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**FILE: ■ Kava (*Piper methysticum*)
■ Sleep Disturbance**

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RE: Kava Extract Shows Efficacy in Anxiety-related Sleep Disturbance

Lehrl S. Clinical efficacy of kava extract WS® 1490 in sleep disturbances associated with anxiety disorders. Results of a multicenter, randomized, placebo-controlled, double-blind clinical trial. *Journal of Affective Disorders* 2004;78(2):101-110.

A frequent symptom associated with anxiety disorders is sleep disturbance. A person may have impairment of initiation, duration, or quality of sleep. Pharmacological treatment of anxiety disorders can be effective, but may have many adverse side effects (i.e., sedation). Kava kava (*Piper methysticum*) rhizome extracts have proven anxiolytic effects, and studies have shown that it can improve sleep quality. WS® 1490 (Dr. Wilmar Schwabe Pharmaceuticals, Karlsruhe, Germany) is a kava extract that was licensed in Germany for the treatment of anxiety, tension, and restlessness until all kava products were banned in Germany in 2002, due to suspected hepatic adverse reactions. It is a monoextract from the dried root of kava and is standardized to 70% kava lactones. Several controlled studies have confirmed the anxiolytic efficacy of WS 1490. This study examines the effect of WS 1490 on sleep disturbances associated with non-psychotic anxiety.

Sixty-one subjects with sleep disturbances associated with symptoms of anxiety, tension, or restlessness participated in this prospective, randomized, placebo-controlled, double-blind study with parallel groups. After a single-blind placebo run-in period of 7 days, subjects underwent 4 weeks of double-blind treatment with 200 mg/day WS 1490 or placebo once daily. After treatment, two weeks of follow-up ensued. Subjects filled out a sleep questionnaire and a battery of anxiety questionnaires.

Both the placebo- and WS 1490-treated subjects had initial improvements in overall quality of sleep, but the WS 1490-treated subjects continued to improve throughout the study. Both groups of subjects had improvement in recuperative effect after sleep, but the placebo group had an aggravation of symptoms during the follow-up period. Compared to baseline, WS 1490-treated subjects had a significant improvement in quality of sleep ($P = 0.008$) and recuperative effect after sleep ($P = 0.032$). WS 1490 reduced psychic

anxiety and improved general well-being along with the normalization of sleep. Both treatments were well tolerated. There were no adverse events suggestive of withdrawal effects during the follow-up period.

The authors conclude that WS 1490 is effective in alleviating anxiety-related sleep disturbances. The sleep improving effects may be due in part to the anxiolytic properties of the kava extract. The authors believe that WS 1490 is an effective therapeutic alternative to pharmaceuticals for treating patients with sleep disturbances associated with anxiety disorders.

—*Heather S. Oliff, Ph.D.*

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