American Journal of Humanities and Social Sciences Research (AJHSSR)
e-ISSN : 2378-703X
Volume-02, Issue-05, pp-01-08
www.ajhssr.com
Research Paper Open Access

Analyzing the Dietary Supplement Health and Education Act and other related regulation relevant FDA approval.

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ABSTRACT: The research introduces the policy of Dietary Supplement Health and Education Act (DSHEA) and relevant regulations and backgrounds with quantitative data analysis. Studying case studies of Dietary Supplement Health Educational Act (DSHEA) might address Food and Drug Administration (FDA) accountabilities and improvements.

I. INTRODUCTION

According to the Department of Health Human Services, dietary supplements were used by 70 % of the U.S. population in 2004. Vitamin and mineral products were accounted for $7.7 billion of the U.S. retail sales and 48% of entire sales in the dietary supplement category. (Brackett, 2004, p. 51). Dietary supplements cause increasing infringement trade over the online, illegal import drugs, qualitative and labeling issues. For instance, the FDA enforcement has refused 1,500 foreign shipments of potentially unsafe dietary supplements offered for the United States (Dickinson, 2004, p. 127).

II. THE HISTORY AND BACKGROUND OF THE DIETARY SUPPLEMENT AND HEALTH EDUCATION ACT

According to Larsen, Berry (2003), the FDA in early 1900s. Over 100 peoples died after taking Elixir Sulfanilamide encouraged passing the Food Drug, and Cosmetic Act (FDCA) in 1938. The guidelines established protecting consumers from false claims in later 1940s and 1950s. The Nutritional Labeling and Educational Act (NLEA) established in 1990. "The Nutrition Labeling and Education Act of 1990 (NLEA) provides FDA with specific authority to require nutrition labeling of most foods regulated by the Agency; and to require that all nutrient content claims (i.e., 'high fiber', 'low fat', etc.) and health claims be consistent with agency regulations. Regulations implementing the NLEA labeling provisions issued on January 6, 1993, with technical amendments published on August 18, 1993"(U.S. Food and Drug Administration, 2009).

Food Additive Amendment included FDCA for ensuring labeling regulations in 1958. The drug law amendment was passed relevant the FDA approval for prescription drug in 1962.

The U.S. congress passed the DSHEA in 1994. The regulation stimulated consumer purchasing power to purchase supplemental drugs. The DSHEA obligated continuing the researcher、and observing new drug entry to the Office of Dietary Supplements in the National Institution of Health (NIH) (Schweizer, 2007, p. 283).

The FDA proposed GMPs in March 2003 (GAP research, 2000).

III. THE DEFINITION OF THE DSHEA IS A REGULATION OF OVER THE COUNTER DRUGS, WHICH CONTAIN HERBS, VITAMINS, AND MINERALS EXCEPT TOBACCO.

"In 1994, DSHEA created a unique regulatory framework for dietary supplements in the United States. Its purpose was to strike the right balance between providing consumers access to dietary supplements that they use to help maintain and improve their health and giving the Food and Drug Administration (FDA or the Agency) the necessary regulatory authority to take action against supplements that present safety problems, have false or misleading claims, or are otherwise adulterated or misbranded…As a summary of the previous testimony, I would like to point out that the DSHEA regulatory framework for dietary supplements is primarily a postmarket program, as is the case for foods in general. Should safety problems arise after marketing, the adulteration provisions of the statute come into play"(U.S. Food and Drug Administration,2009).

The DSHEA was established in 1994, which regulates over the counter drugs, which contain vitamins, minerals, herbs, botanicals, amino acids, and concentrates, metabolites, constituents, extracts, combination of any of above products except Tobacco by the FDA (Berry, 2005, p. 670).

Wollschlaeger (2003) stated that the DSHEA is into 12 sections, which are title, ingredients, definition, safety, labeling requirements, liabilities, distributions, function notification, labeling requirements, Good Manufacturing Practices (GMPs) , commission on dietary supplement labels, office of dietary supplements.
In the detail of the each section is as follow;
The safety established in section 4, which contains safety evidences, appropriate labels, and notifications of the unreasonable risk of injury. If the supplement does not qualify under these provisions, the manufacture must offer evidence safety of a "history of use" within 75 days before the products introduced the markets. The office of Dietary Supplements mandates the Secsetary of Health and Human Services (HHS) to make an Office of Dietary Supplements within the National Institutes of Health (Wollschlaeger, 2003, P. 388).
Regarding Asher, Rice, Sisson (2007), under the Dietary Supplement Health and Education Act (DSHEA), not all supplements are required to have FDA approval. The sales of these over-the-counter products increase substantially before their production or distribution into the markets. (Asher, Rice, Sisson, 2007, pp. 966-969).

