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Targeting drug companies' bottom line

● Off-label promotion: shifting a balance of power that benefits industry.

Federal and state government agencies in the United States have been paid over 500 million dollars by the pharmaceutical company AstraZeneca, accused of promoting a drug for unapproved uses (1).

Promotion of unapproved uses. Legal action brought jointly by the US Departments of Justice and Health and Human Services forced the drug company AstraZeneca to pay a large fine for promoting Seroquel° (*quetiapine*, an "atypical" antipsychotic) for unapproved uses (1).

Between 2001 and 2006, in addition to its approved indications in bipolar disorder and schizophrenia, the company promoted the use of Seroquel° in many other disorders, including aggressive behaviour, Alzheimer's disease, anxiety, dementia, depression and insomnia (1).

To avoid protracted legal action, AstraZeneca agreed to pay 300 million dollars to the federal government and 220 million dollars to the various participating states. In the case brought against the company, the government alleged that it had illegally increased the spending by public health insurance programmes such as Medicare and the Department of Veterans' Affairs (1).

Kickbacks. The public prosecutor also reprimanded the company for paying "kickbacks" to doctors for writing articles (and, in some cases, just for the use of their name on a ghostwritten article) or for speaking publicly on unapproved uses of Seroquel° in continuing medical education programmes (1).

Widespread practice. The public prosecutor has accused AstraZeneca of engaging in illegal marketing practices which are not uncommon and have been frequently denounced in recent years. It is interesting to see what a government, determined to recover sums injustly paid out by public programmes, can obtain from a pharmaceutical company in the way of reparations.

It is also refreshing to see a public prosecutor calling a spade a spade, and referring to the remuneration paid to doctors for participating in pseudoscientific, yet indisputably promotional activities, as "kickbacks". This will fuel the debate on conflicts of interest, and the ambiguous relationships that exist between certain opinion leaders and the pharmaceutical industry.

Prevention rather than compensation. Although public health insurance programmes have been "reimbursed" for the costs generated by the unjustified promotion of the drug, the adverse effects suffered by patients cannot be undone.

A different and more equitable balance of power is conceivable. One in which clinical research is directly funded by government, rather than subcontracted to pharmaceutical companies that recoup their investment through drug sales (2). And in which drug regulatory agencies are financed directly by government, putting them in a better position to monitor the activities of pharmaceutical companies, free from undue industry influence.

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Selected references from Prescrire's literature search.

1- "AstraZeneca confirms $520 million deal for US off-label marketing of Seroquel, as HHS details action; court approves suits against Merck&Co over Vioxx°" www.thepharmaletter.com accessed 18 May 2010: 3 pages.

2- Prescrire Editorial Staff "How to avoid future Vioxx-type scandals" *Prescrire Int* June 2005; **14** (77): 115-117.

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End of life. Some patients want to discuss their prognosis and terminal care

● In a Canadian survey, 18% of seriously ill patients said they had asked their doctors how long they had left to live. Overall, these patients tended to be more satisfied with their terminal care.

● Among the respondents who stated they had not discussed their prognosis with their doctor, 44% said they would be interested in having such a discussion, while the remaining 56% of patients said they would not.

A Canadian team examined whether seriously ill patients remembered having discussed how long they had left to live with their doctor, or whether they were interested in having such a discussion. When possible, the patients' friends and family were also asked the same question (1).

Terminally ill patients. 440 patients and 160 family members identified by the patients were interviewed by Canadian hospital physicians. The patients were at least 55 years old, and half of them were unlikely to survive more than 6 months (**a**), due to the following disorders: chronic obstructive pulmonary disease; congestive heart failure (left ventricular ejection fraction below 25%); cirrhosis with oesophageal varices or an episode of hepatic coma; and metastatic cancer or stage IV lymphoma (1).

Some patients wanted to discuss their life expectancy, while others preferred to avoid the subject. At the time of the survey, in response to the question "Have the doctors told you how long you (or the patient) can expect to live?", 74 (18%) of 412 patients ▶▶

a- More than 50% of the patients died within 6 months after being interviewed (ref 1).

b- The survey did not show how many of the patients who wanted to discuss the end of life with their doctor were able to do so.

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