another contained none at all (18). Since supplements do not undergo premarket testing, the active ingredient may not even be present. Oppositely, consumers risk the supplements exceeding the recommended daily dosage which can surpass toxic levels if combined with foods that are rich with the same vitamins.

Legal Unbalance of Corporate Power:

Federal campaign laws such as The Bipartisan Campaign Reform Act (2002) states that the maximum any individual could give a candidate was up to $2,400 or $5,000 if it came from an outside group. This stems from the intentions that both average citizens and corporations would have an equal ability to potentially influence politics. However, this law is changed through the case of Citizens United v. Federal Election Commission. In 2010, the U.S. Supreme Court ruled that the government cannot restrict independent expenditures by corporations or unions to political campaigns. Corporations are not allowed to give money to campaigns directly since it is considered a donation, but companies are not limited in the amount they could spend in expenditures. Congress ruled that limiting expenditures is unconstitutional since it would limit the quantity of campaign speech, which in turn violated First Amendment rights.

Expenditures allow corporations to donate endless sums of money to super PACs, which are independent expenditure-only political committees that raise funds for political activities. After this court ruling, super PACs began to act in ways like political figures themselves. This allowed corporations to be involved with American politics, since political spending is judged as an extension of free speech.

Orrin Hatch is a Utah representing senator that has since retired in 2019, but was the longest Republican serving senator in history, serving for 42 years. Hatch's signature legislation is the Dietary Supplement Health and Education Act of 1994 (DSHEA). Throughout his time as a senator, he collaborated to compose, pass, and protect DSHEA which limits the FDA's ability to safeguard vitamin and supplement products.

Utah is known as the "cellulose valley" because of the large number of herbal and dietary supplement manufacturers that are headquartered there. Julia Ritchey, a political journalist, highlights in her article that after DSHEA was passed, the industry now generates upwards of $10 billion a year for the state and has been one of Hatch's top donors over the years (4). Open Secrets is an organization that records and tracks money in politics and how it can affect elections, to provide citizens with more governmental transparency. According to this resource database, Orrin Hatch has received $475,637 throughout his career, the most of any member of Congress, from these manufacturing companies (8).

Orrin Hatch had manifold benefits for pushing for the DSHEA legislation to pass. By eliminating the obstacle of clinical testing, manufacturers are able to continuously create and produce products at a low cost for higher profit since they do not have to spend money on clinical testing, research, or approvals. These vitamin and supplement companies generate immense amount of income into Utah along with providing substantial job availabilities. Hatch would have continuous public favor through providing high employment rates and high state GDP, which would solidify his re-election that is demonstrated through the 42 years he has served in the Senate; along with receiving considerable amounts donated from vitamin and supplement companies through super PACs to allow his continuous campaign.

Possible Solutions to a Wicked Problem:

Public health is compromised by a wicked problem through the combination of historical legislative definitions that has since been distorted for personal gain through the allotment of expenditures through corporations made possible by the decision that corporations should have unrestricted freedom of speech. With half of the US population regularly purchasing and consuming some form of dietary supplement, it is ludicrous that public health has been jeopardized because corporate free speech has been made a priority.

A wicked problem is mentioned as one inexhaustible in possible solutions; moreover, a feasible approach to the application of regulation can include the use of third-party regulatory systems much like the company Consumer Lab. Like the company Energy Star, products are independently researched and pose as an unbiased mediator between manufacturers and consumers. Consumer Lab can gain credibility to eventually be governmentally backed so consumers can have more market-autonomy with unbiased and credible information to make well-informed decisions. This would not replace the FDA but simply allow the market to have an additional regulatory agency.

On the other hand, to limit the amount of influence companies have within the creation of policy, distinctions must be made about monetary expenditures and corporate free speech. Guidelines to free speech would not completely silence companies but should be enacted because public health should preface as a priority. The amount of possible influence a company has in government should be equal to that of an average citizen without the loophole of super PACs. It should not matter if the power of expenditures has shifted from a single figurehead to a diffuse entity. **In this case, it should <u>not</u> be unconstitutional to limit corporate first amendment rights on the account of public safety and to reject corruption.**

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