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Dietary Supplements Consumer Protection in a Global Market

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Summary

This article is a review paper, which aims to present a global analysis of a real issue contemporary society is facing: safety in food supplements consumption. More specifically, we intend to answer the following questions: Are the dietary supplements offered on the global market harmless for the consumers? How do dietary supplements protect consumers' health and life against risky and fake products? Who regulates the food supplements market in the United States and in the European Union?

The international literature approaches studies regarding the efficacy and effectiveness of dietary supplements, and research papers which highlight the dietary supplements consumer behavior from a medical or consumer protection point of view. We are interested in finding out not only if the consumption of dietary supplements is risky for the consumers health, but also the perception and initiatives performed by the authorities concerning the dietary supplements safety and the measures taken in order to solve the consumer protection issue in that field. In this context, we started our study using as background the specific features of the dietary supplements global market, the regulation of this market in Europe and in the USA, discussing which are the ways used by the main international organizations in order to inform/protect consumers all over the world regarding the risks involved when buying or consuming such products.

This article intends to be just a preamble for further research on the same topic.

Keywords: consumer protection, food supplements, dietary supplements, controversies, safety.

JEL Classification: M31, D18, I12, C10

1. Introduction

As an important aspect of the social protection programs which must be promoted by a democratic society, consumer protection presents a set of provisions on public and private initiative, designed to ensure and continuously improve the consumers' life standards and safety.

Recently, consumer protection has experienced an unprecedented development. If until recently the food or cosmetics industry consumer protection was actively advertised, nowadays, the studies have become so numerous that it is interesting to analyze not only the consumer protection related to traditional goods and services: textiles, toys, travel services, insurance services, banking and financial services etc, but also the sector of some "special" goods/services, like: drugs, health care services, postal services, air transport services, and so on.

Human needs have been increasing in number year after year, while the economic resources have been drastically decreasing. Human requirements exceed the resource needs of the natural systems of the Earth, generating high expectations in goods

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and services consumption. Contemporary consumers no longer purchase - like in the past - products/services which are necessary on strictly everyday basis, regardless of their quality. The quality of the products and services has become a key determinant of the competitiveness of producers and suppliers.

In terms of quality, nowadays food does not have the same characteristics as in the past, when massive pollution and chemicals were not part of people's lives. At the same time, the industrial processing techniques have led to decreasing the natural content of food, creating also a toxic nutritional medium for the body. Because of the trend observed in risky food consumption, conditions for the development of a dietary supplements market were created, taking also into consideration the fact that necessary ingredients which favor the wellbeing of the human body can be found in the form of dietary or food supplements. The importance of food supplements results from their property to complement regular food, in order to achieve certain goals: good health, boosting energy, loss of weight, delaying aging processes, boosting mental and sexual performances, improving digestion and boosting immunity.

International literature is subjective in defining the dietary/food supplements concept. This involves the need for raising the following question: are dietary and food supplements synonymous? Some studies showed that the two concepts highlight the same type of product, Sirico et al. (2018). Another point of view suggests that food supplements are just a type of dietary supplements (nature.com, 2018). We concluded that the term "dietary supplements" refers to one used mostly in America in order to indicate food supplements, while "food supplements" is the same concept and product (dietary supplement), but used mostly in Europe. In order to formulate a final opinion regarding this issue, we have to state, first of all, that in Romania, the greatest part of the consumers do not distinguish between food supplements and dietary supplements. A dietary supplement is a manufactured product intended to supplement the diet, and its nutrients are either extracted from natural products or are synthetic. Food supplements, also called nutritional supplements, are any dietary supplements that intend to provide nutrients that may otherwise not be consumed in sufficient quantities. Food supplements are concentrated sources of nutrients (minerals and vitamins) or other substances with a nutritional or physiological effect that are marketed in "dose" form (e.g. pills, tablets, capsules, liquids in measured doses) (nature.com/subjects, 2018). Dietary supplements could be found in different forms: vitamins, herbal supplements, botanical, sport, beauty supplements, and so on. So, without diminishing the importance of the definitions presented above, and even if nutritional supplements are just a type of dietary supplements, in this paper we will consider the two terms as being synonyms.

The Dietary Supplement Health and Education Act (DSHEA, 1994) defined a dietary supplement as a product that supplements the food consumed daily; contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, other substances); comes in pill, capsule, tablet or liquid form and is labeled as a dietary supplement.

Generally, there are different types of dietary supplements, like (DSHEA, 1994):

a) Vitamin and mineral supplements - micronutrients that serve a specific purpose and benefit the body in a unique way, having also a positive effect on mental health. Vitamin and mineral deficiency can reduce the body's ability to heal and protect itself. A general multivitamin and mineral supplement can be a good safeguard against periodic nutrient shortfalls in the consumer's diet. Mineral supplements come in tablet or gel-capsule form, in powders added to water, in

meal replacement bars and shakes which are used for weight loss.

b) Herbal supplements - they are different from vitamins and mineral supplements because they are considered to have medicinal value. Herbs (botanicals) are one of the oldest health care tools, and the basis of many modern medicines. Primitive and ancient civilizations relied on herbs for healing, as do many contemporary cultures around the world. In fact, WHO (The World Health Organization) has estimated that 80% of the world's population continues to use traditional therapies, a major part of which are derived from plants.

c) Whole food supplements - made of blends of concentrated, dehydrated whole foods, sometimes with added vitamins and minerals. Since the nutrients are combined in the way as they are in natural food, the body can use and absorb them better. Whole food supplements tend to be much more expensive than conventional supplements.

