

# Review of Nutraceutical and Dietary Supplement in Toxicology

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## Abstract

*This article explores the expanding role of dietary supplements and nutraceuticals in toxicology. Although they are widely consumed, there is little proof that using supplements or nutraceuticals can improve health in people who are eating a healthy diet. However, some of these products can be extremely toxic. Moreover, very few people tell their doctors they take supplements. Therefore, there is a high chance of negative drug-supplement interactions. An outline of the main nutraceutical and supplement products is given in this article, as well as information on known adverse effects and potential drug interactions. The review focuses on the balance between increasing health benefits and limiting hazards. Due to the detrimental effects of modern lifestyles on public health, herbal dietary supplements have gained popularity due to their medicinal and nutritional advantages. However, things like adulteration, contaminants, numerous substances, and inadequate processing or storage can all jeopardize their safety and effectiveness. Adverse clinical outcomes are still a major worry because regulation is laxer than for pharmaceutical medications. Common herbal supplements like aloe, green tea, ginseng, ginkgo, tongkat ali, flaxseed, St. John's wort, and withania are reviewed in this article along with their toxicological consequences. Uncontrolled supplement use can be harmful to one's health. This article aims to the mechanism action behind these toxicities and regulatory challenges that come with assessing risk moreover. In which highlight some current trends and methods that can help enhance safety assessment to make medical professional and government agencies well informed decisions. Understanding the complex relationships between toxicology, dietary supplements, and nutraceuticals is essential for promoting public health and well-being.*

**Keywords:** Nutraceutical, dietary supplement, toxicology herb drug interaction, safety assessment, pharmacovigilance

## INTRODUCTION

The Department of Health and Human Services is home to the government agency known as the

Food and Drug Administration (FDA). It is in charge of regulating all foods and medications to make sure they are safe for people to consume and that they work. A product designed to complement the diet is referred to as a dietary supplement under the Dietary Supplement Health and Education Act (DSHEA) of 1994. This study is to investigate a few severe side effects brought on by dietary supplements and offer recommendations about supplement use and regulation to lessen the incidence of side effects. Also, this study illustrates why stricter supplement restrictions ought to be issued. This could encourage more study into how supplements work, leading to helpful recommendations for resolving people's safety issues [1]. Although typically safe, taking dietary supplements carries some risk. The goal of the

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current review is not to provide an exhaustive list of all known side effects for any dietary supplement. Rather, we have chosen to talk about side effects for the most widely taken supplements, including vitamins, minerals, omega-3 fish oil, soy protein, and antioxidant and anti-inflammatory nutraceuticals produced from plants. We also go over body-building and weight-loss supplements, as well as a number of botanical supplements that have been linked to more serious side effects [2]. Nutraceuticals are bioactive substances that are present in everyday foods and plant-based sources. They can be obtained through functional foods or dietary supplements and provide benefits beyond meeting basic nutritional needs. Probiotics, fatty acids, amino acids, phytochemicals, antioxidants, and other bioactive substances obtained from edible sources are all included in this category of nutraceuticals. Nutraceuticals are well-known for their known or potential health benefits. They are important in the treatment and prevention of diseases, have anti-aging qualities, and help prevent cancer. Given their significant role in the prevention and treatment of gastrointestinal disorders, probiotic consumption is advised. Garlic, for example, has been suggested as a supplemental strategy for controlling elevated blood pressure and cholesterol [3] (Figure 1).



