The Frequency of Herbal and Dietary Supplement Mislabeling: Experience of the Drug Induced Liver Injury Network

AASLD Liver*Learning*®. Navarro V. Oct 24, 2017; 201449

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ABSTRACT FINAL ID: 264

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Study supported by NIDDK, NIH. See DILIN website http://dilin.org/publications/ for a complete listing of funding sources, sites, investigators, co-investigators, coordinators, and staff.

ABSTRACT BODY:

Background: As Herbal and Dietary Supplements (HDS) are not FDA approved, they could contain unlabeled ingredients, such as chemical and microbial contaminants, pharmaceutical adulterants, or other compounds, some with known hepatotoxic potential. The Drug Induced Liver Injury Network (DILIN) collects and stores HDS consumed by patients enrolled into its prospective study, making them available for chemical verification.

Aim: To analyze the contents and determine the frequency of HDS mislabeling in samples collected by the DILIN prospective study.

Methods: Between 2003 and March 2016, DILIN collected 341 HDS from 1268 enrolled patients; to date, 229 products have undergone chemical analysis at the National Center for Natural Products Research (NCNPR) at the University of Mississippi; 203 of the 229 HDS had their contents labeled. Product ingredients as determined through chemical analysis for each HDS product were compared with the ingredients listed on the product labels. HDS were grouped per the composition of the product, such as if principally of botanical, vitamin, or steroidal ingredients; and per their purported use, such as for body building or weight loss. Mislabeling was defined as when the chemical analysis did not confirm the ingredients listed on the label. Analysis of HDS was performed at the NCNPR using standard liquid chromatography-mass spectroscopy with electrospray ionization source protocol.

Results: We found that only 90 of 203 (44%, 95% CI: 37%-51%) HDS had labels that accurately reflected their contents as determined through chemical analysis. Based on the composition of the product, mislabeling rates (95% CI) were 80% (48%-95%), 54% (35%-73%), 48% (39%-56%) within HDS principally of steroidal (n=10), vitamin (n=26) or botanical ingredients (n=122), respectively. Based on the purported use, products used for bodybuilding (n=34),

weight loss (n=36), energy boosters (n=5), and general health/well-being (n=35) had mislabeling rates (95% CI) of 79% (66%-93%), 72% (46%-76%), 60% (23%-88%), and 51% (35%-68%) respectively. Similar rates of mislabeling were also found for the 166 HDS product judged to be responsible for liver injury by DILIN investigators through a structured causality assessment process.

Conclusions: Using comprehensive chemical analysis, we observed that HDS mislabeling is common, occurring in over half of products collected from DILIN subjects. Products used for bodybuilding, and weight loss have the highest rates of mislabeling. These findings should inform how these agents are evaluated as potential causes for liver injury.