

Lack in Regulations on Dietary Supplements

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Abstract:

The lack of regulations on the dietary supplement industry can harm consumers. The quality, safety and standards on labels are the most significant issues. The Food and Drug Administration needs to increase the research on supplements, hold the companies to higher standards on their labels and continue to ban certain supplements that may be deemed unsafe. This research identifies the specific problems with dietary supplements and details the necessary steps to fix those problems.

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Introduction

Background:

The dietary supplement industry is a multi billion-dollar industry that continues to grow every year. With this growth of this industry, regulation standards have fallen behind.

The current regulations on dietary supplements are:

- Federal Law requires the labels to say dietary supplement or a similar term.
- Federal Law does not require supplements to be safe in terms of FDA regulations before they are sold.
- Claims on the labels do not need to be proven.
- The FDA does not take action on products until after the products are released onto the market.
- Ads by companies selling the products are under the jurisdiction of the Federal Trade Commission.
- Once the product hits the market the FDA looks into reports of serious and adverse side effects reported to them.
- Firms are responsible for reports of adverse effects.
- The FDA does not have to approve the product before it is made and is sold in markets.
- It is illegal for a company to market a dietary supplement to cure or prevent diseases. (Add citation for FDA newsletter)

Objective:

Over the last decade, many problems have arisen, and changing just a few of the regulations above could have prevented these problems. The FDA holds food and pharmaceuticals to a very high standard when it comes to the production, safety and quality of the products. These regulations set in place by the FDA do not transfer over to the dietary supplement industry. With an increase in regulations that closely mirror the food and drug regulations currently set in place, supplements would become safer, be of higher quality, and be more effective when used.

Significance:

With the lack of regulations currently in the industry, many problems have arisen and persisted. The quality of products has slowly declined while companies still produce products with higher margins. The regulations for the supplement fact label are so bad that some of these labels are almost impossible to read. Below is an example of the supplement facts on the bottle of a pre-workout called 1MR Vortex. These supplement facts make it hard for the consumer to know what exactly they are getting in their product.

<h2 style="text-align: center;">Supplement Facts</h2> <p>Serving Size: 1 Scoop (3 grams), Servings Per Bottle: 30. Amount Per Serving: Niacin (as nicotinic acid) 20 mg (100% DV), FULL SPEED VORTEX™ MATRIX (Proprietary) 1,705 mg, Glycerol (as glycerol monostearate) (* DV), <i>Indigofera pulchra</i> (aerial) (* DV), Caffeine (as caffeine anhydrous) (* DV), White leadwort (root) (* DV), <i>Securinega</i> (<i>Securinega suffruticosa</i>) (leaf and root) (* DV), Yohimbe (<i>Pausinystalia yohimbe</i>) (bark) (* DV). *Daily Value (DV) not established.</p>
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Other Ingredients: Citric acid, natural and artificial flavors, sucralose, malic acid, acesulfame-K, silica, maltodextrin, and FD&C Red No. 40.

Figure 1: Supplement Facts for 1MR Vortex
Source:

New products are being made often and being sold both in store and online. These companies do not have to abide by any regulations and are free to sell their product without concern for safety or effectiveness. The safety of supplements over the years has become better but there are still products out in the market that are unsafe and can cause harm to the consumer. These products range from pro-hormones, to fat burners to pre-workouts.

Current Problems:

The quality of products due to the lack of FDA regulations is always a chance the consumer currently has to take into account when deciding which products to take and which to avoid. ConsumerLab is an independent testing company that tests various supplements for composition identity, strength, purity, and bioavailability. The findings from some of these tests are listed below:

- Seven out of eight milk thistle products contained less than the stated amount of silymarin (Webb, G. P. (2011)).
- A small minority of fish oil supplements contained only small amounts of EPA or DHA, with sometimes misleading labels (Webb).
- Some probiotic preparations contained as little as 7-58% of the number of cells listed on the label (Webb).
- One vitamin C supplement provided less than half the stated vitamin C content (Webb).
- Several glucosamine products were contaminated with lead and two preparations contained 6% or less of the stated chondroitin content (Webb).
- One saw palmetto preparation contained no saw palmetto (Webb).

The safety of dietary supplements is a serious concern today when a consumer makes a decision to buy a certain product. The FDA has recently been preventing certain items like Methylhexanamine (DMAA) and designer steroids from reaching the market, but unsafe products are still reaching consumers. Using a simple Google search one can easily order designer steroids from many sites online. Without

proper education, many people are still having problems and side effects caused by these unregulated supplements. Some common problems include liver malfunction and disease along with issues when the body attempts to restart natural



testosterone production. Recently a supplement called Craze had to be taken off the market due to the presence of an amphetamine-like substance found during laboratory tests **(Insert craze classaction lawsuit cite)**. Safety may be a huge concern but incorrect labeling has also found its way into the supplement industry, as well to make products seem more effective than they actually are.