In the last years, a growing number of people have been concerned about maintaining and improving their health; because of that they become loyal customers of food supplements. More than half of the adults in the USA daily use at least one type of food supplement, the most common being multivitamins. The increasing number of older people in North America leads to an increase in the demand for food supplements. Europe is on second place in the list of the largest food supplements markets. Growing aging population, increasing lifestyle diseases and rising healthcare costs are some of the significant factors driving the growth of the dietary supplements market not only in Europe, but all over the world (nutraingredients.com, 2017).

Dietary supplements aren't always safe or harmless. Even "natural" supplements can be risky or may be tainted with dangerous chemicals. That's why this paper aims to focus on the dietary supplements consumer protection issue, which is common in today's global market all over the world. Reducing the area of consumer protection only to the dietary supplements consumption, it focuses, in essence, on the following objectives:

- high quality supervision of the dietary supplements offered on the global market (including the counterfeit supplements sold over the Internet);
- correct and complete consumer information regarding the safety and the hidden adverse effects of the food supplements launched on the market;
- high protection against subliminal and aggressive advertisements.

The main goals of the dietary supplements consumer protection must be effectiveness and safety. As all drugs can harm as well as help, safety is relative. To use food supplements in a responsible way, the consumer must adhere to a list of principles. Dietary supplements users must understand and inform themselves about the effects and legal status of the product they are taking, to measure accurate dosages, to take other precautions to reduce a potential risk which may occur when consuming those supplements (Duncan and Gold, 1982).

This article is a review paper, which aims to make a global analysis of the above mentioned actual issue of the contemporary society: how are the dietary supplements consumers around the world protected? At the same time, the paper analyzes the international dietary supplements market and the way this market is regulated, especially in the USA and EU, taking into account, first of all, the adverse side of consuming improper dietary supplements which are easily marketed through several channels. The federal corporations are playing a main role internationally, because they have to satisfy the greatest part of the demand coming from the global dietary supplements market. However, factors such as subliminal advertising, the risk of buying fake products and the lack of information regarding the use and dosage of dietary supplements

are expected to impact negatively the food supplements market growth in the future, should the global consumer protection policies in that field prove inefficient.

2. The global dietary supplements market

New food supplements brands and products that promise good health are offered every year on the global market. The growth of the food supplements market is determined by an increase in the consumer's awareness of preventing health problems.

The segmentation of the global market for dietary supplements is based on the demand for weight loss, nutrition, sports, general wellbeing, immune and digestive health, bone and joint health, heart health, beauty supplements etc. In terms of value, the general welfare segment represents 26.5% of the revenue share of the global food supplement market, while the immune and digestive health segment represents 19.6% of the international market (futuremarketinsights.com, 2016).

The major producers of food supplements on the world market are Herbalife International, BASF SE, E. I. Du Pont de Nemours, Glanbia Plc, Royal DSM NV, Abbott Laboratories, Amway Enterprises, NBTY Inc, Bayer AG, Aboca, Sanofi, Pfizer and GlaxoSmithKline Limited. These companies are mainly focused on product innovation, in order to expand their product portfolios, to meet the diverse requirements of various end-user industries and to enhance their market presence.

It was estimated that in 2015 the global food supplements market amounted to 68 billion US dollars and was segmented into seven major regions: North America, Latin America, Eastern Europe, Western Europe, Asia-Pacific-Japan, Middle East and Africa. Taking into account the ingredients found in dietary supplements, the market was divided into botanicals, vitamins, minerals, amino acids, enzymes.

The global dietary supplements market was valued at USD 132.8 billion in 2016 and is expected to reach USD 220.3 billion in 2022, estimated to grow at a CAGR (compound annual growth rate) of 8.8% between 2017 and 2022. According to the National Center for Complementary and Integrative Health, almost 40% of the adults in the U.S. use multivitamins, the most common food supplement. Sports nutrition is expected to be one of the fastest growing dietary supplements market segment because of the increasing number of health clubs and fitness centers. Vitamin supplements were used extensively, accounting for around 42% of the global market share in 2016 (futuremarketinsights.com, 2016).

Asia-Pacific was the largest market for dietary supplements in 2016, followed by North America with 28% of the total market (zionmarketresearch, 2017).

In terms of value, North America reached a 32% share of the food supplements global market in 2016, being the world leader, while Europe owned 14% of the global market in the same year (nutraingredients.com, 2016).

Latin America is seen as a market with a high potential for dietary supplements in the upcoming years, because the urban population and the middle-class consumer income is rising and the retail channels are being modernized.

The Middle East and Africa present a region with a huge potential for dietary supplements, with an economic activity which is expected to boost the dietary supplements market in the region (zionmarketresearch, 2017).

In 2016, Europe was one of the leading markets for dietary supplements. Recently, European consumers have started showing great interest in healthy lifestyle which in turn drives the consumption of healthy food. In Europe, Western Europe is the leading market for dietary supplement, having a high growth potential in the future.