IV. THE DEFINITION AND IMPLEMENTATIONS OF FOOD AND DRUG ADMINISTRATION

The FDA regulates new products for monitoring unsafe, useless, inadequate manufactured products before they are sold (Smith, Wertheimer, Fincham, 1997, P. 150). Jiang (2009) explained that the 75-day Pre-market Notification Requirement contains 'new dietary ingredients' before drugs can be marketed in the United States, which apply only for food additives of supplements. The FDA must receive notification that the product meets the safety requirement within 30 days of product marketing. The marketer of the new dietary resources must supply the FDA with a history of use, evidence of safety, and information.

V. GOOD MANUFACTURING PRACTICE (GMPS) REGULATION

The FDA proposed Good Manufacturing Practice Regulations (GMPs) in2003. Regarding Silverglade (2004), the author determined that " DSHEA authorized the FDA to issue GMPs based on those established for foods. That requirement is bit odd because dietary supplements more closely resemble non-prescription drugs and should be manufactured to the same quality standards as those products. In any event, GMPs help ensure that the product contains the precise amounts of ingredients specified on the label and specify production processes that reduce the chances that products are contaminated with undesirable substances".
Indeed, regarding Degnan (2003), FDA proposed rulemaking announcements, which developed GMPs, which defined the packaging of dietary supplements with iron in 1997. The FDA determines the publication of a proposed law for dietary supplement GMPs improves criteria in final stage of the proposal process. The agency has a commitment to adapt "outreach program" after the publication of GMPs proposal.
The new rule will improve the dietary supplement industries; especially in manufacture processes because there are many counterfeit dietary supplements and expensive products without adequate ingredients. The FDA would reduce the time of approvals by GMPs enforcements.

In the detail of GMPs in DSHEA as follow;
Labeling, and substantiations are the resources that must not be misleading of GMPs in the DSHEA. The notification determines for a lack of nutrition, structure body functions, mechanisms, and suggestion for the result. Labeling requirements require notifying "dietary supplements". The GMPs are specially applying to dietary supplement products. The commission on the Dietary Supplement Labels is two-year studies and issue a report on the regulation of label claims and statements for supplements (Wollschlaeger, 2003, pp. 387-390).

VI. THE FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT

Pinco (1999) stated the Food and Drug Administration Modernization Act (FDAMA) regulates using health labeling without FDA approval. The U.S. Government or the National Institutes of Health or the National Academy of Science or any of its subdivisions can provide authorization to firms instead of FDA approvals. The innovative criteria reduce the burden of FDA responsibilities.

VII. FEDERAL AGENCIES

According to the United States General Accounting Office (GAO) research (2000), there are three major agencies restrict product labels and in advertising of health claims, which are Food Drug Administration (FDA), Federal Trade Commission (FTC), and the United State Department of Agriculture (USDA).

-Mechanism for FDA Oversight Different Types of Products

(Graph 1)

Product class	Product registration	Manufacturer registration	Pre-market approval of products	Specific good manufacturing practices	Voluntary post-market adverse event reporting system	Mandatory manufacturer reporting of adverse events	Safety-related labeling requirements
Dietary supplements		x		Proposed in 2003	x		Some
New Drug Application drugs	x	x	x	x	x	x	x

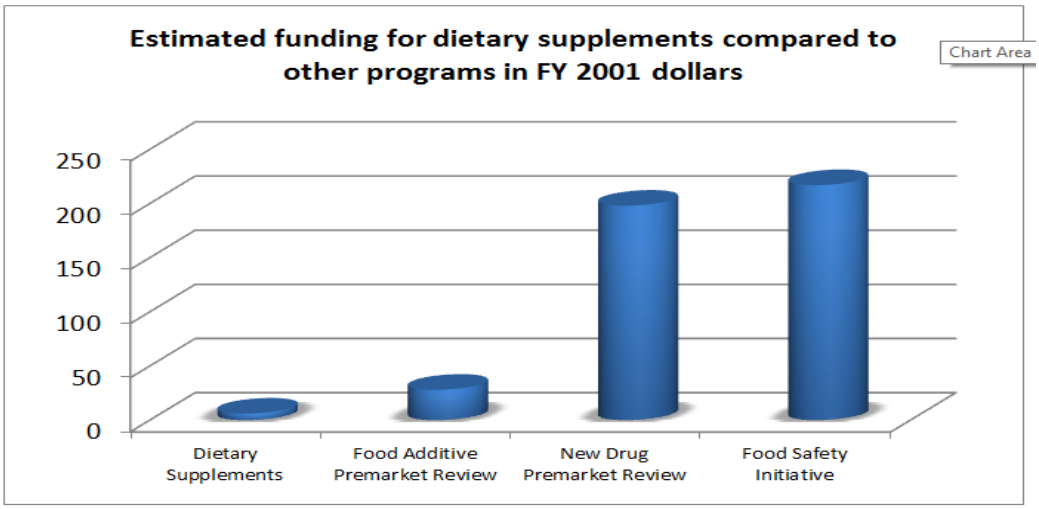
Graph 1 shows that manufacturer and distributors relevant norms are required by FDA approval. Indeed, the FDA proposed GMPs in 2003. Graph tells that only the voluntary post-market adverse event reporting system to dietary supplements is required. (The U.S. General Accounting Office, 2003).