Figure 2: Picture of Craze Supplement
Source:

The supplement facts on every supplement should always be examined, because it's the one part that consumers should be able to trust. There have been a few major concerns when it comes to how companies falsified their product labels. Protein spiking has recently been a huge concern for consumers when it comes to picking which protein product to purchase. Protein spiking refers to a practice where companies add more protein to the supplement facts without actually having to pay the price to add that protein. Companies can add creatine, taurine, glycine, and arginine, which will improve the nitrogen content of their product (Oliver, A. (n.d.)). The amount of carbohydrates listed on the supplement facts also brings up another huge concern for consumers. Companies are finding new ways to trick consumers into thinking their product is lower in carbohydrates than the reality of the level. Certain protein bars have recently been accused of not having the correct calorie count and carbs on their supplement facts. This can cause trouble for people with diabetes because of the blood-sugar effect from the carbs that were not counted. The amount of each supplement in a product can also affect the outcome seen from using the products.

The dosage of supplements, just like drugs given by doctors, impacts the effectiveness of the product. Many weight lifters take a pre-workout before beginning their strenuous activity. Pre-workout supplements usually consist of a nitric oxide boost, an energy boost and some sort of creatine to support ATP production. The effective doses of typical ingredients in a pre-workout are as follows:

Supplement	Effective Dose
Caffeine	100 - 200 mg
Creatine	3 - 5 grams

Beta-alanine	3.6 - 6.4 grams
L-Arginine	3 grams

Table 1: Effective Doses

Source: (Volek, J. (n.d))

These doses for each ingredient and a few others are put in a proprietary blend in most pre-workouts so the true dose of each one is never known, hindering the effectiveness of the pre-workout. The American consumer is not getting the best product because of under dosed products.

Proposed Program

With these problems currently being faced, the supplement industry needs to be held accountable and also to higher standards. Below are some new regulations that would give consumers safer products and also force companies to abide by the parallel safety standards set forth by the FDA for food and pharmaceuticals.

Every food company tests their products multiple times throughout the production process. These tests help control the quality and safety of the food as it comes off the line for human consumption. These companies are held to a high standard on how much variance is allowed on their label. If those standards are not met, the company is met with a hefty fine. Converting this regulation over to the dietary supplement industry would force companies to test their products, ensuring the quality of the product and also minimizing any variance from the supplement facts. Also the correct amount of certain drugs is vital to their function, and every drug that is FDA approved is researched to understand its particular side effects and also the correct dosage. A simplified process should be put into place when analyzing and testing each supplement. Many vitamins and minerals have recommended daily allowances already, but other supplements do not. These supplements should be researched, and companies should not be allowed to claim any benefits caused by the product until confirming research is performed. An example of this would be the product Garcinia Cambogia. "In 2011, the Journal of Obesity published a meta-analysis of 12 trials involving Garcinia Cambogia that failed to find any weight loss benefits. And in 2013, research published in Complementary Therapies in Medicine found that overall the evidence backing Garcinia Cambogia's weight loss benefits was "not compelling."(Oliver, A. (n.d.)). Although testing each and every product out there would be a huge problem for the FDA and would be almost impossible, the FDA should set standards on how much of each ingredient is needed in a product for a company to be allowed to state claims.

Currently, only certain companies pay third party investigators to check their products. A program currently in place by United State Pharmacopeia (USP) allows companies to pay them to participate in their Dietary Supplement Verification Program. To earn this verification, a company must submit many documents on their product and also pay a fee required by USP. (insert citation from OSU catalog)

Converting this program into one that the FDA is in charge of would force every company to register their product. This would also force every company to comply with "Good Manufacturing Procedures" and keep their products accountable for purity. This would end the protein spiking and variance in carbs with certain products. This regulation calls for fines and forced recalls for any company whose product exceeds these threshold variances.

The last program is the prevention of sales of products deemed unsafe. Lately they have cracked down and sent warning letters out on many different supplements, but the Internet continues to thrive with sales of these products. The FDA needs to shut down these sites and prevent them from selling dangerous products to the consumer in the same way it sends out recalls on dangerous food and prevents drugs from being approved due to safety concerns.

Qualification and Experience

My qualifications for pursuing these programs make me a great candidate to get them in place and keep these programs active. Through extensive research on current lawsuits and problems in the supplement industry I can guarantee that these programs will get these unsafe products off the market and keep the consumer safe. There should be very minimal health concerns and dramatically fewer deaths related to supplements after these programs are set in place. My research has also given me insight on some of the researched supplements out there that have established effective doses. This would give the FDA a jump start in tracking down companies who do not follow the effective doses but still state claims of their product working. I also bring to the table extensive experience using certain supplements and have witnessed the dangers first hand allowing me to speak about consumer experience with certain products. I am qualified to complete these proposed programs due to my experience in the industry and the research that has been done on the current problems and situations. Please allow me to pursue these programs and give the consumer what they need, safer more effective products.