Some of the key manufacturers of global dietary supplements in the European market include Amway Enterprises, Integrated BioPharma, Inc, NBTY Inc, Herbalife Ltd., Omega Protein Corporation, Nu Skin Enterprises, Inc, Bayer AG, Naturalife Asia Co., Ltd., Blackmores Ltd., BASF SE, Epax AS, Surya Herbal Ltd., Koninklijke DSM N.V., Bio-Botanica Inc., The Himalaya Drug Company, Ricola AG, Pharmavite LLC, among others.

The European dietary supplements market is diverse, changing rapidly, registering strong growth in several categories and regions. According to Euromonitor, the European dietary supplements market is expected to mark a 9.5% growth in the next years, reaching an estimated value of 7.9 billion euro in 2020. Although Italy, Russia and Germany were the three countries in top ten of the global markets in 2014, the most spectacular developments can be observed in the Eastern European national markets (www.zf.ro, 2016).

Eastern Europe registered a huge increase in sales between 2010 and 2015 (by 60%), while in Western Europe the market increased by just over 11.3%, in the same period.

Euromonitor shows that the Eastern European countries will be champions in sales of dietary supplements until 2020. Romania, Turkey, Bosnia and Herzegovina, Russia and Macedonia may constitute five of the top six world markets with the fastest growth all over the world.

Although Germany was the second largest national market for dietary supplements in Europe in 2014 and the seventh in the world, it has been in a continuous decline in the recent years. While in 2009, Germany was the largest European market for food supplements, in the period 2010-2015 it dropped 6.6%, equivalent to a 68.7 million euro decrease in sales. Germany's decline was beneficial for Italy and Russia, Italy being currently the biggest European market and Russia the second.

The growing interest in leading a healthy lifestyle in Romania facilitated the growth of the food supplements market exponentially, attracting many new producers. That might be because the greatest part of the food supplements is sold through pharmacies, being considered drugs by the greatest part of the consumers. In 2015, the food supplements sold through pharmacies reached 210 - 215 million euros, but an estimation of the total sales (including the on-line sales) showed that Romania was an almost 500 million euros market (www.bizlawyer.ro, 2016).

Table 1. *European rankings based on sales of supplements (2015). Estimation for 2020*

	Market Value (million euro)		Expected growth in period 2015-2020
	2015	Estimation 2020	
Italy	1424.2	1601.5	12.40%
Germany	966.6	967.2	0.10%
Russia	887.7	1079.9	21.7%
England	737	755.2	2.59%
France	683.8	724.8	6%
Poland	353.4	407.5	15.30%
Norway	231.5	220.4	- 4.80%
Finland	201.2	207.4	3.10%
Belgium	193.6	194	0.20%
Spain	182.6	193.5	6%
Sweden	181.5	199.3	9.80%
Netherlands	142.1	169.2	19.10%
Hungary	116.6	136.3	16.80%
Denmark	96.5	98.7	2.20%
Turkey	96	121.7	26.70%
Switzerland	93	92.7	- 0.30%
Czeh Republic	84.7	96.1	13.4%
Austria	81.7	91.9	12.4%
Ukraine	75.7	87.1	15%
Romania	72.2	101.8	41%

Source: author's adaptation after Euromonitor International (statista.com/statistics, 2018)

Food supplements market in Romania grows annually by around € 25-30 million. Pharmacies and specialty stores' revenues exceed 90 million euros annually, because around 10 million euros are rolled out through the internet and supermarkets.

More than 18, 000 food supplements are legally registered at the National Institute of Research and Development for Food Bioresources - IBA Bucharest, Romania. Over 1,500 such products are registered every year, 17.6% of all Romanians use dietary supplement (Euromonitor International, 2014).

Romania is estimated to record the largest increase in sales in the coming years, having the potential to reach the 20th place in the world and the 15th place in Europe, in terms of sales (www.roaliment.ro, 2016).

All over the world, food supplements are marketed through several channels, like pharmacies, supermarkets, specialty shops, internet, individual sellers etc. The food supplements market is growing due to the launch of new brands, of new campaigns for existing brands and because the food supplements segment is cash-generating for pharmacies. This also poses risks related to the consumption of some dietary supplements. Even if doctors, nurses and pharmacists work hard to keep us healthy, we are also responsible for our life and health. Medication errors which may hurt consumers happen in hospitals, pharmacies, or even at home. The more information people have, the better able they will be to prevent errors and to take care of themselves.

3. Historical overview regarding the regulation of the dietary supplement market in the United States and in the European Union

The Food and Drug Administration (FDA) and the European Medicines Agency (EMA) are the two main bodies which – among other competencies – approve the dietary supplements designated to meet the demand in our global market. So, the potential consumers might conclude that to consume the advertised dietary supplements must be healthy and safe. Then why do the Consumers Union and the consumer protection organizations all over the world bother to publish alerts about dietary supplements hazards?