**Figure 1.** Nutraceutical & dietary supplement in toxicity (safety concerns).

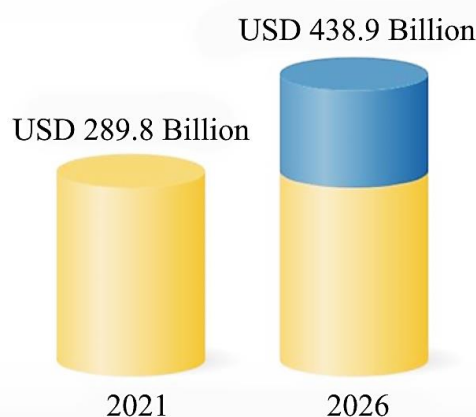
#### OBJECTIVE OF NUTRACEUTICAL DIETARY SUPPLEMENT

- To increase the nutrition factor of food.
- Activities immunity.
- Increase feed consumption.
- Induced maturation.
- Anti-microbial capability.
- No negative environment impact or hazard or problems.
- State the definition of a dietary supplement, Nutraceutical and a functional food.
- State the regulation of dietary supplements in the market [4].

## NUTRACEUTICAL MARKET GROWTH

The nutraceutical industry has three primary segments: functional foods, dietary supplements, and herbal/natural goods. India is set to become a major player in this industry. The company's market value is projected to reach \$4-5 billion, indicating significant growth potential. Around \$18 billion by 2025. The Indian nutritional supplements market was valued at USD 3,924.44 Million In 2020 And is Expected to Reach USD 10,198.57 Million By 2026, With a 22% annual growth rate. The Pandemic's impact and increased attention on healthcare have led to fast expansion in this sector. Indian customers are embracing immunity-boosting supplements, leading to significant shifts in purchasing behavior and market patterns. Health-conscious people purchase products like vitamin capsules, chewable tablets, and gummy bears with an open mind. The epidemic has highlighted the importance of preventive healthcare, and the nutritional sector has emerged as a strong economy for individuals. The nutraceutical sector in India is projected to be worth \$117 billion, contributing significantly to the country's GDP [5] (Figure 2).

Global Nutraceuticals Market  
Market forecast to grow at a CAGR of 8.70%



**Figure 2.** Nutraceutical Market Growth.

## DIETARY SUPPLEMENT MARKET GROWTH

According to the Financial Times (April 19, 2002), the US food supplement business was valued at USD 16.7 billion in 2000, while the global market was valued at approximately USD 46 billion in 2001. The food supplement market was valued at roughly USD 104 billion worldwide in 2013, and by 2015, the U.S.A. market was projected to be worth USD 27.2 billion. Additionally, it was predicted that the market will continue to develop at a compound annual growth rate of 5–6% over the next two years. The following are some of the well-known food supplement brands currently on the market: Himalaya, Longrich, Amway, Forever, Herbalife, etc. The global market for dietary supplements was valued at around 132.8 billion USD in 2016, and it is expected to reach about 220.3 billion USD in 2022, according to market research is presented clearly in to a different Research and industry study the worldwide dietary supplement industry was estimated to be worth approximately 163.1 billion USD in 2019. According to an FMI analysis, the market for dietary supplements is expected to continue expanding quickly as more people become aware of the importance of eating a healthy diet for good health. By 2025, it was anticipated that with a compound annual growth rate of 7.4%, the global market for dietary supplements is expected to reach a considerable value of over \$252,100 USD [6].

## NUTRACEUTICAL AND DIETARY SUPPLEMENT TOXICITY STUDIES

In order to gather this literature review, searches regarding the levels of toxicity of plant chemicals present in botanical dietary supplements and herbal medications were mainly conducted using PubMed, EBSCO, and SciFinder. To get the best results, a variety of search phrases were employed, including “toxic plant compounds,” “herbal supplement adverse effects,” “plant compound adverse effects,”

“toxic herbal medicine,” “toxic botanical supplements,” and “toxic alternative medicine.” Additionally, these terms were used in conjunction with the scientific names of the botanical dietary supplements available on the market to look at the possible toxicity of the goods that the general public consumes the most [7].

## **Preclinical Toxicity Studies**

### ***In Vitro Studies***

- *Purpose:* Characterize genotoxicity, oxidative stress, cytotoxicity, and interactions with metabolic enzymes.
- *Techniques employed:* test methods for liver toxicity using hepatocyte culture. Neurotoxicity models using glial and neuronal cells. tests for cell viability using MTT. Necrosis and apoptosis using flow cytometry [8].
- *Example:* When tested on primary human hepatocytes, for instance, garcinia cambogia extract demonstrated dose-dependent cytotoxicity.

