



The Ongoing Problem of Mislabeling of Herbal Dietary Supplements Implicated in Hepatotoxicity in the Drug Induced Liver Injury Network (DILIN)

Victor J. Navarro, MD¹; Bharathi Avula, PhD²; Dina Halegoua-DeMarzio, MD¹; Ikhlas Khan, PhD²; Huiman Barnhart, PhD³ for the Drug Induced Liver Injury Network⁴

BACKGROUND

The U.S. DILIN enrolls patients with liver injury due to drugs or herbal and dietary supplements (HDS). In 2019, DILIN demonstrated that over 50% of HDS consumed by its enrollees were mislabeled.

AIM

The aim of this study is update our 2019 findings and analyze contents of HDS and determine the rate of product mislabeling.

METHODS

- The DILIN enrolls patients with liver injury due to drugs and HDS. Between 2003 and April 2024, DILIN collected 810 HDS from 2627 enrollees.
- To date 633 of the 810 HDS for which product labels were available were analyzed at the National Center for Natural Products Research (NCNPR) at the Univ of MS, using high-performance liquid chromatography-mass spec with electrospray ionization source protocol.
- Chemically verified product ingredients were compared with the ingredients listed on the labels.
- Mislabeling was defined as a mismatch between chemical analysis and then the ingredients listed on the label.
- HDS were categorized according to their main marketed purposes for use, such as weight loss or bodybuilding.

RESULTS

- 262 of 633 (41%) of HDS were mislabeled;
- Overtime, there was a decreasing trend in HDS mislabeling (p=0.0004) (Table below)

DILIN Enrollment Period	Number of HDS Products	Rate of HDS Mislabeling
2004-2005	12	33%
2006-2007	36	56%
2008-2009	64	58%
2010-2011	54	50%
2012-2013	56	41%
2014-2015	116	41%
2016-2017	83	30%
2018-2019	97	42%
2020-2021	54	39%
2022-2023	61	26%
Total	633	41.4%

- The most commonly mislabeled category of HDS were products marketed for weight loss, followed by detoxification and bodybuilding. (Table below)

HDS Category	Number of HDS	Mislabeled (%)
Weight Loss	70	42 (60)
Detoxifiers	17	10 (59)
Bodybuilding	77	44 (57)
Energy boosters	20	11 (55)
Sexual enhancers	8	4 (50)
Immune support	44	19 (43)
Sedative/hypnotic	19	7 (37)
Circulation/CV health	16	5 (31)

RESULTS continued

- 360 HDS of the 810 HDS collected from patients were implicated as being responsible for liver injury through the DILIN's structured causality assessment process.
- Of these 360 HDS directly implicated in liver injury, 134 were collected and analyzed at the NCNPR.
- 62 of the 134 HDS (46%, 95% confidence interval, 38% - 54%) were mislabeled
- Of the 62 mislabeled HDS directly implicated in liver injury, the most commonly mislabeled categories are listed in the Table below.

HDS Category	Number of HDS Implicated in Liver Injury	Mislabeled (%)
Sexual enhancers	2	2(100%)
Immune support	5	5(100%)
GI Health	5	4(80%)
Bodybuilding	17	13(76%)
Energy boosters	4	3(75%)

CONCLUSIONS

- The problem of mislabeling of HDS continues, although the overall trend is favorable.
- Nearly half of products directly implicated as a cause for liver injury were mislabeled; mostly commonly sexual enhancers and immune support products.
- Mislabeling is particularly common in products used for weight loss; given the current focus on agents to achieve weight reduction, there may be considerable risk to consumers.

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