Comprehensive consumer protection dealing with physical products was first applied to drugs, foods and food additives. Regarding pharmaceutical drugs, the inadequacies of the common law were glaringly apparent even at the turn of the 20th century. At that time, the only way to identify a company that was selling dangerous drugs was to have a number of people becoming seriously ill or dying as a result of consuming its products. The common law did not allow customers to inspect or require a seller to prove the safety of a new product prior to its commercial sale. When talking about drugs it is impossible to determine the safety of a product just by inspecting it. So, it is not a mere historical happenstance that the Pure Food and Drugs Act (The Food, Drug and Cosmetic Act) was enacted in 1906 and that the Food and Drug Administration was created in 1927 as the US government initiated an activist role in the pursuit of consumer protection. The 1938 legislation was enacted only after some 100 people had perished when a drug sold on the market was found lethal. This was a reason why a large scale animal testing and human clinical trials were conducted by the FDA regulations. The 1938 Act also required the FDA to classify all drugs as either prescription or nonprescription, the latter commonly referred to as over-the-counter drugs. The Kefauver Harris Amendment (The Drug Efficacy Amendment, 1962) required drug manufacturers to prove to the FDA that their products were both safe and effective (fda.gov/cder, 2017).

It takes pharmaceutical companies several years to prove that their products are safe and

effective. Recognizing this problem, the Food and Drug Modernization Act was passed in 1997 and included provisions for speeding up approvals of new drugs, especially those that have a high potential for therapeutic gain and those for which there are no satisfactory alternatives available on the market.

Nowadays, FDA regulates over $1 trillion worth of products, which account for 25 cents of every dollar spent annually by American consumers. It is part of FDA's job to see that the medicines and medical devices used by the consumers are safe and effective, Jackson et al. (2010).

There are a number of regulatory issues that the FDA has so far avoided, but which demand resolution. One of these issues is linked to food supplements. Dietary supplements are regulated by the FDA as food, not as drugs. According to the Food Act, a nutritional supplement is food that is used to supplement regular food, and which is a concentrated source of nutrients or other substances with nutritive or physiological effects for humans. Food supplements are not meant for treating or alleviating any diseases, but, indeed many dietary supplements are being used as pharmaceutical drugs to treat ailments, including depression, high blood pressure, and even cancer. That way, many food supplements directly compete with FDA-approved pharmaceutical drugs. Dietary supplements must be approved by the FDA before being introduced to the market, but the approval process is not nearly as rigorous as that required for introduction of new pharmaceutical drugs. This is the reason why sellers of dietary supplements cannot get proof, through clinical trials or any other tests that traders of pharmaceutical have to submit to, that their products are either safe or effective.

Across the Atlantic, The European Medicines Agency is an agency for the evaluation of medicinal products, which was known from 1995 to 2004 as the European Agency for the Evaluation of Medicinal Products (set up by EC Regulation no. 2309/93 as the European Agency for the Evaluation of Medicinal Products and renamed by EC Regulation no. 726/2004 as the European Medicines Agency). Roughly similar to the American Food and Drug Administration, but without FDA-style centralization, EMA was set up in 1995, with funding from the European Union and the pharmaceutical industry, as well as indirect subsidy from the member states, in an attempt to harmonize (but not replace) the work of the existing national medicine regulatory bodies. The hope was that this plan would not only reduce the €350 million annual cost drug companies incurred by having to win separate approvals from each member state, but also that it would eliminate the protectionist tendencies of the states unwilling to approve new drugs that might compete with those already produced by domestic drug companies. The EU is currently the source of about one-third of the new drugs brought into the world market each year, Sherwood (2008).

EMA operates as a decentralized scientific agency of the EU, and its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. More specifically, it coordinates the evaluation and monitoring of centrally authorized products and national referrals, developing technical guidance and providing scientific advice to sponsors. The Agency decentralizes its scientific assessment of medicines by working through a network of about 4500 experts throughout the EU.

Another European institution with activities in the dietary supplements field is The European Food Safety Authority (EFSA), an agency funded by the European Union, that operates independently of the European legislative and executive institutions (Commission, Council and Parliament) and EU Member States. It was set up in 2002 following a series of food crises in the late 1990s to be a source of

scientific advice and communication on risks associated with the food chain. The agency was legally established by the EU under the General Food Law, Regulation no. 178/2002 (efsa.europa.eu, 2018).

Between 2005 and 2009, EFSA carried out a comprehensive assessment of substances that are permitted for use as sources of vitamins and minerals in food supplements in Europe. Companies wishing to market a nutrient source not included in the permitted list have to submit an application to the European Commission. Under Directive 2002/46/EC, EFSA issues a scientific opinion to support the European Commission's evaluation of the request. Based on EFSA's work, the European Commission reviews and updates the list of vitamin or mineral substances that may be used in dietary supplements.

If a substance intended to be used does not have a history of safe use in the EU before 1997, EFSA is requested to provide a scientific opinion on its safety according to Regulation (EC) no. 2015/2283 on novel foods (efsa.europa.eu, 2018).

EFSA provides the most up-to-date and comprehensive scientific advice to support EU policy makers in their decision making process in the field of nutrition. EFSA's advice on nutrient intakes provides an important evidence base to underpin nutritional policies, the setting of diet-related public health targets and the development of consumer information and educational programmes on healthy diets.

Moreover, EFSA has performed a comprehensive evaluation of the possible adverse health effects of individual micronutrients at intakes exceeding the dietary requirements and, where possible, established tolerable upper intake levels (ULs) for different population groups. ULs represent the highest level of chronic daily intake of a nutrient that is not likely to pose a risk of adverse health effects to humans. The ULs defined by EFSA and by the former Scientific Committee on Food are used as a reference in EFSA's evaluations of the safety of nutrient sources added to food supplements. Throughout this work EFSA provides support to the European Commission in establishing maximum limits for vitamins and minerals in food supplements and fortified foods. For all substances added to foods, including food supplements, that are claimed to have an effect on the nutritional or health status of consumers, EFSA carries out an assessment in line with Regulation (EC) no. 1924/2006 on nutrition and health claims (efsa.europa.eu, 2018).