### ***In Vivo Animal Studies***

- *Purpose:* Evaluating systemic impacts (acute, sub-chronic, and chronic toxicity) is the goal.
- *Techniques employed:* OECD recommendations (e.g., OECD 407 for repeated dose 28-day toxicity, OECD 423 for acute oral toxicity). keeping an eye on biochemical indicators (creatinine, BUN, ALT, and AST). assessment of the liver, kidney, and heart histopathologically [9].
- *Example:* dose-dependent hepatotoxicity caused by green tea catechins (EGCG) in rodents was verified by an increase in ALT/AST.

## **Clinical Toxicity Studies**

### ***Observational & Epidemiological Studies***

- *Purpose:* Identify trends in adverse occurrences linked to supplements in populations
- *Techniques Employed:* FAERS stands for FDA Adverse Event Reporting System. surveillance in the emergency room and hospital records. studies using a retrospective cohort [10].
- *Example:* an analysis of hospital data in the United States revealed that 23,000 emergency visits per year were caused by adverse events related to dietary supplements (most frequently weight loss and energy products).

### ***Clinical Monitoring and Case Studies***

Caffeine and yohimbe were the most common causes of symptoms in 41% of cases of supplement usage, according to a retrospective examination of poison center data [11]. Systematic reviews have reported adverse reactions in older adults, including drug-supplement combos (e.g., warfarin with vitamin E, omega-3 fatty acids) that cause bleeding issues [12].

## **Reporting of Adverse Events**

The bad incident must be reported in order for the regulatory official to be aware of it. The unfavorable event will serve as evidence to support subsequent occurrences if it is a new occurrence in the database. The event must be reported to the FDA by the sponsor. The safety data will be used by the FDA, IRB, and sponsor to support critical choices that may impact human clinical studies. Because customers believe that nutraceuticals and dietary supplements are safe and do not cause any negative side effects, there is little reporting of these goods. The FDA controls dietary supplements and nutraceuticals, although consumers are not completely aware of this Consumer and medical professional reporting comprises a). Use the FDA's safety portal to complete the safety report form. Sign in with a guest ID. Select “Dietary Supplement Report (voluntary). Enter the information. Direct reporting to the healthcare provider is an option for the patients. Included in Industry Reporting is a). Use the FDA's safety portal to complete the safety report form. Please log in as a guest. Select the “Mandatory Dietary Supplement Report” [13].

## MECHANISM TOXICITY

### Hepatotoxicity (Liver Toxicity)

- *Green Tea Extract (Camellia sinensis)*: Hundreds of millions of people use green tea every day, making it one of the most popular drinks in the world [14]. Some safety concerns surfaced as green tea use rose. In particular, when used for weight control, green tea has been linked to hepatotoxic responses (Mazzanti et al. 2009; Sarma et al. 2008). In this regard, Exolise® (Arkop harma, Carros, France), a green tea preparation that was sold as a herbal weight-loss supplement, was recalled in 2003 following 13 reports of hepatotoxicity brought on by its use (Gloro et al. 2005). In order to reassess the safety class that green tea products were previously assigned, the US Pharmacopoeia (USP) Dietary Supplement Information Expert Committee (DSI EC) conducted a systematic evaluation of the safety data for these products (Sarma et al. 2008). This safety review's outcome [15] (Figure 3).



**Figure 3.** Green Tea.

### Nephrotoxicity (Kidney Toxicity)

- *Aristolochic Acid (Aristolochia species)*: Because it acts through a genotoxic mechanism, AA is classed as carcinogenic group I to humans by the International Agency for Research on Cancer (IARC) Therefore, numerous countries have prohibited the use of herbs or treatments that contain AA However, people are still exposed to AA because Aristolochia plant species are found all over the world and because herbal treatments are widely used in some areas. In this regard, studies to comprehend the molecular processes of AA-induced nephrotoxicity may eventually lead to the discovery of effective protective mechanisms or a model for examining drug-induced organ toxicity [16] (Figure 4).



