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To the Corresponding Author:

Dr. Li-Xuan Sang

Email: sanglixuan2008@163.com

Cc : Director of The Third Editorial office

Baishideng Publishing Group Inc

Jin-Lei Wang

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June 5, 2020

**Re: The article of “Probiotic mixture VSL#3: An overview of basic and
clinical studies in chronic diseases”**

World J Clin Cases 2020 April 26; 8(8): 1361-1384

DOI: 10.12998/wjcc.v8.i8.1361

尊敬的桑教授，

Dear Prof. Sang,

本人，李长宝律师，是 Claudio De Simone 教授的委托代理人，特代表 Claudio De Simone 教授向您转达关于题述文章中提及的 VSL#3 产品的重要信息。

I, Li Changbao, attorney-at-law, am the authorized attorney of Prof. Claudio De Simone. On behalf of Prof. Claudio De Simone, I would like to convey to you the important information about the VSL#3 product mentioned in the subject article.

Claudio De Simone 教授注意到您发表在《World Journal of Clinical Cases》期刊上的文章《Probiotic mixture VSL#3: An overview of basic and clinical studies

in chronic diseases》，其认为有责任向您提供关于该文章中提及的益生菌配方的重要信息，该配方在 2016 年 1 月 31 日之前以 VSL#3 品牌销售，但目前以 VSL#3 品牌销售的产品的内含配方已不同于原配方。

Prof. Claudio De Simone has just come upon your article “*Probiotic mixture VSL#3: An overview of basic and clinical studies in chronic diseases*” published on the *World Journal of Clinical Cases* and he thought it was his duty to give you important information relating to the probiotic formulation mentioned in your article, which was sold under the VSL#3 brand before January 31, 2016. And the products sold under the VSL#3 brand currently contain the formulation which is different from the original formulation.

2019 年 9 月，我事务所曾受 Claudio De Simone 教授委托向中国有关部门发送了一份《关于：VSL#3 益生菌产品危及公众健康安全的紧急报告》，请详见附件，以便您快速了解 VSL#3 产品的相关情况。

In September 2019, our office was entrusted by Prof. Claudio De Simone to send an *urgent report on VSL# 3 probiotic products endangering public health and safety* to relevant Chinese authorities. Please refer to the attachment for details, so that you can quickly understand the situation about VSL#3 products.

Claudio De Simone 教授发明了 De Simone 配方，该配方自 2002 年开始在欧盟和美国市场以 VSL#3 品牌销售，教授是配方相关专有技术的唯一所有人，Actial 集团/VSL 制药公司仅拥有 VSL#3 的品牌。教授在 Actial 集团/VSL 制药公司的前业务合作伙伴，正以 VSL#3 为品牌生产一款假冒原始配方（De Simone 配方）的产品，即当前由 Ferring 公司在欧洲，由 AlfaSigma 公司在美国销售的 VSL#3 产品。伴随此款假冒版本而对外发放的推广和科学资料向公众及医学界人士作了虚假陈述，即声称当前版本 VSL#3 产品与 2002 年以来在欧盟和美国市场销售的 De Simone 配方产品一致，且系超过 60 项已发表的临床研究的研究课题。更

具体地说，当前 **VSL#3** 产品的推广和科学资料的虚假陈述包括声称当前销售版本 **VSL#3** 产品包含与原配方相同的 8 个菌种、使用相同的菌种比例，且该产品已经过临床研究并成功销售 15 年以上。

