

## ECCO: Official Statement

Until the year 2016, the probiotic blend sold under the brand name VSL#3® contained the formulation that is known as the De Simone Formulation (DSF). This specific formulation was the subject of extensive scientific research and demonstrated proven efficacy in the management of inflammatory bowel diseases.

For the record, it is imperative to acknowledge that final and non-appealable judgments have been rendered by the United States District Court for the District of Maryland in the year 2019, as well as by the United States Court of Appeals for the Fourth Circuit in 2021. These judicial determinations mandated the immediate cessation of deceptive advertising practices by the distributors of VSL#3® and awarded damages in the sum of \$18 million USD in favor of Professor De Simone and his United States-based entity, Exegi Pharma, LLC. These verdicts carry transnational implications as the product VSL#3® that is distributed both within the United States and internationally is identical. Consequently, the legal conclusions reached by the United States judicial system hold global relevance.

Given ECCO's ethical responsibility to disseminate accurate and current medical information, it is absolutely vital to revise its guidelines. ECCO's decision is not merely a formality but a necessary measure to uphold the integrity of medical practices and the welfare of patients. In addition, ECCO's decision to amend its guidelines is in harmony with the directives from the Court of Justice of the European Union (CJEU). CJEU has consistently emphasized the importance of accurate representation and transparent disclosure in healthcare products and treatments, thereby endorsing the right of the consumer to make informed decisions. ECCO's initiative to update its guidelines aligns perfectly with CJEU's commitment to consumer rights and well-informed healthcare choices.

To clarify its revised stance, ECCO has issued the following Official Statement:

"Until 2016, the De Simone Formulation (DSF) was sold as VSL#3® and had established its efficacy in inflammatory bowel diseases. After 2016, the VSL#3® product no longer contains DSF. Accordingly, the VSL#3 references in the ECCO Guidelines 2017 exclusively endorse DSF supported by scientific evidence."

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