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Evaluation of accurate dietary supplement product labeling

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Introduction /Purpose

Herbal supplement sales in the U.S. increased by 7.5% between 2014 and 2015, from $6.441 billion to $6.922 billion, according to newly released data from the *Nutrition Business Journal (NBJ)*.[1]

Dietary supplements and over-the-counter medications (OTC's) do not have to be proven safe or effective before being sold to consumers like prescription medications. Under the Dietary Supplement Health and Education Act of 1994, manufacturers only have to prove their product causes no harm to consumers.

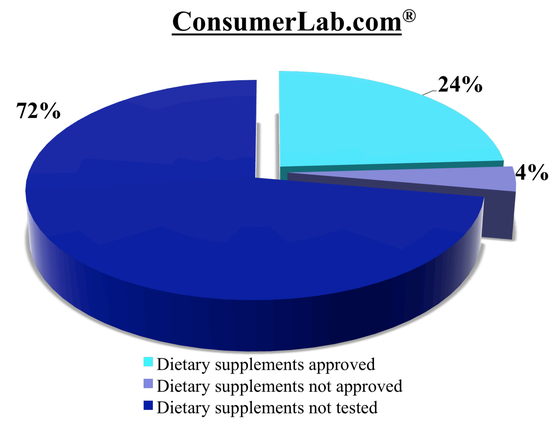
Dietary supplement labels are not reliable, since they are not regulated. Without verification a consumer cannot be sure that what is stated on the label is what is actually in the bottle. Some dietary supplements are known to contain saw dusts, lead, pesticides, arsenic, glass particles, and insect parts. Consumer Reports found that an estimated 23,000 people every year end up in emergency rooms after taking supplements.[2] A 2013 report from the Government Accountability Office (GAO) found that from 2008 through 2011, the FDA received 6,307 reports of health problems from dietary supplements, including 92 deaths, hundreds of life-threatening conditions, and more than 1,000 serious injuries or illnesses.[2] The GAO suggests that due to underreporting, the actual number of incidents may be much greater since there are not any concrete reporting policies for dietary supplements as they make their way to consumers and have the potential to cause many problems. They can be ineffective, contaminated with microbes or heavy metals, dangerously mislabeled, or intentionally spiked with illegal or prescription drugs.[2] Shockingly, Consumer Reports also found that over 1,000 supplements have been found to contain prescription or experimental drugs.[2]

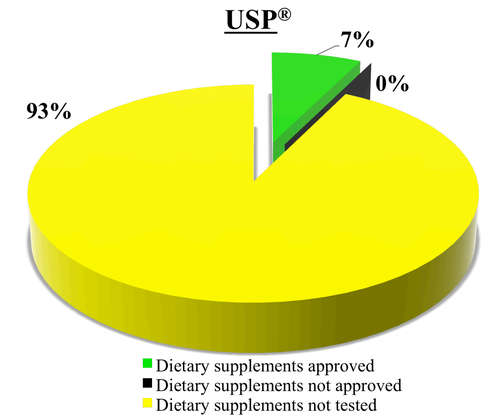
The specific aim of this study is to verify whether dietary supplements and OTC's contain the amount of ingredients claimed on the label of a product by using ConsumerLab.com® and USP® verification systems. ConsumerLab.com® and the USP® are the leading providers of independent test results, which approve whether products are accurately labeled with the correct amount of active ingredients and whether they contain harmful ingredients.

Methods

- University of New England College of Pharmacy faculty, staff, and consumers who consumed dietary supplements were included in this study
- Sixteen participants voluntarily shared the names of the dietary products that they use, including product name, manufacturer, and strength
- Sixteen participants shared a total of 54 dietary supplements that were then evaluated. ConsumerLab.com® and the United States Pharmacopeia® (USP) verification system were then used to evaluate if their dietary supplements were approved
- Once information was evaluated, participants were contacted and informed whether ConsumerLab.com® or USP® tested and approved their product
- The primary outcome measure was percent of dietary supplements used by participants that were approved by ConsumerLab.com® and/or USP®
- Secondary outcomes included percentage of dietary supplements not approved by ConsumerLab.com® and/or USP®, and percentage of dietary supplements not tested by ConsumerLab.com® and/or USP®

Results





	# Dietary supplements (Total = 54)	Percentage
ConsumerLab.com®		
• Approved	13	24.07
• Not approved	2	3.70
• Not tested	39	72.2
USP		
• Approved	4	7.40
• Not approved	0	0
• Not tested	50	92.6

Conclusions

- ConsumerLab.com® approved more dietary products used by participants than USP®
- ConsumerLab.com® disapproved more dietary products than USP®, since there were not any dietary supplements that were tested by USP® and not approved
- Overall, both verification databases failed to provide information on a majority of supplements inspected
- Verification systems need to expand their number of supplements tested to give consumers correct information

References

1. Smith T, Kawab K, Ecklb V, et al. Sales of Herbal Dietary Supplements in US Increased 7.5% in 2015 Consumers spent $6.92 billion on herbal supplements in 2015, marking the 12th consecutive year of growth. *HerbalGram*. 2016; 111: 67-73.
2. Interlandi J. "Supplements Can Make You Sick". *Consumer Reports*. July 27, 2016. Retrieved from: http://www.consumerreports.org/vitamins-supplements/supplements-can-make-you-sick/

Disclosure

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter:
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