Prof. Claudio De Simone invented the formulation (**De Simone Formulation**) that has been sold in the EU and U.S. markets since 2002 under the brand **VSL#3**. He is the sole owner of the know-how associated to the product; Actial Srl/VSL Pharmaceuticals Inc only owns the brand name **VSL#3**. His former business partners in Actial Srl/VSL Pharmaceuticals Inc, are manufacturing a counterfeit version of his original product formulation under their brand name **VSL#3®**, and this counterfeit version is the **VSL#3** product now sold as **VSL#3®** by Ferring in Europe and by AlfaSigma in the United States. Accompanying this fake version of the product are marketing and scientific materials falsely representing to the public and the medical community that **VSL#3®** is the same as the De Simone Formulation that has been sold in the EU and U.S. markets since 2002 and that has been the subject of more than 60 published clinical studies. More specifically, the scientific and marketing materials for **VSL#3®** falsely represent that the formula currently being sold as **VSL#3®** contains the same eight distinct strains of bacteria, in the same proportions, as the original formula, and that the product has been clinically studied and sold successfully for more than 15 years.

当前版本的 **VSL#3** 产品配方（1）仅包含 7 个菌种，而不像 **De Simone** 配方含有 8 个菌种，（2）包含与 **De Simone** 配方不同的菌种比例，（3）在与 **De Simone** 配方不同的生产设施中生产，除其他差异外，使用完全合成的培养基培养菌株，以及（4）与 **De Simone** 配方已有超过 60 项临床研究以证明其安全性与有效性形成对比，没有可证明当前版本 **VSL#3** 产品具有药效的单个动物或人体临床研究。



The current formulation of VSL#3 (1) contains just seven strains of bacteria, not eight as does the De Simone formulation, (2) contains different ratios of bacteria than the De Simone formulation, (3) is produced in a different manufacturing facility than the De Simone formulation and, among other differences, uses an entirely synthetic growth medium for the bacteria, and (4) has not completed a single animal or human clinical study showing the product has medical efficacy, as opposed to the De Simone Formulation which has over 60 clinical studies to support its safety of use and efficacy.

Actial 集团通过诸多举措试图在已销售多年的 De Simone 配方产品与当前版本的 VSL#3 产品之间建立虚假联系，这已引发美国、德国、意大利、奥地利等不同国家的数个诉讼案件。例如，在美国马里兰州联邦法院，陪审团一致裁定，VSL#3 产品在美国的经销商对于虚假宣传当前 VSL#3 产品与 2016 年年中之前在该品牌下销售的原始配方（De Simone 配方）保持一致的行为负有责任。另外，Luca Guarna，在全世界范围内授权使用 VSL#3 品牌的 Actial 集团的负责人，已在意大利罗马法院被以欺诈为案由进行刑事调查。同时，奥地利法院对于 ECCO（克罗恩病与结肠炎组织）颁布了一则临时禁令，禁止 ECCO 在其指南中提及 VSL#3 的产品名称，以免误导消费者。

Actial tried to establish a false connection between the De Simone Formulation products which have been sold for many years and the current version of VSL#3 products through many measures, which has led to several court cases in countries such as the United States, Germany, Italy and Austria. For example, in the Federal Court of Maryland, the Jury unanimously found that the distributors of the product VSL#3® were liable for false advertising by misrepresenting VSL#3® to be the same as the original formulation (De Simone Formulation) previously sold until mid 2016. As further information, please be informed that Mr. Luca Guarna, the president of Actial Farmaceutica, the company licensing VSL#3 worldwide, is under criminal investigation for

fraud in the Court of Rome, Italy and an injunction has been issued in Austria against ECCO, the European Crohn and Colitis Organization forbidding them to mention the name VSL#3 in its guidelines as it is misleading to consumers.

近期，VSL#3 产品已经进入中国大陆市场开始销售，我事务所受 Claudio De Simone 教授委托，已于四月中旬就 VSL#3 产品事宜向有关部门提出正式举报，相关举报已受理并正在处理过程中。

Recently, VSL#3 products have entered the mainland China market for sale. Our office, entrusted by Prof. Claudio De Simone, has submitted formal complaints to related authorities about VSL#3 products in mid-April, and the complaints have been accepted and are being handled.

