

## Letters to the Editor

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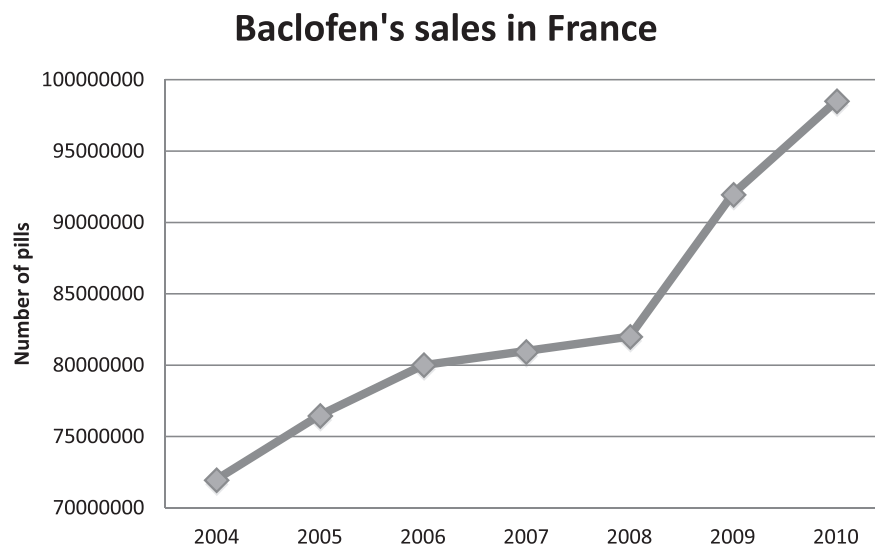
### ALCOHOL-DEPENDENCE: THE CURRENT FRENCH CRAZE FOR BACLOFEN

Over the last 3 years, the word 'baclofen' has appeared on the cover of numerous non-specialized French journals, which sing the praises of its potentially miraculous effects on alcohol dependence. Baclofen is a gamma-aminobutyric-acid-B (GABA-B) receptor agonist, approved for many years for spasticity. Some recent works reported promising effects of low-dose baclofen (30 mg/day) for alcohol dependence [1], but these data remained largely confined to the medical community. A few years ago a French cardiologist suffering from alcohol dependence, Olivier Ameisen, tested baclofen on himself, at doses reaching a maximum of 270 mg/day, and published an atypical 'autocase' report in which he maintained that high-dose baclofen (HDB) had suppressed his dependence [2]. Ameisen also wrote a best-selling book describing the story of his addiction, and of his use of HDB. This book attracted media attention and popularized baclofen among the French general public. An overwhelming number of patients now beg their physicians to be treated with HDB, and sales of baclofen increased by 20% between 2008 and 2010 (see Fig. 1). Moreover, an association of physicians prescribing HDB and patients proclaiming that they were cured of their alcohol dependence through this treatment are now lobbying for official approval to extend HDB to alcohol dependence.

Thus far, the Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), the French health

authority, has refused to officially recommend baclofen for alcohol-dependence. In a recent online publication [3], the AFSSAPS called for caution in the use of HDB, noting that no scientific data were currently available concerning the efficacy and the tolerance of this medication in alcohol-dependent patients, and officially encouraged the realization of well-conducted trials. In practice, AFSSAPS faces a dilemma. If they refuse to approve the use of HDB for alcohol dependence because of insufficient scientific data, as has been their position thus far, they are immediately accused by pro-baclofen associations of depriving alcohol-dependent patients of a potentially miraculous treatment; but if they approve it prematurely under the pressure of the same associations, and if serious adverse events are reported secondarily, they will be accused of laxity.

Currently, the issue of baclofen in France seems to have taken quite an emotional turn. Perhaps this current craze will end soon. Some clinical trials should start in the near future [4], and it is hoped that they will provide definitive answers on the efficacy and tolerance of HDB in alcohol dependence. However, until such results are available patients will continue to clamour for the treatment the media is talking about, and many general practitioners (GPs) and addiction specialists already face the same dilemma as the AFSSAPS: refuse to prescribe HDB because of the lack of scientific data or prescribe off-label. A decline in the prescription could lead to a self-medication trend by patients who can easily buy baclofen on the internet, but it also seems risky for isolated GPs



**Figure 1** Evolution of baclofen's sales in France (source: AFSSAPS, published with their kind permission)

and specialists to provide regular and numerous HDB prescriptions. As long as this very specific situation lasts, our personal perspective is that the least negative solution is to entrust off-label HDB prescription to specialized medical teams that can provide a sufficient supervisory system, based on the same rules required for clinical trials [5]. Protocols for HDB prescriptions should be validated by a collegial expert group of practitioners, and patient follow-up should be monitored strictly to identify immediately any adverse events during treatment. Such a supervised prescription system fits into a logic of harm reduction. Because it would be illusory to prevent patients from obtaining baclofen by their own means, it seems preferable to deliver HDB under close observation by teams with good scientific knowledge and regular use of the product.

