ToxTalks:

A Bulletin for Healthcare Professionals Who Manage Poisoned Patients

Blue Ridge Poison Center | University of Virginia Health | September 2023

Dietary Supplements: Regulation and Clinical Issues

Regulation

Unlike pharmaceutical drugs, dietary supplements are regulated with less scrutiny. Governed by the Dietary Supplement Health and Education Act (DSHEA) of 1994, dietary supplements do not require FDA approval before they hit the market. The responsibility for ensuring safety and efficacy lies with the manufacturers, not the regulatory authorities. This opens avenues for potential health risks, challenges in quality control, and presents unique complexities for healthcare providers.

Labeling Requirements

Manufacturers are mandated to provide accurate information on dietary supplement labels, including ingredients, quantity, and suggested usage. However, this information may not necessarily reflect the actual content or potency of the product. Despite labeling requirements, inconsistencies in labeling often occur, and manufacturers may fail to adhere to guidelines, leading to variations in product quality and potential misinformation.

Major Cases and Controversies

The case of Ephedra, once a popular ingredient in weight-loss products, highlights the issues related to dietary supplements. Ephedra was banned by the FDA in 2004 after it was linked to serious health issues, including heart problems and deaths. Moreover, the lack of strict regulatory oversight means that dietary supplements can be contaminated with harmful substances such as heavy metals,

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bacteria, or undisclosed pharmaceutical agents, leading to unforeseen adverse effects.

Problematic Supplements

There are innumerable supplements that can interact with other drugs or cause adverse effects. St. John's Wort (Hypericum perforatum), for example, is known for its antidepressant effects and acts as an inducer of CYP 3A4 and CYP 1A2, thereby affecting the metabolism of various medications such as birth control, anticoagulants, and HIV drugs. This can lead to reduced efficacy of these medications and pose serious clinical implications.

Kava (Piper methysticum), used for its stress-relieving properties, has several pharmacologic effects including GABA receptor agonism, likely responsible for its reported anxiolytic effect. However, its use has been associated with liver toxicity by unclear mechanisms. The risk is especially high if taken with alcohol or other hepatotoxic substances.

There are a variety of other supplements which can lead to drug interactions and toxicity. It is estimated that approximately 20% of US adults use dietary supplements, and 23,000 ED visits each year in the US are attributable to dietary supplement use, underscoring the need for vigilance and education regarding these substances.

Management and Reporting

Providers encountering adverse events due to dietary supplements should consider both immediate patient care and long-term reporting. Concerns for adverse events should be reported to the FDA at http://safetyreporting.hhs.gov. Additionally, healthcare providers are encouraged to reach out to the local poison center at 1-800-222-1222 (or the dedicated provider hotline at 1-800-451-1428) to report or discuss these cases.

Poison safety tips, free materials, & more: