

CASE STUDY: BRINGING TRADITIONAL MEDICINE TO THE MARKET



SUMMARY: As an active research neurobiologist in training at the NYU/VA Medical Centers in New York City in the 1980s, David Segarnick Ph.D., BERYL's Managing Director and head of our China's Healthcare Division, made a serendipitous discovery that would change the way scientists thought about the neurobiology of alcohol and the treatment of alcohol abuse, tolerance, dependence and withdrawal. His published findings launched Evening Primrose Oil as the richest natural source of the essential fatty acid precursor to prostaglandin formation in the brain. This natural compound then became a leading nutritional supplement sold over-the-counter in health food stores across Europe and the US.

SITUATION ANALYSIS

- Little was understood about the neurobiological effects of alcohol other than the fact that acutely, it induced euphoria, intoxication, CNS depression and ultimately coma and death in high doses.
- Chronic alcohol induces an adaptive reordering of the brain cell lipid membrane that underlies the development of behavioral tolerance and dependence; upon abrupt discontinuation, anxiety and convulsions can commonly result.
- *In vitro* and behavioral work performed and published by Dr. Segarnick (see references below) demonstrated that physiologically relevant doses of alcohol stimulated the formation of prostaglandins in human platelets and brain tissue from precursor metabolic pools of essential fatty acids.
- These biochemical findings led to studies demonstrating that many of the adverse behavioral effects of chronic alcohol (eg, dependence and withdrawal) could be inhibited by reversing the down-regulation of this biological system by providing the prostaglandin precursor – gamma-linolenic acid (GLA).
- Evening Primrose had been regarded by some as having potential health benefits. In fact, the richest natural source of GLA (other than human breast milk) comes from the oil extract of the Evening Primrose plant (*Oenothera biennis*).
- Studies done in other laboratories have extended these new findings to alcohol-induced fatty liver and to alcohol-induced birth defects (teratogenicity).

Essential fatty acids, prostaglandins, and nonsteroidal antiinflammatory agents: physiological and behavioral interactions., Segarnick D, Rotrosen J. Alcohol Clin Exp Res. 1987 Feb;11(1):19-24.

Prostanoid modulation (mediation?) of certain behavioral effects of ethanol., Segarnick DJ, Cordasco DM, Rotrosen J., Pharmacol Biochem Behav. 1985 Jul;23(1):71-5.

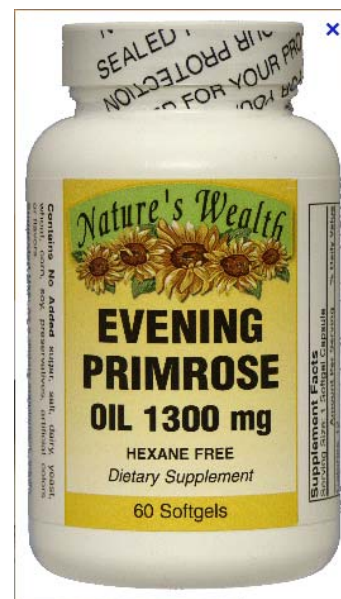
Precursor- and pool-dependent differential effects of ethanol on human platelet prostanoid synthesis., Segarnick DJ, Ryer H, Rotrosen J., Biochem Pharmacol. 1985 Apr 15;34(8):1343-6.

OBJECTIVES

- Use clinically-relevant basic research findings regarding natural/traditional/herbal compounds (revealed by laboratory research or found in culturally rich traditional medicine communities) to develop commercially viable prescription and OTC products globally.
- Provide clinical study, product development and co-development guidance to manufacturers of Traditional Chinese Medicine (TCM) to achieve global regulatory approvals to gain entry into prescription or OTC markets globally.

CONCLUSION

BERYL Pharma360 can provide product development, market assessment and consulting services for manufacturers of Traditional Chinese Medicine to achieve global regulatory approvals to gain entry into prescription or OTC markets globally.



RESULTS

- **Evening Primrose Oil is sold around the world by a variety of manufacturers as a dietary supplement and the richest natural source of gamma-linolenic acid (GLA).**

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