In the EU, food supplements are regulated as food and are subject to the same requirements like in the US, regardless of whether the product is sold at a shop, pharmacy, from hand to hand, via post or online. Harmonized legislation regulates the vitamins and minerals, and the substances used as their sources, which can be used in the manufacturing of food supplements. For ingredients other than vitamins and minerals, the European Commission has established harmonized rules to protect consumers against potential health risks and maintains a list of substances which are known or suspected to have adverse effects on health and the use of which is therefore controlled. However, if a consumer purchase food supplements online from a place outside of the EU, they might not comply with the EU requirements. This is why people should always make sure in which country the seller is registered, prior to purchasing the product. This information has to be available for the consumers.

Through EMA and other similar organizations (e.g. EFSA), the EU strategy in the health care field target to reach the following three objectives (ec.europa.eu/health, 2016):

- promoting good health in an aging Europe;
- protecting the people against health threats;
- supporting a dynamic and innovative health care system.

Economically, the pharmaceutical sector (which produces and sells drugs, and also a huge quantity of dietary supplements) is one of the most robust industries globally, with an important potential contribution to the welfare of the population. Because of that, in 1965 the market authorization and the classification/ labeling of drugs were regulated. The main legislative acts in that field were Directive 2001/83/CE relating to medicinal products for human use and the regulation no. 726/2004, laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use.

All the drugs marketed internationally are and must be subject to a strict testing and assessment of their quality, efficacy and safety, before being authorized. Once launched on the market, they must continuously be monitored so as to assure that any aspect which could impact the safety profile of the product is detected, assessed, and necessary measures are taken. This monitoring is called Pharmacovigilance, which includes activities like (ec.europa.eu/health, 2016):

- Collecting and managing data about the safety of the product;
- Evaluating the data and making decisions with regard to safety issue;
- Pro-active risk management, minimizing any potential risk associated with the use of the medicine;
- Acting to protect public health (including regulatory actions);
- Communicating with and informing stakeholders and the public;
- Audit, both of the outcomes of action taken and of the key processes involved.

This process is a key public health function of monitoring the safety of drugs, taking action to reduce their risks and increase their benefits.

The absence of FDA/EMA/EFSA oversight and strict regulation of the dietary supplements industry's leads to the existence of many detractors who would like to see the industry undergo more rigorous standards for both safety and efficacy to better serve the consumers, Dickinson and MacKay (2014).

4. The FDA's role in assuring the dietary supplements consumers' safety

More than half of all the prescription drugs cause adverse effects that aren't detected until after the Food and Drug Administration approves them, sometimes many years later. Such delayed detection contributes to the high number of drug-related injuries all over the world (including here the food supplements consumption too).

Dietary supplements may seem like harmless health boosters. But while some have proven benefits, many don't. Many dietary supplements contain ingredients that have strong biological effects which may conflict with medicines consumers are taking. Products containing hidden drugs are also sometimes falsely marketed as dietary supplements, putting consumers at even greater risk. Unlike drugs, dietary supplements aren't always evaluated or reviewed by FDA, EMA, EFSA (or any similar institutions) for safety and effectiveness so, from certain point of view, those may be more risky for people's health. It costs about $1.3 billion to bring a drug to the market. In that way, many dietary supplements never receive an approval (investopedia.com, 2017).

It's hard to resist promises made for a quick cure or solution for a serious health problem, but supplements claiming to prevent or cure diseases, aren't proven. Besides cheating the consumers out of their money, they also may be unhealthy. Many dietary supplements can't be promoted either legally and ethically for the treatment of a disease because they aren't proven to be safe and effective. To prove the safety and efficacy of those supplements requires clinical trials that would be prohibitively large-scale, long and costly. In addition, the American system

for identifying drug risks before approval is flawed. The practice showed that it is not possible to detect every risk of the dietary supplements before doctors start prescribing it or before consumers ingest them. Maybe this is the reason why, during the years, a lot of scandals unfolded all over the world (not just in the mainstream media), regarding the negative effects of dietary supplements and drugs upon the health and safety of the consumers.

In the last years, FDA has discovered hundreds of dietary supplements containing drugs or other chemicals, particularly in products for weight loss, sexual enhancement or bodybuilding. These ingredients generally aren't listed on the label, but could cause serious side effects or interact in dangerous ways with medicines or other supplements. Consumers have suffered strokes, acute liver injury, kidney failure, pulmonary embolisms or, have died. Such tainted supplements are often sold with false and misleading claims like "100% natural" and "safe". But just because a product claims to be natural doesn't necessarily mean it is safe or effective.

The active ingredients of food supplements require no FDA pre-approval to be used. The so-called "energy products" and manufacturers of these products have labeled some as dietary supplements and others as conventional foods. FDA regulates both dietary supplements and conventional foods under the Federal Food, Drug and Cosmetic Act, but the requirements for them are different. FDA cautions consumers that products marketed as "energy shots" or "energy drinks" are not alternatives to proper rest or sleep. It is important for consumers to realize that, while stimulants such as caffeine may make one feel more alert and awake, judgment and reaction time can still be impaired by insufficient rest or sleep (fda.gov/Food, 2012).

