

1/6/2020

To

1. Sri. Sameer Gupta,  
Publisher – STM Journals,  
Elsevier South & South-East Asia.
2. The Editor in Chief,  
Journal of Clinical and Experimental Hepatology.
3. Indian National Association for the Study of Liver,

**Sub :** Corrigendum on removal of article, Slimming to the Death  
..... Herbalife in the Journal of Clinical and Experimental Hepatology

**Ref :** 1. The publication of the article "Slimming to the Death:  
Herbalife" published in the Journal of Clinical and  
Experimental Hepatology in March – April, 2019  
2. Erratum published for author information that the publisher  
has withdrawn the article due to legal reasons

3. Corrigendum – removal notice of article "Slimming to the  
Death .... Herabalife" published by the publisher

4. The notice dated 06-05-2020 issued by my clients through  
e-mail

5. The reply dated 12-05-2020 from Sri. Sameer Gupta to  
my clients

I am instructed by my clients (1) Dr. Philip Augustine, Sr. Co-Author, Director and Head, Department of Gastroenterology, Cochin Gastroenterology Group, Cochin and (2) Dr. Cyriac Abby Philips, EMC Pvt.Ltd. Cochin - 682 028 to address you as follows:-

1. The 1<sup>st</sup> party among my client Dr. Philip Augustine is a renowned and reputed Medical Gastroenterologist having a long-standing practice of 42 years. He has been practicing Gastroenterology and Hepatology for 37 years having vast experience and thorough knowledge in the subject. He has much name and fame not only in Kerala but nationally and internationally. He has been publishing various articles on Gastroenterology in various national and international reputed journals.

2. The 2<sup>nd</sup> party among my clients, Dr. Cyriac Abby Philips is a holder of D.M. in Hepatology. He has been conducting research in the field of Hepatology and has 142 publications in peer reviewed journals and has co-authored various chapters in reputed Hepatology books.

3. A woman aged 24 years, with hypothyroidism without any chronic illness was referred to my client, Dr. Cyriac Abby Philips, for acute liver failure. On investigation, her family informed that she was in the habit of taking three Herbalife slimming products – (1) formula-1 shake mix, 2 scoops daily with skim milk; (2) personalized protein powder, 2 table spoons into the shake mix twice daily and (3) Afresh energy drink, 10 gm. twice daily. According to the patient's husband, the above said products were purchased from local nutrition club. My client, Dr. Cyriac Abby Philips, was told that the patient was not on any other alternative drugs before or during the period.

4. As per history, two months after consuming Herbalife slimming products, she developed loss of appetite followed by jaundice and transient pruritus. Blood investigations in a previous hospital revealed bilirubin level as 12.4 mg., direct bilirubin 9.9, aspartate amino transferase 582, alanine amino transferase 648, Alkaline phosphatase 248, gamma glutamyl transferase 398 and Albumin 3.

5. Even though she was put on medications in the previous hospital, 12 days later the level of bilirubin shot up to 28.6 mg./dl. Since the condition of the patient worsened, she was referred to my client Dr. Cyriac Abby Philips. She was having grade 3 hepatic encephalopathy at the time of admission in the hospital, where my client works. Blood investigations for acute and chronic viral hepatitis and other acute liver diseases were negative. The serum gamma globulin was 2682 mg./dl. Possible drug induced liver injury was considered with RUCAM score 6. A subsequent liver biopsy revealed extensive periportal and perivenular bridging necrosis, mixed inflammatory infiltration, interface hepatitis, cholangitis, cholestasis, severe ballooning and steatosis which were

consistent with DILI. Even though, the patient was urgently referred to a transplant centre, she breathed her last soon after.

6. The cause of liver injury was suspected to be due to the intake of Herbalife Slimming Products. Since Herbalife products used by the patient could not be retrieved, similar products were collected from various sellers and also from where the patient had initially purchased products of Herbalife. The products so collected were subjected to heavy metal analysis and toxicology and bacterial contamination analysis in renowned laboratories. The result showed rise in heavy metals in all the products and toxic compounds including traces of psychotropic substances in 75% of samples. On microbial analysis bacterial DNA was isolated from 63% of the samples which were not expected of such products, including highly pathogenic species.