我们注意到您的文章中有引用大量之前的临床研究资料、学术文献等，且其中绝大部分产生于 2016 年之前，即您所引用的绝大部分文献资料指向的对象实际为当时以 VSL#3 品牌销售的 De Simone 配方，而非当前版本的 VSL#3 产品，因此您在文章中直接使用“VSL#3”的名称易导致公众的混淆，使公众误以为您所指向的是当前版本的 VSL#3 产品。

We noticed that your article cites a large number of previous clinical studies and academic literatures, most of which were published before 2016, that is, the subject of most of the literature materials you cited is actually De Simone Formulation sold under the brand name “VSL#3” at that time, rather than the current version of VSL#3 product. Therefore, your direct use of the name "VSL#3" in your article is likely to cause confusion among the public that you are referring to the current version of VSL#3 product.

鉴于上述，Claudio De Simone 教授提出如下请求：

In light of the above, Prof. Claudio De Simone kindly makes the following request:

(1) 停止在综述文章和指南中引用 VSL#3 是极为重要的；

it is important to stop making reference to VSL#3 in review articles and guidelines;

(2) 参照 Cochrane、Medicine 等其他期刊及 ESPEN、ESPGHAN 等组织的做法，请确保与使用 De Simone 配方所做的研究有关的提及“VSL#3”术语的引用是准确的而不会就研究中使用的益生菌配方引发混淆。因此，Claudio De Simone 教授要求您立即发表一份更正说明，以通用名称“De Simone 配方”代替“VSL#3”名称（如可能的话，提及该产品当前在美国以 Visbiome 为品牌销售，在欧洲以 Vivomixx 为品牌销售）。

as already done by other journals such as Cochrane, Medicine and organizations such as ESPEN and ESPGHAN, please make sure that any reference to the term VSL#3 in relation to studies conducted with De Simone formulation is correctly reported to avoid any confusion as to the specific probiotic formulation used in the studies. Prof. Claudio De Simone therefore asks you to publish immediately a corrigendum and replace it the generic name of the formulation “De Simone Formulation”, (possibly mentioning that the product is now available as Visbiome in the USA and Vivomixx in Europe).

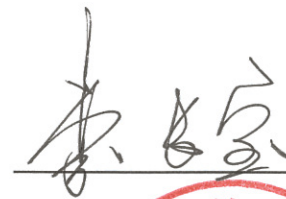
我们认为，作为医学专家，您有道德与伦理责任认真考量上述信息并相应通知所有该文章的其他作者。

We do think that as a medical expert, you have a moral and ethical duty to take into account the above information and inform all other authors of the Article accordingly.

如果您决定不进行该更正, Claudio De Simone 教授将保留采取法律措施的权利。

Should you decide not to proceed with the corrections, Prof. Claudio De Simone will reserve the right to take legal action against you.

Yours sincerely,

 (SEAL)

Changbao
Attorney-at-law of Zinger Law Office

Authorized and on Behalf of
Prof. Claudio De Simone

附件: 《关于: VSL#3 益生菌产品危及公众健康安全的紧急报告》

Attachment: Urgent Report on VSL# 3 Probiotic Products Endangering Public Health and Safety



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To:

Lian-Sheng Ma (l.s.ma@wjnet.com)

Company Editor-in-Chief,

Editorial Office

Baishideng Publishing Group Inc

Cc :

Dr. Li-Xuan Sang (the Corresponding Author)

Email: sanglixuan2008@163.com

Sept. 29, 2020

**Re: The Rejection Decision Made By World Journal of Clinical Cases on
Correction Declaration to the Article of "Probiotic mixture VSL#3: An
overview of basic and clinical studies in chronic diseases"**

World J Clin Cases 2020 April 26; 8(8): 1361-1384

DOI: 10.12998/wjcc.v8.i8.1361

尊敬的马先生（女士），

Dear Mr./Ms. Ma,

本人，李长宝律师，是 Claudio De Simone 教授的委托代理人，特基于如下背景信息向您及贵刊转达 Claudio De Simone 教授的明确要求及期望：

I, Li Changbao, attorney-at-law, am the authorized attorney of Prof. Claudio De Simone. On behalf of Prof. Claudio De Simone, I would like to convey to you and your journal the specific requirements and expectations of Prof. Claudio De Simone based on the following background information.