While overall confidence in dietary supplements remains high, many consumers are not aware of the FDA's limited role in testing or regulating supplements. The investigators suggested that consumers might associate FDA approval with overall safety, but not with effectiveness, Jackson et al. (2010). Under existing law, including the Dietary Supplement Health and Education Act passed by Congress in 1994, the FDA can take action to remove products from the market, but the agency must first establish that such products are adulterated (e.g., that the product is unsafe) or misbranded (e.g., that the labeling is false or misleading).

In order to do that, on 6 October 2009, the FDA sent a letter to health care professionals regarding some types of dietary supplements founded to contain colloidal silver. FDA advised consumers who used it or were considering the use of dietary supplements that contain silver, to discuss any concerns they may have about the safety of those supplements in their particular circumstances, with their health care provider, Noble (2015).

On 16 July 2013, the FDA continued to advise consumers not to buy dietary supplement products that contain DMAA due to the health risks they present (in 2012, FDA issued for the first time warning letters to companies notifying them about the risk of consuming products with DMAA content). DMAA, also known as geranium extract, is an ingredient found illegally in some dietary supplements and often touted as a natural stimulant. DMAA, especially in combination with other ingredients such as caffeine, can pose a health risk to consumers. Dietary supplements containing DMAA are illegal and FDA tried to remove these products from the market. Most companies that were warned are no longer distributing products with DMAA.

On 23 April 2015, the FDA issued warning letters to five companies regarding a total of eight products for which the product labeling lists BMPEA as a dietary ingredient. Two of the companies further identified the source of this stimulant as the botanical *Acacia rigidula*. Even if BMPEA was listed as a

dietary ingredient on the product labels, the substance did not meet the statutory definition of a dietary ingredient (fda.gov/Food, 2017).

On 28 April 2015, the FDA issued warning letters to 14 companies regarding a total of 17 products for which the product labeling identified DMBA as a dietary ingredient. The FDA considers these products to be adulterated (fda.gov/Food, 2017).

On 1 September 2015, the FDA issued warning letters to five distributors of pure powdered caffeine because these products were dangerous and presented a significant or unreasonable risk of illness or injury to consumers. Pure powdered caffeine products have contributed to at least two deaths. One teaspoon of pure powdered caffeine is equivalent to the amount of caffeine in about 28 cups of regular coffee. While consumers of caffeinated products such as coffee, tea and soda may be aware of caffeine's less serious effects – such as nervousness and tremors – they may not be aware that these pure powdered caffeine products can cause serious health effects, including rapid or dangerously erratic heartbeat, seizures and death, Fox (2018).

On 30 November 2015, the FDA issued warning letters to five companies whose products marketed as dietary supplements claimed to contain picamilon. These products were misbranded because picamilon does not meet the statutory definition of a dietary ingredient (fda.gov/Food, 2015).

According to Mark S. Miller, a regulatory review officer at the U.S. Food and Drug Administration, bodybuilding products that contain steroids or steroid-like substances are associated with potentially serious health risks, including liver injury. Miller was the lead reviewer assessing hundreds of adverse event reports made to the FDA from July 2009 to December 2016. Thirty-five reports showed evidence of serious liver injury, and in addition, anabolic steroids have been associated with serious reactions such as severe acne, hair loss, changing mood, irritability, increased aggression, depression, heart attack, stroke, pulmonary embolism and deep vein thrombosis (fda.gov/ForConsumers, 2017).

Cara Welch, senior advisor in the FDA's Office of Dietary Supplement Programs, explains that many of the bodybuilding products sold online, as well as in retail stores, are labeled as dietary supplements. If consumers buy imported "dietary supplements" and nonprescription drug products from international or ethnic stores, or online, they also risk to be harmed, because many of these products are fake, being marketed illegally, without a previous approval (fda.gov/ForConsumers, 2017).

In order to educate the consumers regarding how risky the consumption of unapproved fraudulent dietary supplements are, in 2016, as part of the National Consumer Protection Week, U.S. General Attorney L. Lynch recorded a video message that highlighted the Justice Department's (DOJ's) recent work against fraudulent, deceptive and unsafe dietary supplements. She noted that DOJ had partnered with other federal law enforcement agencies to make the policing of such products a priority, and that, in 2015, over 100 civil and criminal actions involving fraudulent or unsafe "supplements" were filed (in some cases, the products were so unlawfully marketed that she hesitated to label them as actual dietary supplements). So, consumers have to become more educated and informed when talking about the dietary supplements consumption, Hawana (2016).

At the same time, FDA launched a new initiative on supplement safety that provides information for consumers in several foreign languages, in order to explain the consumers in an easy way the dangers posed by the imported, tainted products falsely marketed as dietary supplements. Some of the consumer safety concerns cited by FDA included (www.FDA.gov/SupplementSafety, 2018):

- imported products marketed as "dietary supplements" or non-prescription drugs which may be contaminated or contain undeclared, potentially harmful drug ingredients;
- dietary supplements claiming to prevent, treat, or cure serious conditions like cancer, HIV/AIDS, or diabetes.