My analysis of the facts reveals that the dietary supplements should be reported adverse events because some dietary products contain risks for death due to the weight loss functions. Indeed, product registration should mandate filing of dietary supplements because of the ban of counterfeit products. My other suggestion is that safety-related labeling requirements for all dietary products require avoiding misuse of the products, even though three federal agencies are controlling the products.

VIII. FDA FUNDING

Regarding the National Council for Science and the Environment report (1998), for every dollar spent on the FDA products, 25 cents is contributed to the FDA funding. The purposes of spending the FDA funds are for premarket application and new product approvals, crisis conditions, amending the existing regulations, and meeting consumer safety needs.

(Graph 2)



(Committee on Government Reform House of Representatives, 2001, p. 163) Graph shows the different funding for a each product of FDA approval. The results show the Food Safety Initiative would receive the most FDA funding. Graph 2 also implies the U.S. consumers are concerned about food safety because dietary products are luxury products.

IX. NEW DRUGS APPLICATIONS BY FDA APPROVAL

According to Schweitzer, the FDA, Center for Drug Evaluation and Research (CDER) and the Biologic Evaluation and Research (CBER) monitor for new drug application in pharmaceutical research the pharmaceutical research process address. Drug firms looking for marketing opportunities for NCEs, antibiotics, hormones, and enzyme drug products file a New Drug Application (NDA) with the CDER (Schweizer, 2007, p. 196). After new drugs passed the phase III trials and filed a NDA, firms can introduce their drugs to the market (Schweizer, 2007, p. 35). The NDA function is the application form to receive FDA approvals. The DSHEA notifications contain regulation for vitamins, minerals, herbs, botanicals, amino acids, and concentrates, metabolites, constituents, extracts, and any combination of above products. I believe new drug would utilize the herb products, which address radical the FDA approval issues. Whereas, many firms, which do not have large enough budgets should shift to the dietary supplements markets because of volunteering filing to the FDA.

X. FOOD DRUG AND COSMETIC ACT

Cohen (2005) stated the FD&C Act prohibited foods, drugs, and cosmetics containing narcotics and cannabis. Indeed, the regulation regulates labels of patent medicines shipped in interstate commerce, and provides the evidence requirements for approval, burden of proof, and claim acceptations.

XI. ISSUE BETWEEN THE DSHEA AND THE FD&C

The FD&C and the DSHEA overlap definitions of herb parts. The herb has capabilities to utilize as drugs, foods, and dietary supplements. The similarities induce confusion into the industries.
Additionally, the FD&C Act defines “drug” based on “intended use ” for treatments, mitigation, treatment, and prevention of disease (Cohen, 2005, p. 181). Again, the herb is sometime utilizing cure for diseases indirectly. The government has to determine the interpretation of herb on each regulation in precisely.

XII. THE NUTRITION LABELING AND EDUCATION ACT (NLEA)

The NLEA reduces misuse of supplements. According to GAO research (2000), the Nutrition Labeling and Education Act (NLEA) was established in 1990, and requires food labels to have food substance and disease information.
-Addressing labeling ambiguity
The comparing between labeling of foods and supplements would imply labeling ambiguity as follow;
(Figure 1)

(GAO research, 2000)

Two products contain different ingredients. However, the labeling is similar, which induces consumer’s misinterpretations. The NLEA would constrain the amendment of regulations and differentiate foods and supplements.

-Safety-related requirements for functional foods and dietary supplements
(Graph 3)

Safety-related requirements	Functional foods	Dietary supplements
An added ingredient must be generally recognized as safe by qualitative by FDA as a food additive before marketing	x	
Firms must have a basis for concluding that a supplement containing a "new" dietary ingredient is reasonable expected to be safe under the conditions of use recommended or suggested in the product labeling.		x
Firms must notify FDA new dietary ingredients safety within 75 days before the marketing.		x
Firm must require safety material notifications.	x	x

(GAO research, 2000)

Supplements are more regulated than foods because supplements contain a large quantity of herbs, which sometimes used for Ex drugs. I strongly suggest that regulation mandates clear labeling that shows the difference between dietary supplements and food products.