背景信息:

Background information:

1. 桑力轩 (Li-Xuan Sang) 博士团队曾于 2020 年 4 月 26 日在贵刊 (《World Journal of Clinical Cases》) 发表文章《Probiotic mixture VSL#3: An overview of basic and clinical studies in chronic diseases》(桑力轩博士系该文的通讯作者), 该文章重点介绍了 VSL#3 品牌的益生菌产品。但是, 本所委托人 Claudio De Simone 教授认为有责任向该文作者提供关于该文章中提及的益生菌配方的正确及重要信息, 也即, 该配方在 2016 年 1 月 31 日之前以 VSL#3 品牌销售, 但在此之后以 VSL#3 品牌销售的产品的配方已不同于原配方, 为此, 本律师代表本所委托人 Claudio De Simone 教授于 2020 年 6 月 5 日向桑力轩博士致函, 并抄送给贵刊的 Jin-Lei Wang (第三编辑室负责人 j.l.wang@wjgnet.com), 明确提出了希望桑博士在贵刊刊登修订声明的要求 (见附件一)。

The team of Dr. Li-Xuan Sang published the article "Probiotic mixture VSL#3: An overview of basic and clinical studies in chronic diseases" (Dr. Li-Xuan Sang is the corresponding author of this article) on your journal (*World Journal of Clinical Cases*) on April 26, 2020. This article focuses on introducing the VSL#3 brand probiotic products. However, Prof. Claudio De Simone, our client, thought it was his duty to give the authors of this article the accurate and important information relating to the probiotic formulation mentioned in this article, that is, this formulation was sold under the VSL#3 brand before January 31, 2016, but since then, the formulation of the products sold under the VSL#3 brand has been different from the original formulation. To this end, I, on behalf of our client Prof. Claudio De Simone, sent a letter to Dr. Li-Xuan Sang and also sent a copy to Jin-Lei Wang of your journal (Director of The Third Editorial office, j.l.wang@wjgnet.com) on June 5, 2020, in which, we clearly put forward

the request that Dr. Sang publish a correction declaration on your journal (see Appendix 1).

2. 桑博士书面回复表示在组织撰写前述文章时的确不清楚 VSL#3 品牌益生菌产品与 De Simone 配方益生菌产品存在的不同，同时，作为对 Claudio De Simone 教授明确要求的积极回应，撰写了相应的修订《声明》（见附件二），并承诺与贵刊积极联系并及时在贵刊发表该《声明》。

In Dr. Sang's written reply, he said his team was indeed not aware of the difference between VSL#3 brand probiotics and the De Simone formulated probiotics at the time of organizing and writing the above mentioned article. And then, as a positive response to the explicit requests of Prof. Claudio De Simone, Dr. Sang drafted the corresponding correction *Declaration* (see Appendix 2) and promised to keep in active contact with your journal for publication of the *Declaration* on your journal in a timely manner.

3. 近日，桑博士书面向本律师反馈，称虽经与贵刊努力沟通，但贵刊明确拒绝发表其《声明》，贵刊的拒绝回复见附件三。

Recently, Dr. Sang gave a written feedback to me, saying that although he has made efforts to communicate with your journal, eventually, you still explicitly refused to publish the *Declaration*. Please refer to Appendix 3 for the refusal reply of your journal.

