

there is reliable evidence of benefit. It is also important to distinguish between lack of evidence of benefit and evidence of lack of benefit; sometimes no studies may have been done in a population, such as the elderly or children, who might benefit from off-label prescribing. Sometimes there may be little financial incentive for companies to conduct trials for an indication which is widely accepted but not approved by drug regulatory authorities.

The gabapentin story is a reminder, however, of the need for caution, especially when the evidence is unreliable or being promoted by vested interests. Much of the enthusiasm for gabapentin's off-label uses appears to have been driven by case reports, uncontrolled studies and other unreliable forms of evidence. A recent review of prophylactic migraine treatments noted that gabapentin had been suggested to be effective despite a lack of rigorous, reliable data.⁷ A Cochrane review said anticonvulsants are used widely in chronic pain, although surprisingly few trials show analgesic effectiveness.⁸ It also raised questions about the increasing use of gabapentin in neuropathic pain.

Given the uncertainties that can surround off-label prescribing, there is an extra imperative to carefully weigh the potential benefits and harms involved, and to ensure these are openly canvassed, where possible and appropriate, with patients and their families.

E-mail: sweetcom@tig.com.au

REFERENCES

1. Oncology/Hematology Associates of Central Illinois. http://www.ohaci.com/palm/trials/misc_cancer_control_trials/N00CB_trials.htm
2. Neurontin (Gabapentin) – The illegal corporate creation of a blockbuster drug. *Worst Pills, Best Pills* 2002;8:36-8. <http://www.citizen.org/>
3. Update on the illegal promotion of Gabapentin (Neurontin). *Worst Pills, Best Pills* 2002;8:68-71. <http://www.citizen.org/>
4. Dinsdale P. Pfizer gets a public dressing down over promoting unlicensed drugs. *Br Med J* 2002;324:753.
5. Frye MA, Ketter TA, Kimbrell TA, Dunn RT, Speer AM, Osuch EA, et al. A placebo-controlled study of lamotrigine and gabapentin monotherapy in refractory mood disorders. *J Clin Psychopharmacol* 2000;20:607-14.
6. Pande AC, Crockatt JG, Janney CA, Werth JL, Tsaroucha G. Gabapentin in bipolar disorder: a placebo-controlled trial of adjunctive therapy. *Gabapentin Bipolar Disorder Study Group. Bipolar Disord* 2000;2(3 Pt 2):249-55.
7. Krymchantowski AV, Bigal ME, Moreira PF. New and emerging prophylactic agents for migraine [review]. *CNS Drugs* 2002;16:611-34.
8. Wiffen P, Collins S, McQuay H, Carroll D, Jadad A, Moore A. Anticonvulsant drugs for acute and chronic pain (Cochrane Review). In: *The Cochrane Library*, Issue 3, 2002. Oxford: Update Software.

Conflict of interest: none declared

Greed and gabapentin

Editorial comment

Some of the recent corporate collapses show that the relentless pursuit of profit can have disastrous consequences. Although the pharmaceutical industry aims to help patients it may not be immune from questionable corporate practices.

The New York Times has reported an accusation that rules were broken in the promotion of gabapentin.¹ 'Worst Pills, Best Pills', an American drug bulletin, has been keeping its readers and other members of the International Society of Drug Bulletins (including *Australian Prescriber*) informed of the case.²

Allegedly, the manufacturer concocted uses for gabapentin to boost profits. Despite a lack of independent supporting evidence, the company is said to have aggressively promoted these 'off-label' indications to doctors. The promotional strategy is alleged to have involved payments to opinion leaders and the placement of ghost-written articles in medical journals.

These strategies appear to have worked well as sales of gabapentin reached US\$1.3 billion in 2000. 'Worst Pills, Best Pills' reports that as much as 78% of these sales were for uses without evidence that gabapentin was safe and effective.²

Although these allegations are yet to be tested in court, and the manufacturer involved has now been taken over by

another company, the Editorial Executive Committee of *Australian Prescriber* believes readers will be interested in how big business might influence prescribing. As gabapentin is an extraordinary case, the Editorial Executive Committee has asked well-known medical journalist Melissa Sweet to provide more details.

Could it happen here? The code of conduct for the Australian pharmaceutical industry prohibits claims which are not consistent with the product information approved by the Therapeutic Goods Administration. Although the code offers some protection, similar rules in the USA did not prevent the gabapentin controversy. To strengthen the code it is important that health professionals contact Medicines Australia* if they have evidence of drugs being promoted for unapproved indications.

REFERENCES

1. Petersen M. Whistle-blower says marketers broke the rules to push a drug. *New York Times* 2002 March 14; Section C, Page 1 (col. 5).
2. Neurontin (Gabapentin) – The illegal corporate creation of a blockbuster drug. *Worst Pills, Best Pills* 2002;8:36-8.

* Medicines Australia
Level 1, 16 Napier Close DEAKIN ACT 2600
Phone (02) 6282 6888
Fax (02) 6282 6299
www.medicinesaustralia.com.au