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Dextromethorphan-Quinidine for Agitation in Alzheimer Disease

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Letter re: Dextromethorphan-Quinidine for Agitation in Alzheimer Disease.

To the Editor:

Behavioral complications of dementia can be highly distressing, and new interventions to treat this condition are needed. However, several aspects of the trial on the effect of dextromethorphan-quinidine on agitation in patients with Alzheimer disease dementia by Dr Cummings and colleagues caused us concern[1].

First, the increase in falls associated with use of dextromethorphan-quinidine (8.6% vs 3.9% for placebo) was substantial and calls into question the conclusion that the drug was "generally well tolerated." Although the finding of excess falls may be due to chance or an imbalance in baseline characteristics between the intervention and control groups, this effect should be presumed real until proven otherwise. This interpretation is supported by previous randomized trials of dextromethorphan-quinidine for pseudobulbar affect, in which rates of dizziness were consistently and markedly higher in the active treatment group, although data on falls were conflicting[2-4].

Second, we have concerns about the patenting and use of proprietary study designs in research, such as the Trimentum methodology (a form of crossover study design) used in the study. Regardless of the merits of the methodology, the study cannot be replicated as performed without license from the patent holders. This gives the patent holders a veto over the replication of this particular study and indeed over any validation of the methodology in general. Patented study designs violate the long-cherished principle that scientific findings must be able to be readily reproduced by an independent party. Moreover, allegations of patent infringement and the

threat of legal action, whether reasonable or not, are bludgeons that could be used to halt

competing research.[5] If there is any place in medical research for patented study designs, it must

include universal, default, open-access licensing to academic or federally funded researchers to

permit free replication of scientific results and the free development of improved methodologies

without fear of legal reprisal.

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