XIII. THE JAPANESE DIETARY SUPPLEMENTS REGULATION

Jiang stated that Japan does not have precise regulations for dietary supplement (Jiang, 2009, p. 297). Japanese regulation of supplements is similar to its regulation of prescription drugs. As a matter of the fact, the standard dosage norms are setting low amounts. Indeed, the Japanese drug regulation is getting stricter. As a common knowledge, sadly, the Amendment of Japanese Drug regulation restricts free global markets.

-Comparing the U.S. and Japanese supplement regulations

Analyzing Japanese pharmaceutical regulations and the U.S. pharmaceutical regulations would extend their marketing opportunities. Japanese supplement regulation is based on avoiding deficiency symptom such as maintenance of minimum standard ingredients. However, the DSHEA claims the function of supplement products for preventing diseases. The submitted recommended daily allowances (RDA) by FDA approval are different with Japanese criteria. Physiologically necessary dosage is what human beings require for living. Pharmaceutical amount of dosage is what human beings need for a health life. Indeed Japanese and American body structures are different. For instance, many of Japanese have gastric inflammation. However, many American stomachs are strong, which address differences in manufacturing levels between two countries (Japan Health Pass Co., 2009).

Even though the Japanese robust drug regulation exists, Japanese consumer demand for drug supply is booming. The consumers tend to buy the supplements products by parallel trades. For instance, " The supplement is supporting condition of suffer from symptoms of premenstrual syndrome" is a legal label in the U.S. markets. However, this label would be illegal in Japan (Japan Health Pass Co., 2009).

My analysis reveals that supplemental markets including drug markets in Japan are inactive for high risks and high returns from consumers. Even though, the labeling and commercial advertisements of supplements notify the strong cosign of the usages.

I believe Japanese ineffective drug marketing methods to the market led to lagging Japanese drug markets. Indeed the location can be placed of the supplement is ambiguous in Japan. However Japanese firms have more marketing opportunities in the U.S. dietary supplement markets.

XIV. CASE AND ISSUES ANALYSIS

-Labeling issue cases

This case addresses how the Mislabeling infringements increase consumers' misinterpretations by insufficient descriptions. The U.S. Marshals Services acquired 3,000 bottles of EverCLR as dietary supplements, which were valued at more than $100,000 in California on December 16, 2002. The merchandise was marketed to Halo Supply Companies. Their labeling was an infringement of labeling, and components were actually illegal drugs with "natural" notifications (Brackett, 2004, p. 64). Congress requires "Dietary supplements to meet standards established by the United States Pharmacopeia for identity, strength, quality, purity, packaging and labeling" under DSHEA regulations (Davis, 2004, p. 90).

Brackett (2004) stated that the FDA enforcement had refused 1,500 foreign shipments due to potentially unsafe dietary supplements offered for the United States, suggests a need for the potential amendment of regulations by lobbying activities.

Ordinarily, the functions of supplements can substitute for the nutrition of foods. However, the labeling infringement or lack of descriptions should be treated in strictly because supplements are utilized for personal uses. My suggestion is that the DSHEA makes the line clear between food and supplements under the provisions.

-Cardiovascular issues

This case addresses how to dose with other drugs causes adverse effects. In fact, as for dietary supplements, ephedrine alkaloids are selling over the counter. The drugs contain the adverse effects such as increasing heart rates. According to Lindsay, the working group's recommendation introduced proposals, which contains "1, Limit the dose of ephedrine alkaloids to 8 mg per 6-hour period or a total of 24 mg/d, 2. Require labels to state that the product should not be used for more than 7 days, 3. Prohibit the use of ephedrine alkaloids in dietary supplements with ingredients such as caffeine, which have known stimulate effects, 4. Prohibit inaccurate labeling claims, 5. Require a "warning label" (Linsay, 2002, pp. 7-8). The functions of ephedrine alkaloids are much likely as drugs, which contain adverse effects. The FDA needs to restrict more for herb functions as a dietary supplement.

