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LETTERS TO THE EDITOR

Baclofen and Protecting the Patients During Research

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Rigal *et al*.'s retrospective analysis on the effect of baclofen in a series of 132 high-risk drinkers deserves comments because it challenged several basic principles (Rigal *et al*., 2012).

First, it is not clear whether non-pharmacological intervention was systematically offered, even though some research has found that brief physician advice can help some alcohol-dependent patients (e.g. Grossberg *et al*., 2004; Fleming *et al*., 2010)

Second, Rigal *et al*. bypassed the usual phase II step in pharmacotherapy trials, that is, to determine the most effective and safe dose. They have not spelt out their grounds to justify a dose of 145 ± 75 mg/day (max = 400).

Thirdly, although patients would presumably have been told that that off-label prescription is not reimbursed by the French mandatory national health insurance scheme, it is not clear what they were told about medical liability insurance. Usually, the doctor's own medical indemnity insurance covers prescribing off-licence when it is based upon expert opinion, but it is not clear whether that would have been the case for these patients.

Lastly, the authors chose to avoid a review by a research ethics committee, regarding their research as an audit. Such a review would have meant an external review of the information and consent documents; and might have recommended specific insurance.

In the period since this study was conducted, the French medication control agency, Afssaps (L'Agence française de sécurité sanitaire des produits de santé) warned against off-label prescription of baclofen for alcoholics on the basis that evidence was lacking, pending a planned randomized controlled trial in France (Afssaps, 2011). However, this was revoked in April 2012, with a statement that the use of baclofen could be considered on an individual basis with dose adjustment because new observational data had shown clinical benefit (Afssaps, 2012).

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Patient Protection: from Compassion and Pragmatism to Research: Reponse to Dr Braillon's Comments

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We thank Dr Braillon for his comments on our report of the results of a retrospective study of alcohol consumption among high-risk drinkers a year after they began high-dose baclofen treatment.

Let us begin by describing the conditions in which we performed this study because the principal responses to Dr Braillon's interrogations flow directly from them. Our team was in the process of developing a protocol for a randomized placebo-controlled double-blinded trial of high-dose baclofen. While attempting to determine the number of subjects necessary and to estimate the quantity of drug that we would need, we found that the modest literature on our subject was not very helpful. A retrospective survey from the files of two prescribers allowed us to overcome this lack of data and formulate hypotheses about the efficacy of baclofen and its dosage. Learning later that other trials were in the process of development, we decided to publish our results, because we thought they could be similarly useful to others.

Accordingly, we did not circumvent a phase II trial (second point) but rather designed a phase IIb/IIIa trial. The maximum dosage of baclofen observed in our study is the fruit of the prescribers' dose adaptation according to the following rule: increase the dose of baclofen 'progressively until it abolished craving, to the extent possible, thereby