基于上述背景信息，本律师认为：

Based on the above background information, I hold the following opinions:

1. 桑力轩博士作为《Probiotic mixture VSL#3: An overview of basic and clinical studies in chronic diseases》一文的责任作者与联系作者，其原属国为中国，根据中国著作权法第十条规定，修改权，即修改或者授权他人修改作品的权利是作者的重要权利之一，任何人无权剥夺或侵害，因此，桑力轩博士对其原文章进行修订《声明》的行为应视为对其原文章的修改，是其合法行使作者修改权的体现，该行为应得到贵刊的理解及尊重；

Dr. Li-Xuan Sang is the responsible author and corresponding author of the article "*Probiotic mixture VSL#3: An overview of basic and clinical studies in chronic diseases*", with his nationality being China. According to Article 10 of China's Copyright Law, the right of modification, that is, the right to modify or authorize others to modify his/her work, is one of the important rights of the author, no one has the right to deprive or infringe it. Therefore, Dr. Li-Xuan Sang's correction *Declaration* of his original article shall be regarded as the amendment of the original article and it is the manifestation of his legitimate exercise of the author's right of modification, such modification should be understood and respected by your journal.

2. 桑力轩博士的原文章客观上会误导公众将生产于 2016 年 1 月 31 日后的 VSL#3 品牌益生菌产品与 De Simone 配方益生菌产品视为同一配方产品，贵刊在明知二种益生菌产品的配方实质不同的情况下，仍然作出拒绝桑力轩博士在贵刊刊发修订《声明》的决定不但客观上使原文章的错误内容得以延续，主观上更是对前述存在的错误内容以及导致的公众混淆结果的漠视与纵容，不但与贵刊理应具备的科学、严谨的精神不相符，更有可能因为贵刊拒绝“纠错”行为而可能造成公众使用益生菌产品的安全隐患。

Dr. Li-Xuan Sang's original article objectively misled the public to think the VSL#3 brand probiotics manufactured after January 31, 2016 and De Simone probiotics contain the same formulation. Your journal, knowing that the two kinds of probiotics have different formulations, still made the decision to refuse to publish the correction *Declaration* on your journal. This kind of behavior not only objectively makes the wrong content of the original article be continued, it is also subjectively the disregard and indulgence of the above mentioned wrong content and of the result of public confusion. It is not only inconsistent with the scientific and rigorous spirit that your journal is supposed to possess, but also more likely to

cause safety risks for the public when using the probiotic products due to your journal's refusal to correct errors.

基于上述认识，本律师特代表 Claudio De Simone 教授郑重要求贵刊：

On the basis of the above understanding, I, on behalf of Prof. Claudio De Simone, solemnly request your journal to:

1. 重新审核桑力轩博士的修订《声明》；

Review Dr. Li-Xuan Sang's correction *Declaration* again;

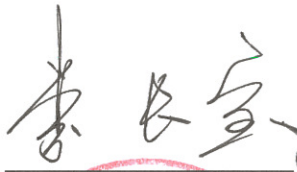

2. 尽快安排在贵刊合适位置刊发该修订《声明》，以消除原文章可能造成的公众混淆及不良影响；

Arrange for the publication of the correction *Declaration* at an appropriate place in your journal as soon as possible, so as to eliminate the public confusion and adverse effects that the original article may cause;

期望在本函发送后十日内收到贵刊的明确及积极回应，逾期，Claudio De Simone 教授将保留采取进一步法律措施的权利。

It is expected to receive a clear and positive reply from your journal within 10 days after your receiving this letter, otherwise, Prof. Claudio De Simone will reserve the right to take further legal action.

Yours sincerely,

 (SEAL) 

Li Changbao
Attorney-at-law of Zinger Law Office
Authorized and on Behalf of
Prof. Claudio De Simone

附件（Appendix）：

1：本律师代表 Claudio De Simone 教授于 2020 年 6 月 5 日发送给桑博士的函件；

The letter I sent to Dr. Sang on June 5, 2020 on behalf of Prof. Claudio De Simone;

2：桑博士起草的修订《声明》；

The Correction *Declaration* drafted by Dr. Sang;

3：贵刊有关拒绝刊登修订《声明》的回复；

Your journal's refusal reply on the publication of the Correction *Declaration*