A study concerning the presence of banned drugs in dietary supplements after FDA recalls found that as many as two-thirds of the recalled products remained adulterated, and readily available, at least six months after the initial FDA recall, Picciano et al. (2007).

It's complicated to determine the cause of a medical problem when consumers use more supplements or medications or when using them in an improper way. At the same time it's difficult (for the FDA too) to prove a significant scientific evidence that shows a strong link between a food substance and a disease or health condition.

The FDA compiles evidence to make decisions regarding the safety of marketed supplements primarily through mandated manufacturer/distributor reporting of adverse events and also through health care provider and/or consumer reporting through the FDA's adverse event reporting portal, Briefel and Johnson (2004). FDA takes every adverse event report seriously, investigates and evaluates other possible causes before deciding whether a product actually caused medical problems. The existence of an adverse event report does not necessarily mean that the product identified in the report actually caused the adverse event. FDA assesses the relationship, if any, between a product or ingredient and the reported adverse event.

While FDA investigates all reports to the best of its ability, it does not always have access to all the information needed to conclusively determine the cause of the event. Challenges include:

- reports with incorrect, incomplete or no contact information, which make following up with the complainant, difficult or impossible;
- variability among the completeness of the reports. Some reports may consist only of a single sentence with little detail;
- reports that list the brand, but do not identify the specific product;
- absence of or lack of FDA access to other information related to the report, such as medical records and medical histories (in fact, some state medical privacy laws prevent FDA from obtaining medical records related to the adverse event report).

Manufacturers, packers and distributors of dietary supplements are required by the federal law to report any serious adverse events to the FDA within 15 business days, and to provide any additional medical information they obtain within a year of the adverse event report.

However, it is estimated that a small fraction of consumers who have experienced an adverse effect from a dietary supplement report such an event either to the corporation who produce the supplement, to a health care provider, or directly to the FDA, Stewart et al. (1985).

5. The EFSA's role in assuring the dietary supplements consumers' safety

Although dietary supplements are not regulated as strictly as drugs are, consumers from various demographic believe that the products they take are safe and/or effective in helping them to meet their goals, Satia-Abouta et al. (2003). This tendency can be observed in a 2013 survey conducted by the Council for Responsible Nutrition, which found that 85% of those surveyed were confident in the safety, quality and effectiveness of dietary supplements, Bailey et al. (2013). The 2014 edition of the same survey found that consumer confidence had remained steady at 83%.

Even if consumers tend to have a high credibility in the quality of the marketed food supplements, a lot of injuries were identified

and warnings were published by specialized institutions.

Regarding the safety of food supplements and the system for identifying drug risks, the European market encounters similar problems like the American one. EFSA is the institution with a huge role in assuring safe consumption of such products.

In the last years, EFSA published warnings for the food supplements consumers regarding some chemicals, which may be harmful for the people's health and security. Some of these warnings are results of the EFSA research, while others are alarm signals coming from other similar European organizations.

On 21 October 2015, EFSA published the results of a research concerning the supposed harmful effects of isoflavones (naturally occurring substances found in food supplements). A comprehensive review of the available scientific evidence has revealed no indication that isoflavones at levels typically found in food supplements may cause harm, especially to post-menopausal women. More specifically, the evidence reviewed does not suggest there are harmful effects on the three organs considered for this assessment - mammary gland, uterus and thyroid gland, specifically by peri- and post-menopausal women (efsa.europa.eu, 2018).

On 27 July 2017, EFSA updated its 2011 advice on the risks for human and animal health from pyrrolizidine alkaloids, a large group of toxins produced by different plant species that can unintentionally enter the food chain. In 2011, EFSA concluded there were possible long-term health concerns for toddlers and children who are high consumers of honey, the only food category for which sufficient data were then available. The European Commission requested the updated risk assessment, which takes account of exposure estimates using more recent data on the levels of these toxins in honey, tea, herbal infusions and food supplements (efsa.europa.eu, 2018).

Exposure to pyrrolizidine alkaloids in food, in particular, for frequent and high consumption of tea and herbal infusions, is a possible long-term concern for human health due to their potential carcinogenicity (efsa.europa.eu, 2018).

On 23 January 2018, EFSA published an article regarding some substances belonging to a group of plant ingredients known as hydroxyanthracene derivatives, which can damage DNA and may cause cancer. This group of substances naturally occurs in plants. Extracts containing them are used in food supplements for their laxative effect.

In 2013, EFSA found that hydroxyanthracene derivatives in food can improve bowel function, but advised against long-term use and consumption at high doses due to potential safety concerns. The European Commission subsequently asked EFSA to assess the safety of these plant ingredients when used in foods, and provide advice on the daily intake not associated with adverse health effects (efsa.europa.eu, 2018).

Based on the available data, EFSA concluded that certain hydroxyanthracene derivatives are genotoxic (they can damage DNA). Therefore it was not possible to set a safe daily intake. When tested on animals, some of these substances have been shown to cause intestine cancer. These conclusions are in line with previous assessments on the botanical sources of these substances by other European and international bodies, including the World Health Organization, the European Medicines Agency and, most recently, the Germany's Federal Institute for Risk Assessment (efsa.europa.eu, 2018).

