

which “we are unable to locate a publication discussing the results”[1] can be addressed. The study was conducted by a multinational company distinct from the French company in which the drug was discovered and developed and its design allowed to assess safety rather than efficacy of racecadotril. Thus, whereas the former studies were performed in a limited number of centres in a single country, during a single period, *i.e.*, under conditions likely to ensure homogeneity in geographical and epidemiological terms, the study in question was performed in 24 centers from 16 different countries scattered in Latin America and Asia, each center providing a small number of cases. Hence, the design and the inherently difficult monitoring of the study led to a large number of missing data and heterogeneity of available ones. These drawbacks did not allow publication of the study in a decent journal. Nevertheless, the study was provided to health authorities and was considered as a safety study (excellent on this parameter).

As a conclusion, we would like to mention that a number of expert groups have recently underlined the interest of racecadotril in the management of acute diarrhea(2-5).

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Reply

We thank the authors for their response to our editorial. Our key concern remains mainly with regard to non-publication of medical trials, the imprecise assessment of effect size in clinical trials of relatively small sample size, and the concern related to sometimes the blurred line between investigations and business interests. There is potential for bias to influence even expert groups, when such groups are promoted and created by industry. We mean no disrespect to the investigators in question, but the issues we raised are those that have in the recent past, received attention in the best scientific journals.

Our condition remains that benefit of this drug for treatment of acute diarrhea has not been documented to an extent and in a manner that is required minimally to recommend its use.

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