Facsimile of pages 1 and 2 of the Food and Drug Administration (FDA) statistical review and evaluation of valdecoxib.^{w2} Publicly available at www.fda.gov/cder/foi/nda/2001/21-341_Bextra_statr_P1.pdf (accessed 20 May 2005)

The US Food and Drug Administration (FDA) and other licensing authorities are an important source of relevant data. The FDA reviews clinical trials worldwide before approval and labelling, and again before relabelling of approved drugs. As part of the 1966 Freedom of Information Act, the agency is required to make available its reports on all drugs that are approved. Unfortunately, these reports are not as useful as they could be. We found that the criteria for including trials in reports were often unclear. For example, only 16 out of at least 27 trials of celecoxib that were performed up to 2002 in patients with musculoskeletal pain were included in the relevant reports. In any event, reporting on study characteristics and adverse events was not always transparent, and complete data on cardiovascular safety were available for only three trials. In the case of valdecoxib, we found that many pages and paragraphs had been deleted because they contained “trade secret and/or confidential information that is not disclosable” (figure).^{w2}

Surely, the protection of the public's health justifies full access to the safety data submitted by industry to the FDA and other drug licensing authorities, and mandates transparent reporting on harms, in accordance with international guidelines.¹⁰ Meta-analyses of adverse events might not resolve controversies, but will help decision making about issues such as the need for additional trials.

Observational studies “simply cannot test definitely whether there are small to moderate risks or benefits of

a class of drugs when the factors associated with prescription of a particular drug are difficult to control and perhaps even uncontrollable.”¹¹ This statement referred to postulated adverse events of calcium antagonists in the treatment of hypertension, a controversy finally resolved by large pragmatic trials, including the seminal antihypertensive and lipid lowering treatment to prevent heart attack trial (ALLHAT).¹² Such large trials might be required, ultimately, to establish the best and safest treatment for patients with musculoskeletal pain.

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Alcohol misuse, public health, and public policy

A comprehensive and evidence based approach is needed

Alcohol misuse continues to be associated with as many as 22 000 deaths each year in England, with cumulative economic, health, and social costs estimated at £20bn annually.¹ While people in many other parts of Europe may have consumed a greater amount of alcohol in the past—although varying definitions of categories of consumption hamper accurate cross national comparisons²—the situation in

England is one of increasing concern. According to recent figures, 38% of men and 23% of women in England exceed recommended maximum levels for the heaviest drinking day of the week,³ and alcohol related illness mortality is on the rise.⁴ Drinking patterns vary between England's regions in a predictable manner that reflects persistent health inequalities,⁵ notably with the highest rates of binge drinking found in the north-

east. Formulating effective and palatable public policy to tackle this is difficult,⁶ not least because moderate regular intake of alcohol may benefit health.² Improving the population's health and reducing health inequalities both require comprehensive and evidence based solutions.

Against this backdrop, the Licensing Act 2003 was introduced in England on 7 February 2005. The act is underpinned by four stated objectives: the protection of children from harm, the prevention of public nuisance, the prevention of crime and disorder, and public safety. Previously, concerns about crime and disorder were usually the sole grounds for objecting to the granting of an alcohol licence to premises such as pubs and bars. Under the new act, each of the four objectives must be given equal weight when an application is considered by the licensing authority (in most cases now the local authority). Importantly, however, the act does not allow objections to applications for licences on public health grounds.

In early 2004 the *Alcohol Harm Reduction Strategy* for England was published, identifying four key strands of activity: better education and communication, improving services for health care and treatment, combating alcohol related crime and disorder, and working with the alcohol industry.¹ These activities have subsequently been developed within the government white paper *Choosing Health*.⁷ Although much is to be commended in these documents, they share two traits that affect how effective a public health response to alcohol misuse can be.

Firstly, detail remains limited on how the toll of alcohol misuse on population health and its contribution to health inequalities will be dealt with. As Professor Ian Gilmore, chair of the Royal College of Physicians' Alcohol Committee, cautioned in a recent interview, "the recommendations and policy measures promoted in these two documents concentrate too heavily on the aspects of drinking most closely related to law and order issues at the expense of health."⁸ The fact that references to public health were explicitly removed from the Licensing Act 2003 during its progress as a bill clearly reinforces such concerns.

Secondly, the emphasis given to action being led by the alcohol industry generates unease. The government has praised voluntary schemes such as the Portman Group's Code of Practice on the Naming, Packaging and Promotion of Alcoholic Drinks⁹; and it would be unhelpful to dismiss such schemes solely on a matter of principle, as they may generate legitimate opportunities to take cooperation further than regulation alone would achieve. There is strong evidence, for example, that intensive face to face training of those serving drinks (with strong management support) is effective in reducing levels of intoxication among

customers.¹⁰ The systematic implementation of an evidence based intervention such as this requires balanced partnerships involving the alcohol industry from the outset. Genuine corporate social responsibility within the alcohol industry should be encouraged, and the recent announcement by the British Beer and Pub Association of new standards for drinks promotions and happy hours would seem to be a positive step.¹¹ However, industry led initiatives should be approached with necessary caution and vigilance, as they can be ineffective and even counterproductive (as the tobacco industry's voluntary codes have repeatedly shown).¹²

The Licensing Act 2003 has generated welcome, if often intemperate, political and public discussion about the impact of alcohol misuse on the health and wellbeing of individuals and communities across England. Pragmatic and responsive public policies (whether national, regional, or local) must be comprehensive and grounded in the best available evidence if they are to be truly effective, as the consequences of getting it wrong are too great.

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