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INCOMPLETE ANALYSIS OF HEPATOTOXICITY AND THE INVALID ASSOCIATION OF HERBALIFE PRODUCTS

In the February 2015 issue of the *Sri Lanka Journal of Diabetes, Endocrinology and Metabolism*, the authors (Naser et al.) completed a literature review (1) of the published works related to the anti-obesity effects of green tea (*Camellia sinensis*) on humans. In their review, the authors referenced an earlier article (2) in table 4 with the heading: Hepatotoxicity of green tea extract, with the inclusion of ['Herbalife' products: green tea extract]. Herbalife previously published a response (3) to the aforementioned article regarding concerns of hepatotoxicity related to Herbalife products, but the authors have yet to acknowledge this information into the current topic analysis.

The authors implicate *Camellia sinensis* (*C. sinensis*), used in Herbalife's green tea drink products, by citing case reports of liver injury associated with ethanolic extracts of *C. sinensis*, which contain a concentrated fraction of EGCG (2). The most important safety consideration for green tea is its extraction method. The historical data supporting the safety of green tea is based on the consumption of an aqueous extract over thousands of years, specifically, the typical three cups per day that are commonly consumed in Asian countries. Again, the Chen et al. authors (2) have not considered the clinical significance of these potential differences when reviewing published case reports of liver injury.

The European Food Safety Authority (EFSA) stated that Qualified Presumption of Safety (QPS) "status could be granted to dried extracts of unfermented and dried leaves and leaf buds of *Camellia sinensis"* (4). Again, reiterating the acknowledged safety of traditional aqueous infusions and extracts of *C. sinensis* for food supplement use. In a related review of green tea extracts (GTE), Teschke et al. (5) concluded that the previously published works involving GTE, "provide no clinical evidence for an increased risk of DILI" with coadministered drugs (including dietary supplements).

In addition, the authors (2) state that Herbalife has refused to provide detailed analyses of ingredients and formulations, although no attempt was made to contact Herbalife to obtain further information. Herbalife has remained compliant with all formal regulatory requests and requirements for product information to date. Contrary to what has been portrayed, government officials and clinicians have been given access to full product dossiers with product formulas and ingredients as well as results of independent testing regarding worldwide Good Manufacturing Practice (GMP) regulations. These GMP regulations assure that the ingredients and quantities listed on the label are actually in the bottle.

In conclusion, the reference to Herbalife products as a cause of hepatotoxicity and generally comparable to all other available dietary supplements or weight loss products is not scientifically supported. Further information regarding patient histories, concomitant medications and other compounds, dechallenge results, and product specifications and usage is indicated to fully assess the association of Herbalife products in the referenced case reports. Therefore, the article does not objectively support a causal relationship between the reported cases of liver injury and Herbalife products or ingredients.

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