**Figure 4.** Aristolochic acid species.

### Cardiovascular Toxicity

- *Ephedrasinica*: The medical literature has reported several cases of negative reactions to dietary supplements containing ephedra alkaloids, some of which led to death or irreversible harm. 1–6

The Food and Drug Administration (FDA) asked for an independent review of reports of adverse events associated with the use of ephedra alkaloids in order to determine the level of risk these products pose to consumers and assess causation, in response to growing concerns regarding the safety of ephedra alkaloids in dietary supplements [17].

- Numerous herbal remedies have been linked to toxicities of this kind, which include convulsions and cardiovascular toxicity. Herbal products also stimulate the sympathetic nervous system [18] (Figure 5).



**Figure 5.** *Ephedra sinica*.

### Neurotoxicity

- *Ginkgo biloba*: One of the most widely used herbal supplements, ginkgo biloba is frequently taken to boost memory, improve circulation, and enhance cognitive function. Fear of Toxicity: Ginkgotoxin, also known as 4'-O-methylpyridoxine, is a neurotoxic substance that shares structural similarities with vitamin B6 and is found in certain preparations of ginkgo seeds and leaves. Ginkgotoxin decreases the synthesis of  $\gamma$ -aminobutyric acid (GABA) by interfering with pyridoxal phosphate-dependent enzymes. GABA is an inhibitory neurotransmitter, which raises the risk of seizures and lowers the seizure threshold. Case studies of people who had seizures after taking supplements of ginkgo biloba were published by Rowin & Lewis (1996) [19] (Figure 6).



**Figure 6.** *Ginkgo Biloba*.

### Heavy Metal Contamination

It is common for herbal and nutraceutical supplements to contain lead (Pb), mercury (Hg), cadmium (Cd), and arsenic (As) contaminants. Poor manufacturing techniques, contaminated soil, or irrigation water can all contain these metals [20]. Risks to Health Neurotoxicity, childhood developmental delays, renal damage, and hypertension are all brought on by lead (Pb). Mercury (Hg): Linked to tremors, cognitive impairment, and neurological damage. Cadmium (Cd): Deteriorates bones and kidneys and may cause cancer. Skin pigmentation and lesions are caused by arsenic (As), which also raises the risk of bladder, lung, and skin cancer [21].

### **Herb Drug Interaction**

Pharmacodynamic interactions, which involve the direct pharmacologic effects of a herbal supplement unrelated to variations in blood concentrations, are one type of herb-drug interaction. When a herbal supplement directly affects how a co-administered medication works, there is a risk of a pharmacodynamic interaction [22]. With the growing use of herbal remedies worldwide, herb-drug interactions (HDIs) constitute a serious problem. Certain interactions between a medicine and a plant can occur and have either positive or negative effects. harmful effect to health [23].

## **PUBLIC HEALTH AWARENESS IN NUTRACEUTICAL & DIETARY SUPPLEMENT TOXICOLOGY**

### **Educate Consumer**

- *Problem:* A common misconception is that “natural = safe,” which can result in abuse, overdosing, or dangerous interactions with prescription medications.
- *Proof:* More than half of American individuals who take supplements do not tell their doctors about their use, which raises the possibility of interactions, according to Gardiner et al. (2006) [24].
- *Awareness Action:* Education initiatives should prioritize risk awareness, safe dosage, and consultation with medical professionals [25].

### **Label Transparency**

- *Problem:* A lot of supplements are mislabeled; some leave out harmful substances or pollutants, or they don't state how much of an active ingredient is there.
- *Proof:* Cohen (2014) discovered that a large number of supplements sold in the United States contained pharmaceutical medicines that were not disclosed (such as sibutramine in weight reduction products) [26]. A study conducted in India found that Ayurvedic supplements contained heavy metals (lead, mercury, and arsenic) (Saper et al., 2008).
- *Awareness Action:* The active ingredients, dose, contraindications, and potential side effects should all be listed on the label [27].

