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**Aggression in Dementia**

The Division is opposed to an indication for "aggression associated with dementia," due to the subjective nature of assessing the motivation for these symptoms, and the lack of a consensus within the medical community on a definition of "aggression." Thus, an indication would be misleading. The prescriber/caregiver would have to make a value judgment as to a patient's motivation for the behavior. For example, if a patient screams (one of the measured behaviors in the aggressive subscale of the BEHAVE -AD), is it because he/she is demented, or because he/she is trying to communicate displeasure or even pain? Many demented patients, particularly those included in our trials, have limited verbal skills. Therefore, an indication for "aggression" could allow a patient's limited capacity for self-expression to be reduced. In summary, Dr. Leber termed this type of indication an "enabling indication," due to its potential, unintended consequences indicating that just because it's being used for these purposes, does not mean it's medically appropriate. He did not dispute that we have demonstrated a treatment effect, but he questioned whether the effect was always a benefit. After reviewing the items we used to assess aggression, "physical threats or violence" was identified as, perhaps, a more objective item. Also, they will consider allowing the description of a treatment effect on behaviors that accompany the decrease in psychotic symptoms. While discussing our sub-group analysis excluding patients with somnolence, Dr. Leber expressed reservation about the appropriate definition and assessment of "somnolence" in this patient population.

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