Herbal Supplements and Consumer Safety

Executive Summary

Herbal supplements are products, such as capsules, tablets, powders, or extracts, that are made from plants and are available widely in retail stores nationwide. Despite their popularity as supplemental health products, these products do not have to be approved by the FDA to be sold without a prescription to consumers.

Research Highlights

- Herbal medicines are the most widely used complementary and alternative medicine approach in the United States.
- There are no laws regulating the sale of general herbal supplements in Missouri (only laws regulating the sale of Kratom).
- Herbal supplements can be linked to negative health outcomes due to many different factors.

Limitations

- The prevalence of adverse effects from herbal supplements is unknown due to infrequent reporting.

Research Background

Adulteration in Herbal Supplements

Herbal supplements are products such as capsules, tablets, powders, or extracts, that contain one or more botanical ingredients and are available without a prescription.[1] In the year 2020, sales of herbal supplements in the United States totaled an estimated $11.261 billion – a 17.3% increase from 2019.[2] Herbal supplements are the most widely used complementary and alternative medicine approach in the United States.[3] Additionally, amongst immigrant and Indigenous communities, where botanical medicines are deeply entrenched in cultural traditions, use of herbal supplements can harmonize with healthcare approaches corresponding to cultural beliefs and heritage.[4,5]

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It is well documented that taking herbal supplements can be linked to negative health outcomes,[3,5,6] for reasons that vary. However, the prevalence of adverse effects from herbal products is unknown because the reporting of adverse effects of herbal supplements within clinical practices is infrequent.[7] One reason is that botanical and common names listed on supplements may not match the plants included in supplements (either due to botanical misidentification or intentional deceit by supplement company).[8] This generally poses a low risk to consumers, although there have been cases where highly toxic plants have appeared in supplements.[9] Another potential safety concern is the sale of pharmaceutical drugs in products listed as herbal supplements, which poses a higher risk of negative health outcomes to the consumer.[10] Interactions between herbal supplements and prescription drugs are another potential safety issue,[11] and one that is exacerbated by lack of disclosure of supplement use by patients and lack of inquiry by doctors.[5] Unpredictable reactions to herbal supplements can occur, leading to conditions such as liver failure, allergic reactions, and other health issues.[8,12]

The quality of medicinal plants may be negatively impacted by several factors, including:

- carelessness or ignorance of the plant collector,
- negligence during preparation and foreign object removal,
- poor storage and preservation practices,
- accidental contamination with another plant or substance,
- adulteration,
- and substitution of a different plant.[13]

There are several types of fraud or adulteration that occur in the herbal supplement industry. Inaccurately labelled plant ingredients, as described above, are common. Supplements may contain plants that have already had valuable constituents removed (common in spice plants such as cinnamon, black pepper, and ginger).[9] Chemical adulterants may also be found, and supplement producers may be savvy enough to evade mechanisms for detecting chemical adulterants.[9] One study found that 29% of evaluated herbal products being retailed in the US were adulterated.[14] However, the likelihood of adulteration varies depending on the specific plant in question. Most types of adulteration do not pose a safety risk; however, they may compromise the efficacy of the herbal product.[9]

Regulation of Herbal Supplements

The Dietary Supplement Health and Education Act of 1994 redefined the Food and Drug Administration's (FDA) power to regulate dietary supplements (products intended to supplement the diet that contain one or more dietary ingredients, including herbs or botanicals).[15] The FDA prohibits manufacturers and distributors from marketing misbranded or adulterated products, and manufacturers must comply with the FDA's good manufacturing practice regulations. However, they do not pre-evaluate product safety and labeling before market entry; rather, the agency is authorized to act on misbranded or adulterated products that have already been made available to the public. This leaves manufacturers and distributors

with the responsibility of ensuring their products are safe before hitting market shelves. Several independent organizations, including the U.S. Pharmacopeia, NSF International, and ConsumerLab.com, offer quality assurance testing. However, there is no requirement to go through any approval process to legally sell supplements to the public.

In Missouri, Act SB 504, the Kratom Consumer Protection Act (effective August 28, 2023) prohibits selling kratom to those under the age of eighteen, selling adulterated or contaminated kratom products, and places other regulations on the contents of these supplements.[16] Presently, there are no other statewide regulations governing the sale of herbal supplements in Missouri or any other state (except those regulating the sale of cannabis and kratom).

In many countries the use of herbal medicines is routine, with an estimated 4 billion people relying on them worldwide as a primary source of healthcare.[17] This prevalence is often reflected in national treatment guidelines, and the efficacy of their use is supported by placebo-controlled clinical trials, meta-analyses, and systematic reviews.[18] In Europe, for example, herbal medicines must undergo approval by national regulatory authorities, ensuring their safety and efficacy in compliance with science-based quality standards that guard against adulteration and contamination.[19]

American Consumers and Herbal Supplementation

Americans are accustomed to high-quality pharmaceutical products, and so have little reason to be skeptical about package label claims on prescription and over-the-counter medicines, as well as dietary supplements.[6] This may leave consumers vulnerable to a market lacking sustainable quality controls, inadequate labelling, and insufficient consumer information.[20] To mitigate these risks, consumers should purchase supplements from brands that outline the precautionary measures taken during formulation. Ideally, seek indicators such as chemical fingerprinting using high-performance thin layer chromatography or genetic techniques, microbiological testing for bacteria and fungi, and evaluations for heavy metals. Additionally, The American Herbal Pharmacopoeia offers comprehensive documentation on individual medicinal plants detailing traditional uses, scientific evidence of efficacy, risk of adulteration or adverse reactions, and information about potential drug interactions unique to a specific plant.[21] The FDA recommends that consumers talk to their healthcare providers before using any dietary supplements.[22] Overall, the consumer is tasked with balancing the risks and benefits of supplement use on their own.

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