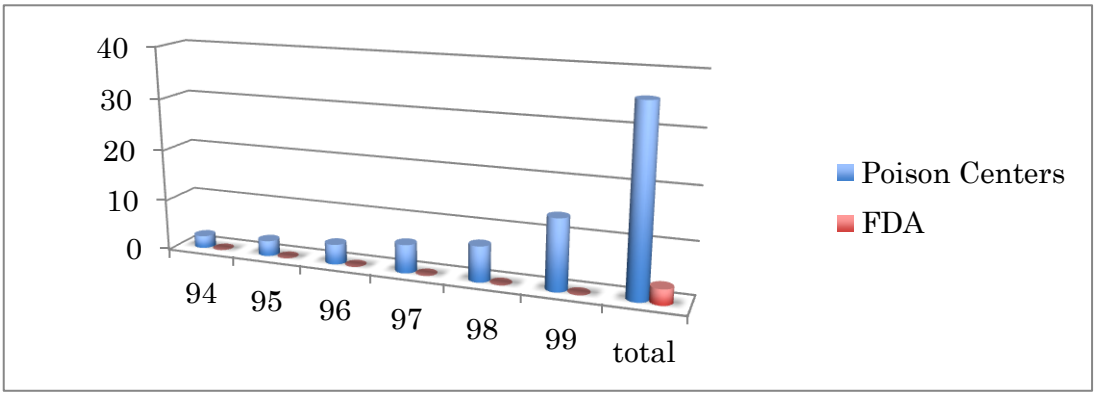
-Ephedra case

In this case Ephedra did not answer precisely in adverse event trials. Regarding GAP research (2003), Ephedra can be cause heart attacks, strokes, seizures, and deaths. OTC drugs sold Ephedra as dietary products, food additives. The FDA received 2,277 reports of adverse effects related with dietary supplements with Ephedra. The facts revealed 15 times more reports than the results of ordinary Herbal Dietary supplements. Eventually, the FDA prohibited selling Ephedra dietary products in 1993.

The above case studies imply containing potential issues such as consuming times for approval terms, and warning of amendments for existing regulations would involve risks due to mislabeling by self-utilizations.

-Adverse Reaction Reports for Dietary Supplements FDA and National Poison Control Centers

(Graph 4)



Graph 4 shows the Adverse Reaction Reports for Dietary Supplements FDA and National Poison Control Centers (Wolfe, 2001, p.93).

This research clearly shows the FDA did not learn ineffective side effects results from Ephedra in 2003. Because the data shows the FDA reverse effects results were flat from 1994 to 1999. The FDA might allocate their research responsibility to third party.

XV. ISSUES

Obviously, the dietary supplements product controls in the manufacture and definition of herb in the DSHEA have issues. Indeed, the FDA has to have more accurate research on the adverse effects of dietary products. Indeed, the NLEA has to conduct ambiguous labeling of supplements description for consumer protection.

XVI. IMPROVEMENT

Amend existing policies to clear notification to distinguish drugs, supplements, and foods that would reduce the FDA's responsibilities. More regulations for importing supplement, and modify domestic supplements. New Drug Applications must be submitted to FDA for all prescription drugs and some over-the-counter drugs prior to marketing. This application must include data that demonstrate the safety and efficacy product. Besides enforcing GMPs, the Public Health Security and Bioterrorism Preparedness and Research Act of 2002 requires manufacturers and to register with the FDA for quality improvement purposes.

-The dietary supplement strategic plan

According to Levitt, the dietary supplement strategic plan will be accomplished by the year 2010, which includes science-based regulation programs as known as "twin pillars". Mainly the subjects establish 6 phases, which are safety, labeling, boundaries, enforcement, science-base, and outreach (Levitt, 2001, pp. 139-145). Based on the above constructions, the FDA establishes the goodwill relationship between stakeholders as leveraging materials with the adequate communication such as providing clear information. The firm must be concerned with improving productivity, qualities, safety criteria, labeling.

XVII. SUGGESTIONS

If the DSHEA carries out structural reforms of the market economy, such as the relaxation of regulations such as reducing furnishing 75 days, introduce other moderate provisions, which replace existing provisions, the pharmaceutical industries will still have potential to continue its economic growth. Indeed, initially, amending the regulation to restrict for import drugs would moderate the relaxation the export ceiling.

XVIII. CONCLUSION

Supplement determines as making up for nutrition, which people could not take from daily foods. Consumer health conscious trends are creating issues for the DSHEA. The existing regulations still need to improve labeling and product control, and accurate research of adverse effects. Two controversies and facts imply that the DSHEA is facing alternative modulation in adjusting pharmaceutical marketing needs. Nobody expected active online supplement trades. The phenomena addressed increasing counterfeit supplements. Adaption of the Dietary Supplement Strategic Plan is a one of the strategy to improve existing polices. I strongly suggest that the modulations of the policies are only for domestic products because of positive aspects for deregulated markets, which affects the U.S. dietary supplement health markets or relaxation of regulations.

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