LETTERS to the EDITOR

Restricting benzodiazepine prescribing

SIR,—Mrs Brahams (Dec 1, p 1372) describes the regulation adopted by New York State to reduce benzodiazepine prescribing. She concludes that the evidence published by the state about the favourable effects of this regulation is "overwhelming". We have reservations about this evidence but our main point is that regulations that may affect the availability of therapeutic drugs should be adopted only after careful evaluation of possible benefits and risks and, before they are adopted, provision should be made for equally careful assessment of effects on legitimate use as well as on possible misuse or abuse.[1,2]

The New York State Department of Health (NYSDH) assumes that benzodiazepine prescribing is excessive and that a reduction will reduce misuse and abuse but will not adversely affect public health. These assumptions have not really been tested, much less substantiated.[1] Who is supposed to benefit from the regulation? According to Brahams the position of the NYSDH is that the primary objectives were "to reduce the diversion of benzodiazepines into illicit use and to reduce inappropriate prescribing". A further objective is that the state is achieving great savings as a result of the reduction in prescriptions the state has to reimburse under Medicaid and other programmes. The primary objectives are desirable. However, Dr Blum notes (Dec 22/29, p 1586) the NYSDH data cited as evidence that the regulation is achieving these objectives refer to events that long predated the regulation. Indeed, it is not at all clear that these objectives can be realised by this type of regulation. Blum makes the point that the savings claimed may easily be offset by additional costs necessitated by the regulation, many of which must be borne chiefly by patients.

More importantly, these objectives neglect the welfare of patients with conditions for which benzodiazepines are effective. As we concluded,[3] and as Blum also points out, these patients vastly outnumber those who intentionally or unintentionally misuse these drugs. Numbers apart, we would argue that it is not acceptable to risk denying reief to one patient on the grounds that one might thereby prevent drug abuse in another person.

Brahams reports that the objectives have been received "without interrupting legitimate use" but neither the NYSDH publication she cites nor any other evidence we are aware of supports this generalisation. Moreover, a chilling effect of the regulation is to risk exacerbating the undertreatment of anxiety and insomnia: most people with these disorders go without treatment,[4,5] and there is evidence linking anxiety disorders with increased risks of depression,[6] alcoholism,[7] suicide,[8] and death due to unnatural causes.[9]

"Allegations that doctors would simply prescribe alternatives has also proved groundless", Brahams states. On the contrary, market research data show that, in the nine months after the regulation took effect, prescriptions for possible alternatives increased strikingly, in contrast to trends in the rest of the United States. For example, prescriptions for meprobamate increased by 17% (as opposed to a 10% decline in the rest of the country), prescriptions for chloral hydrate rose by 158% (4% increase), and barbiturate prescriptions went up by 41% (11% decline).[10] Pharmacological and epidemiological evidence on the relative toxicity of sedative-hypnotics makes it clear that these trends may represent a substantial backward step for the public health in New York State.

Brahams also claims "a 27–53% decrease in benzodiazepine-prescriptions and a startling reduction in overdose emergency admissions [involving benzodiazepines]". The "startling reduction" in emergency admissions was 39% or so (ie, probably corresponding to the overall decrease in prescriptions). Most emergency room episodes in which benzodiazepines are involved also involve other drugs, which are far more likely to be responsible for the toxic effects.[3] The statistics cited by Brahams and by the NYSDH show that the incidence of emergency room episodes in which benzodiazepines are involved reflects not the toxicity of these drugs, but simply the prevalence of their use, and varies in direct relation to their availability.

The regulation of therapeutic drugs has been distinguished by a long history of opinion and bias more than of dispassionate evaluation of evidence. The New York State regulation continues this unfortunate tradition and is more likely to jeopardise than protect the public health. Policies affecting the availability of therapeutic drugs should be subject to the same standards of rational evaluation as the drugs themselves, and should be allowed only if they can be shown likely to prove safe and effective.

Departments of Pharmacology and Psychology,
University of Michigan Medical School,
Ann Arbor, Michigan 48109, USA — JAMES H. WOODS

Department of Pharmacology
and Experimental Therapeutics,
University of Maryland School of Medicine,
Baltimore, Maryland — JONATHAN L. KATZ

Department of Pharmacology,
University of Michigan Medical School — GAIL D. WINGER

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Analysis of treatment outcome in problem drinking

SIR,—In their comparison of specialist and general practitioner (GP) treatment of problem drinking Dr Drummond and colleagues (Oct 13, p 915) ask if their failure to find a significant difference in outcome could have been due to the small sample size ($n_1 = 18$, $n_2 = 19$). They note that such a type II error cannot be excluded but that they did find a significant reduction within the two groups, in the absence of a significant difference between groups.

What size of difference between groups did their study have the power to detect? For their initial sample size ($n_1 = n_2 = 20$) and with $\alpha = 0{\cdot}05$ and power at 80%, the study could detect differences between means of just over 0·9 SD.[1-3] In clinical research in general and certainly for treatment outcome in problem drinking this would be a large difference. In Drummond's study a difference of 0·9 SD would mean, for daily units of alcohol reportedly consumed, decreases of 11 units in one group and 4 units in the other. The study is even more inadequate for comparing proportions between the two groups. Only differences as large or larger than 5% *vs* 39%, 20% *vs* 63%, or 50% *vs* 89%[2] could have been detected with a power of 80%.[1]