Irreversible neurotoxic adverse effects from intakes of manganese (an essential mineral for humans) close to adequate intakes have been reported in humans, in Norway. Main contributors to dietary manganese intake are cereals (57%), followed by fruit, vegetables, nuts and coffee/tea. In Norway, manganese content in drinking water is

low. That's why, on 28 February 2018, The Norwegian Scientific Committee on Food and Environment made an assessment regarding the dietary intake of manganese in relation to tolerable upper intake level, being concerned about the risk of negative health effects after consuming food supplements which contain manganese. The Committee has evaluated doses at 1, 5 and 10 mg manganese per day. The previous maximum limit for manganese in food supplements was 5 mg. A no observed adverse effect level could not be set, because all the doses tested reported negative effects. Consequently, no tolerable upper intake level could be established for manganese.

Norwegian authorities have not suggested any recommendations for intake of manganese. But, in 2013, EFSA suggested 3 mg/day to be an adequate intake of manganese (vkm.no/english/riskassessments, 2018).

On 18 April 2018, EFSA assessed the safety of green tea catechins from dietary sources, following concerns regarding their possible harmful effects on the liver. Green tea is widely consumed for its purported health benefits, but there have also been reports in the EU and beyond of possible harmful effects. EFSA's assessment of green tea catechins (substances naturally present in green tea) was triggered by concerns from Nordic countries following reported cases of liver damage possibly associated with the use of green tea products.

For green tea infusions, EFSA's experts concluded that there is generally no indication of liver damage even after high consumption, and that the few cases of liver damage reported in humans are likely due to rare and unpredictable reactions. So, catechins from green tea infusions and similar drinks are considered safe (efsa.europa.eu, 2018).

To improve consumer protection, EFSA has recommended further studies on the effects of green tea catechins. Experts also proposed clearer labeling of green tea products (in particular food supplements) regarding catechin content and their possible health risks. EFSA's advice was forwarded to the European Commission, which will decide on the most appropriate risk management follow-up (efsa.europa.eu, 2018).

Consumers should permanently remain skeptical when seeing promises on food supplement labels or advertisements. Dietary supplement labels and ingredients aren't fully evaluated by FDA, EMA, EFSA or other similar institutions, before they're sold. That way, even some vitamins and minerals can cause problems. Consumers should not believe in claims related to prevention or treatment of illnesses. Products often lack the wondrous effect that was promised on the label. For example, products claiming to cure cancer are a deception because normally and legally such products must gain an approval before they are marketed and sold. Lack of approval or safety clearance means that the products could also contain dangerous ingredients. That's why, for a consumer it is not safe to only read labels and packages inserts and follows the indicated directions. Consumers must ask for a proper advice from the health care professional, whether a dietary supplement is safe or not.

Conclusion and Limitations

The food supplements consumer nowadays knows that in the relationship with producers or traders, the law confers him a number of rights and defends him against any abuse that might endanger his life and health, or to damage his interests. That's why, the market must offer high quality products without hidden risks, which may threaten or endanger the health and integrity of the consumers, and also, the environmental safety. In that way, the consumer's role becomes more complex, and an increasing number of businesses or institutions can be affected by its behavior and options.

Because of the market globalization, the dietary supplements produced by the American

(European) corporations are available on every market all over the world. This might be just one of the reasons why consumers base the purchase decision of those products mostly on advertising, which is in most of the cases subliminal and unethical, sometimes promoting fake, risky and dangerous products.

We must outline the fact that mass-media cannot play an important role in promoting and protecting the dietary supplements consumers' safety and health. This is why we consider the federal and European laws as being responsible for regulating this area (which has to be open and transparent), with the support of medical professional bodies and a consistent campaign in promoting truly the consumers interest. This way, public policies will become most effective.

This study is limited only on the activity of the US Food and Drug Administration, The European Medicines Agency (EMA) and The European Food Safety Authority (EFSA), because they are the most important institutions with legal power in regulating the dietary supplements policy in the global market. But we can't deny the role played by other similar institutions all over the world, because the evolution of the global dietary supplements market was so rapid that the three main bodies with legal power in regulating it find it impossible to keep pace with such an unpredictable growth. Some of these institutions were mentioned in that paper: The Norwegian Scientific Committee on Food and Environment, The Germany's Federal Institute for Risk Assessment, World Health Organization. At the same time we can't deny the huge role played by each government in this issue, because each country tend to take their own measures to protect the consumer's health, safety and their economic or legal interests, wherever they live, travel or shop.

Food supplements are not a substitute for a diverse diet and they should not be administered without a cause, as excessive use of food supplements can be harmful to the body. At present, sellers of herbal remedies are not allowed to make direct medicinal or health claims but, indirectly, the message gets across to customers that this or that herb is good for digestion, heart irregularities, anxiety, sexual performance etc. A related concern is that, since many herbal compounds are pharmaceutically active, with most herbal remedies taken at the initiative of the patient without physician oversight, dangerous drug interactions that would be easily recognized by doctors goes unrecognized with serious injury or death as possible results. For these reasons, it is important to consult with a health care professional before using any dietary supplement (cfsan.fda.gov, 2017).

This review article intends to be just a preamble for the series of articles we intend to publish as a result of our present and future work in the dietary supplements consumers' protection field. For the future we think it would be appropriate to implement some economic models in that area, in order to find out the consumers and medical professionals' opinion regarding the safety and effectiveness of dietary supplements consumption.

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