



January 15, 2019

**Note to Healthcare Professionals and Patients Regarding the Recent Jury Verdict:
Claudio De Simone *et al* v. VSL Pharmaceuticals Inc *et al***

Professor Claudio De Simone, the inventor of the high potency probiotic previously sold under the brand name “VSL#3®”, recently won a unanimous jury verdict in Federal Court against VSL Pharmaceuticals, Inc., Alfasigma USA, and Lediand Biosciences, Inc. Elements of the case are relevant to those working with high potency probiotics.

The litigation was the product of a business dispute between Claudio De Simone and his former business partners. In the early 1990s De Simone invented the De Simone formulation, a high potency, 8 strain probiotic product. The formulation, and associated patent, was licensed to the VSL Pharmaceuticals, Inc. company (“VSL Inc”) which was subsequently sold under the brand name VSL#3* from 2002 to 2016 (VSL#3 is a registered trademark of VSL Inc). When De Simone terminated his relationship with VSL Inc. the company attempted to produce a copy of the original formulation and then pass off this new product as the original. A legal dispute arose concerning the ownership of the proprietary formulation and claims which were being made about this copy “VSL#3” product.

Outcomes of the Litigation in Federal Court:

- The seller of VSL#3 in the U.S., Alfasigma, was found liable for false advertising under the Lanham Act for making false statements related to the composition and clinical history of new “VSL#3.”
- It was determined that the Know-How required to manufacture the De Simone formulation probiotic is the exclusive property of Professor Claudio De Simone.
- VSL Inc was found to be in breach of contract to De Simone and ordered to pay compensatory and punitive damages

Key legal claims brought by ExeGi Pharma and De Simone regarding new “VSL#3”:

- The probiotic currently sold as “VSL#3” is a formulation different from the formulation invented by Professor De Simone.
- The makers of new VSL#3 did not return to the “original” manufacturing site in Italy. Commercial VSL#3, containing the original formula, was never made in Italy.
- The new VSL#3 product, currently available from Alfasigma, has not been the subject of any published, peer reviewed, controlled trials in humans.
- The new VSL#3 product, currently available from Alfasigma, contains 7, not 8, unique bacterial strains.
- There is no scientific or clinical data that proves that the new VSL#3 product, currently available for sale, is equivalent to the original VSL#3 product sold prior to May 2016.
- Multiple peer reviewed comparative in-vitro and in-vivo studies have found dramatic differences in the quantitative and performance characteristics of original VSL#3 (containing De Simone’s formulation) and the new copy “VSL#3”^{1,2,3,4,5}
- The original De Simone formulation, which was previously sold under the name VSL#3 is currently available only under the name Visbiome.

The original De Simone formulation, which was previously sold under the name VSL#3 is currently available only under the name Visbiome. The Visbiome brands are available online at www.visbiome.com, on Amazon or by special order from a variety of pharmacies.

We invite you to learn more at www.visbiome.com or by contacting ExeGi Pharma at info@ExeGiPharma.com

References

1. Biagioli *et al*. Metabolic Variability of a Multispecies Probiotic Preparation Impacts on the Anti-inflammatory Activity. *Frontiers in Pharmacology*. 2017.
2. Cinque *et al*. VSL#3 probiotic differently influence IEC-6 intestinal epithelial cell status and function. *Journal of Cellular Physiology*. 2017.
3. Cinque *et al*. Production Conditions Affect the In Vitro Anti-Tumoral Effects of a High Concentration Multi-Strain Probiotic Preparation. *Journal PLOS ONE*. 2016.
4. Trinchieri, *et al*. Efficacy and Safety of a Multistrain Probiotic Formulation Depends from Manufacturing. *Frontiers in Immunology*. 2017
5. Palumbo, *et al*. The Epithelial Barrier Model Shows That the Properties of VSL#3 Depends from Where it is Manufactured. *Endocrine, Metabolic, & Immune Disorders*. 2019, 19, 1-8

*VSL#3® is a registered trademark and is manufactured exclusively for, VSL Pharmaceuticals, Inc. Visbiome® is manufactured exclusively for ExeGi Pharma, LLC and is not affiliated with, endorsed by, or distributed by VSL Pharmaceuticals, Inc