Budget

The FDA's current budget is over 4 billion dollars with revenue coming from fines and also companies paying the FDA for their services. Allowing these programs to take place would stretch the current budget but also bring in additional revenue sources. The potential cost of the research done on certain supplements can be spread out to third party companies allow the supplement companies to pay for the research. The FDA makes roughly 60 million from inspection fee and other fee associate to keep our food safe. These fees could be associated in the supplement industry and help fund these programs (Department of Health and Human Services, Food and Drug Administration [FDA], 2014). Overall I estimate these three regulations would cost around \$500 million. Although this is a very large dollar amount it would be going towards the personnel needed to enforce these regulations and also will help pay for research on certain supplements. Some of the regulations can be funded directly by the companies looking to sell supplements.

The FDA can fine companies who are found selling products that do not follow these regulations. The FDA can also give a fee for inspecting the facility the supplements are made in.

Conclusion

The current regulations on the dietary supplement industry are lacking and out of date. Creating new regulations to monitor the expanding industry will create safer, higher quality products. These regulations include banning the sales on products deemed unsafe, ensuring products pass FDA regulations before and after sales begin, and holding the supplement fact list to a higher standard similar to that of the nutritional facts on food. With these funds I believe that these regulations can begin to be put into place and a change will quickly be seen in the safety, quality and effectiveness of dietary supplements. Thank you for your time in reading this proposal. I hope we can start creating a safer tomorrow today with the implementations of these new regulations.

Work Cited:

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Appendixes

Annotated Bibliography

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This document provides information regarding the current budget for the FDA. It also provides exact numbers on where those dollars are used. I used this source to give numbers on what they currently use them for and all used it to show the FDA could make money from the regulating the supplement industry.

Dietary supplements compendium. (2009). Rockville, MD: United States Pharmacopeial Convention.

This source provides a view into a company that does its own testing on supplements for companies. It gives the methods of how USP tests and regulates products. This provides the reader with a view on how a company can make a profit on testing supplements.

Oliver, A. (n.d.). Garcinia Cambogia Lawsuit | Garcinia Cambogia Class Action Lawsuit. Retrieved October 15, 2014, from <http://legalactionnow.com/harmful-drugs/dietary-sports-supplements/garcinia-cambogia-lawsuit-garcinia-cambogia-class-action-lawsuits>

This source contains vital information on the current lawsuit with supplements containing garcinia cambogia. The website also provides information documenting research stating the products do not work. This provides information regarding how well some supplements work and also the safety behind them.

Oliver, A. (n.d.). Misleading Protein Powder Claims Lawsuit Amino Spiking Protein Scam. Retrieved October 15, 2014, from <http://legalactionnow.com/harmful-drugs/dietary-sports-supplements/protein-powder-spiking-lawsuit-class-action-amino-spiking-protein-scam>

This source provides and describes the current problem with protein spiking in that some companies due to make more money. It describes the problem and gives a few examples. This source helped describe exactly what companies can due to spike their protein level and make a cheaper product.

Quest Bars: Actual Nutritional Information differs from Label (*Lawsuit). (2013, December 13). Retrieved October 15, 2014, from

<http://romanoroberts.com.mx/quest-bars-actual-nutritional-information-differs-from-label-lawsuit/>

This source shows pictures of the class action lawsuit that Quest Nutrition is currently facing due to their claims on their supplement facts. The documents shown on this website show that quest protein bars hides the true amount of carbs in their product. This provides the proposal an insight on some of the problems facing lying on the supplement facts.

U.S. Food and Drug Administration. (2014, September 22). Retrieved October 15, 2014, from <http://www.fda.gov/Food/DietarySupplements/>

This website provides an overview of what the current regulations are as of September 2014. This information is used to give the reader an overview of how supplements are currently regulated.

Volek, J. (n.d). What's in your pre-workout formula? - Nutrition Express Articles. Retrieved October 15, 2014, from [http://www.nutritionexpress.com/article/index/authors/jeff s volek phd rd/showarticle.aspx?id=1320](http://www.nutritionexpress.com/article/index/authors/jeff%20s%20volek%20phd%20rd/showarticle.aspx?id=1320)

This source provide information on what a pre workout is. It also provides information on how much of each ingredient is needed to provide positive effects and what the purpose of each on is. I used this source to provide researched effective doses on

Webb, G. P. (2011). Dietary Supplements and Functional Foods (2nd Edition). Somerset, NJ, USA: John Wiley & Sons. Retrieved October 15th, 2014, from <http://www.ebrary.com>

This source provided an insight on how bad some of the labels are of when it comes to correct supplement facts. It provided this proposal with many examples of how off some of the supplements are that are out there. It also names the company that provided these results and this company is very open with their results. Anyone can see these results providing consumers with information on correct supplement facts.