7. My clients jointly conducted the study after obtaining the laboratory results. Since the results were alarming and the products of Herbalife are sold in the market not only in Asia but also in other parts of World, my clients' bonafide believed that they must publish their findings. With utmost bonafide and as a result of the best of the judgment on the study conducted by them, they prepared the article with the caption "Slimming to the Death" akin to a previous published study on the same matter 'titled' "Slimming at all costs".

8. The study along with methods and result on the analysis of Herbalife products were forwarded to the "**Journal of Clinical and Experimental Hepatology**", an international publication having much name and fame in medical field throughout the world.

9. The Journal conducted an independent peer study from the materials supplied with the help of experts. The expert peer review accepted the findings of my client as true and scientifically proved that the Herbalife products resulted in possible drug induced liver injury.

10. The journal published the article of my clients with liver biopsy results as well as the chemical analysis toxicology in the Edition March – April, 2019.

11. Researchers on behalf of Herbalife issued a letter to the Editor criticising the publication of the article "Slimming to the Death..." which was published as Zambrone et al in the Journal of Clinical and Experimental Hepatology. The publisher of the journal in turn published an article as Philips et al in answer to the criticism. The Journal in its reply has justified authenticity of the findings endorsed by my clients.

12. An 'Erratum' dated January-February 2020 was published on the article of my clients, **"Slimming to the Death..."** originally published in the March – April, 2019 edition of your journal, "Journal of Clinical and Experimental Hepatology (JCEH)". My clients were informed regarding the 'removal' of the published article by Mr Sameer Gupta, Publisher-STM Journals, Elsevier South & South-East Asia through email. The decision for 'removal' mentioned to my clients was 'legal reasons'. In fact, the removal notice specifically mentioned **"The article "Slimming to Death" referred to in the first paragraph has been removed by Elsevier for legal reasons following a complaint from Herbalife. According to Elsevier, "The Article, which was published in the March – April, 2019 issue of the journal, has been removed for legal reasons. However, the decision to remove the article does not imply admission of any allegation made about the Article by any party."**

13. My clients say that the article was published after proper peer-review. Further to this, my clients say that, after a complaint from Herbalife, according to Elsevier policy and as per COPE guidelines, a second round of expert peer-review was also conducted. The removal of the article on "legal threat" was after this scientific evaluation.

14. **Now you have published a removal notice in the Journal purely based on legal threat from Herbalife, on the advice of Indian National Association of Study of Liver (INASL, who has no role in editorial and publication process).**

15. M/S Herbalife Nutrition, a multi-level marketing company has been engaged in the sale of nutritional and weight loss supplements in 94 countries including India. It is understood and widely published that there were over 50 reports of liver toxicity attributed to Herbalife products in Spain, Israel, Latin America, Switzerland, Iceland and U.S. These reports have been published in other high impact Elsevier journals such as The Journal of Hepatology.

16. The study of my clients was on the basis of scientifically accepted principles and guidelines and causality tools for the diagnosis of drug induced liver injury which was also supported by findings on the liver biopsy specimen of their patient, the unmasked details of which was shared with the Editor in Chief of JCEH at his request during the second round of COPE guidelines based expert peer-review. As per the COPE guidelines, if there were any instances of scientific misconduct such as data falsification, data fabrication or plagiarism, the same will be notified to the authors for their answers. In the case in hand, repeat peer view of the study report by senior experts in the field were available with the Journal. After having satisfied that the article is as a result of bonafide scientific study, the same was published in the Journal. At the time of 'removal of my client's article, scientific invalidity was not mentioned by the publisher/JCEH. In this connection, it is pertinent to note that the article prepared by my clients is not the only study on the liver toxicity caused by Herbalife products. In the **Journal of Hepatology (published by Elsevier) 47 (2007) 444 – 446**, the editorial with the caption "**Slimming at all costs: Herbalife – induced lever injury**" is noteworthy. According to the distinguished editorial author, herbal combinations taken for weight loss has been recognized as a potential cause for liver injury. It was also noted that the author refers to series of reports from Israel and Switzerland, incidents of severe liver injury associated with the intake of Herbalife products. The Journal of Hepatology had published various reports on Herbalife hepatotoxicity. There were multiple other reports on the hepatotoxicity of various Herbalife products published by other reputed publishers such as Wiley. My clients say that, you are aware of these various scientific reports on hepatotoxicity of Herbalife products, some of which are mentioned above. All these studies have employed approved scientific methods, like my clients did, to suggest herbal and dietary supplement induced liver injury. It is pertinent to note that despite two rounds of expert peer review my clients were not notified of any scientific integrity issues and overall, the scientific contents and conclusions were found to be accurate. The first author, Dr. Philip Augustine and corresponding author Dr. Cyriac Abby Philips in the

month of April 2020 noticed a corrigendum modifying the statement in your website as follows:

**“INASL and JCEH no longer support the content of and conclusions drawn in the article because the scientific methodology, analysis and interpretation of data underlying the article were insufficient for the conclusions drawn, and, with its removal, the article can no longer be relied upon.”**

17. My clients are of the opinion that the above corrigendum appeared in your website as well as in the scientific repository was at the request of Editor in Chief of JCEH and INASL.

18. Before making any corrigendum, which is highly defamatory and against the principles of professional ethics and natural justice, you have not cared to furnish to my clients any further data to support your above conclusions regarding their study. You may also recall the study published by my clients, in your journal (**J Clin Exp Hepatol. 2018 Dec; 8(4):**

**471–473; published online 2018 May 17) titled “Chemical Analysis of Weight Loss Herbal Supplement Safe Lean™ Associated with Acute Liver Injury – A Concern for Spurious Drug, Misbranding and Adulteration”** which employed the same principles of investigating hepatotoxicity. In the article in question a second round of expert peer review to the best of my clients’ knowledge did not find any scientific pitfalls - otherwise the decision would have been to ‘RETRACT’ rather than ‘REMOVE’ the article according to article withdrawal guidelines laid by Elsevier. But all on a sudden you turned round, disregarding proper guidelines and conduct, to question and endanger the scientific and professional integrity of the authors of the study, my clients, and made the corrigendum. The corrigendum was not on the basis of any scientific conclusions nor expert peer review.

19. Since the corrigendum above mentioned was published behind the back of my clients and is highly defamatory, touching upon their integrity and professional ethics, my clients by the email dated 06-05-2020, called upon to furnish the results of the enquiries conducted by you to reach such a conclusion within 7 days of receipt of this

communication and, also delete the corrigendum from your website within 7 days of receipt of the communication.

20. The email communication dated 06-05-2020 was received by you. Sri. Sameer Gupta by his e-mail dated 12-05-2020 acknowledged the receipt of the e-mail dated 06-05-2020, intimating that JCEH is owned by Indian National Association for Study of the Liver and Elsevier does not control or interfere in the editorial process. It was further informed that the removal of the article was done on the instructions of the Editorial Board of JCEH.

21. My clients say that the communication from Sri. Sameer Gupta is only an eye wash, to shirk the responsibility for removing the article with reasons that amount to negligence that resulted in failure to comply with guidelines laid by the Publisher, Elsevier. None of you other than Sri. Sameer Gupta has responded to the e-mail dated 06-05-2020 issued by my clients.

22. My clients say that the removal of the article from the Journal by the corrigendum is highly defamatory and tells upon the integrity and efficiency of my clients. My clients say that after viewing the corrigendum, thousands of Doctors and also others engaged in the research work, and patients has called upon my clients and expressed their anguish and surprise. After viewing the corrigendum all right thinking people, not only in the medical profession but also others began to look upon my clients with hatred and contempt as if they had committed some heinous sin. My clients say that you published corrigendum by removing the article from the Journal, to splash mud on the face of my clients and to tarnish their image and reputation in the medical field as well as among the patients and right-thinking people.

23. You are jointly and severally liable for the publication of the 'unjustified' corrigendum and removal of article from the Journal and consequent disgrace to my clients.

24. You are hereby called upon to delete the corrigendum from your website and restore the article as "removed" for legal reasons only in Journal of Clinical and Experimental Hepatology within 7 days of receipt of this notice or pay a sum of Rs.100 Million to my clients towards damages sustained by them due to your callous and blasphemous

publication of corrigendum and removal of article from the Journal within 14 days from today, failing which my clients have left instructions with me to initiate civil and criminal prosecution against you and you will be jointly and severally held liable and responsible for all the costs and consequences thereof.

Advocate