### **Surveillance Systems**

- *Problem:* It can be challenging to spot toxicity trends because many supplement-related adverse events go unreported.
- *Proof:* Cases of liver damage from supplements such as kava and green tea extract are documented in the NIH-maintained U.S. LiverTox database (Hoofnagle et al., 2013) [28]. (Global safety problems are brought to light by the international reports of supplement-related toxicity that are sent to the WHO VigiBase system.
- *Awareness Action:* Urge doctors and patients to notify national and international monitoring systems of any adverse effects [29].

### **Regulation**

- *Problem:* Supplements frequently enter the market without undergoing thorough preclinical and clinical safety assessment, in contrast to medications.
- *Proof:* After Ephedra (2004) was connected to strokes, arrhythmias, and hypertension, the FDA prohibited it (Bent et al., 2003) [30]. The European Medicines Agency (EMA) requires risk warnings on packaging and provides safety standards for herbal products. The Food Safety and Standards Act of 2006, which governs nutraceuticals in India, is enforced inconsistently by the Food Safety and Standards Authority of India (FSSAI).
- *Action Awareness:* More stringent post-marketing monitoring, safety labeling, and unified international standards are required [31].

## **SAFETY FUTURE PROSPECTIVE**

Safety concerns have overshadowed the potential advantages of nutraceuticals in recent years. The list of products that regulatory bodies in different jurisdictions have recalled is getting longer

Unreported active ingredients and inaccurate labeling are among the causes of recalls for supplementary drugs [32]. In a similar vein, dietary supplements have been recalled due to microbial contamination and unknown substances. However, even at prescribed dosages, nutraceuticals may produce toxicities, mostly because there aren't enough controlled or longitudinal clinical investigations on people to determine a safe dose. Hepatotoxicity has been observed with green tea, for instance [33]. Garlic consumption of about 12 g per day can cause bleeding irregularities and have antiplatelet effects [34]. The health risks of not correctly identifying and listing all the ingredients and the dosage include the possibility of allergic reactions as well as drug interactions, such as the way St. John's wort interacts with anticoagulants, psychotropic medications, and concerns about how it might affect the effectiveness of other medications and oral contraceptives [35]. When taken as refined supplements, certain flavonoid types, such as soy-derived isoflavones, have been demonstrated to cause abnormalities of the reproductive system. A few studies have also found developmental toxicity and an elevated risk of Kawasaki illness in children who consume soy milk or formula [36]. Bleeding can be made worse by fish oil and omega-3 supplementation, which is especially worrisome for those on other anticoagulants [37]. Even more crucial is the role that improved public education plays in terms of labeling to encourage the proper use of these agents. Stricter penalties for violations can provide an additional degree of consumer safety.

## CONCLUSION

In this review that concluded Getting a grip on the tricky connections between toxicology, dietary supplements, and nutraceuticals is absolutely essential, and that's exactly what this review points out. When we dive into toxicology, it becomes clear just how complicated dietary supplements and nutraceuticals can be. It's super important to really evaluate their safety and effectiveness. Sure this product can be helpful as complementary and alternative therapies for various health issues, but have to tread carefully to avoid any interaction and side effect. Improve to maximize the benefits of nutraceutical and dietary supplements while keeping risk at bay, we needed going research-diligent oversight from regulatory and important for better education for consumers. Think about herbal supplements like green tea extract, ginkgo biloba, aristolochic species, kava kava, epihedrasinica, garlic and aloe vera each of these can offer some improve health but here's think; everyone body is different and people can react in divers ways to t and the supplement. So Before jumping in, it's crucial thoroughly check their effectiveness and safety. Proper with guidance from a health care professional. We need to focus on educating safety consumers and awareness to help people make informed use about using to nutraceutical dietary supplements. By addressing these challenges and staying updated with new research in the field we can do much better job for protecting public health and wellness in this fast changing world of dietary supplement.

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