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### Declarations of interest

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BENJAMIN ROLLAND<sup>1,2,3</sup>, RÉGIS BORDET<sup>1,3</sup> &  
OLIVIER COTTENCIN<sup>1,2,4</sup>

Université Lille Nord de France, Lille, France,<sup>1</sup>  
Department of Addictionology, CHU Lille, Lille, France,<sup>2</sup>  
Department of Pharmacology, CHU Lille,  
Lille, France<sup>3</sup> and EA 4559, Lille, France<sup>4</sup>.  
E-mail: benjamin.rolland@chru-lille.fr

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### THE CALL FOR EVIDENCE-BASED DRINK AND DRIVING POLICIES IN BRAZIL

It is often said that awareness of health issues arises only when people identify themselves as subject to the problem under question. Concerning the drink and driving situation in Brazil, it appears that driving under the influence of alcohol (DUI) has finally reached a national debate level. Furthermore, the discussion has now involved different society groups, creating a common sense that urgent political action is needed to control a public health issue which can affect virtually every individual, regardless of whether or not one drinks.

Our recent study, showing positive results from the new enactment which implemented a 'zero-tolerance' DUI law in Brazil, raised important questions on how to proceed effectively with alcohol policies when resources and infrastructure for supporting enforcement of such laws are scarce [1]. Moreover, as pointed out by Madruga and colleagues [2], the broader change that is necessary to decrease the high alcohol-related traffic accident rates in Brazil relies on many other aspects besides policies addressing the blood alcohol concentration (BAC) limit for drivers.

In fact, the current drink-driving policies and related legislations that are emerging in Brazil do not take into consideration the accumulated research-derived evidence on this issue. Instead, the measures proposed seem more like a patchwork of strategies that do not integrate scientific evidence and policy makers' opinions, further frustrating practitioners who are on the front lines.

For example, increasing the severity of sanctions for drivers who consumed any amount of alcohol was aimed theoretically to enhance the general deterrence effect in order to increase the perceived risk of DUI sanctioning. However, this strategy has limitations that should not be ignored, as 'zero-tolerance' policies tend to fall short when the sanctions capacity and enforcement resources are not calibrated to the population size and legislation specificities of each locality [3].

The increase in the likelihood of refusing a BAC test to avoid criminal conviction is the most notable example of these limitations in the present Brazilian scenario, in addition to the inherent low probability of being apprehended for a DUI offence (e.g. the chance of being

arrested for drunk-driving is estimated at once every 300–2000 times a person drives drunk in the United States) [4].

In this case, it seems more reasonable to follow the principle stated by Kleiman & Kilmer on the dynamics of deterrence: 'It is better to control someone than to fail in an attempt to control everyone' [3]. Therefore, in combination with researchers, policy makers should search for the key to changing the perceived risk of DUI sanctioning in countries such as Brazil, which may not rely on the strictness of drink-driving laws but rather on the creation of policies emerging from research.

Due to the lack of evidence on this issue in the region, the knowledge acquired by developed countries should serve as a model, including the possibility of applying innovative strategies that have shown promising results in these countries. In particular, the creation of specific DUI courts, based on drug court models [5] which can rapidly put into effect DUI sanctions, may help to improve the desirable deterrence effect of previous laws, as well as give support to practitioners in the field to implement enforcement accordingly.

Additionally, this kind of strategy also provides the chance to further develop a public health approach to the drink and driving problem in Brazil; for instance, by offering the possibility of implementing mandatory drinking monitoring and treatment programmes, paid by offenders [6], which might receive strong support from the public, that advocates for more severe punishment for convicted drunk drivers instead of stricter DUI laws for everyone.

In summary, we believe that it is time to bring together legislators, researchers and practitioners to help create an evidence-based DUI national programme in Brazil to form and evaluate drink-driving policies more clearly. Given that alcohol-related health policy research has proved to be an effective way to reduce alcohol-related traffic injuries and deaths in many other regions in the

world, the question now is whether the public and the government in developing countries such as Brazil are able to invest in that, or risk paying the price for not following the same pathway.

#### Declarations of interest

None.

GABRIEL ANDREUCCETTI<sup>1,2</sup>,

HERACLITO BARBOSA DE CARVALHO<sup>1</sup>,

CHERYL J. CHERPITEL<sup>2</sup> & VILMA LEYTON<sup>3</sup>

*University of São Paulo Medical School, Department of Preventive Medicine, Avenue Dr Arnaldo, 455 – 2º Andar, CEP 01246-903 São Paulo/SP, Brazil,<sup>1</sup> Alcohol Research Group, Emeryville, CA, USA<sup>2</sup> and Department of Legal Medicine, University of São Paulo Medical School, São Paulo, Brazil<sup>3</sup>.  
E-mail: gabriel.bioups@gmail.com*

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