

News and Legislative Update

Pharma Pays Out - Who Pays Pharma?

Pfizer probably knew this would come back to bite them: on September 3rd it became public that they would pay US\$ 2.3 billion to settle a case involving illegal marketing of Bextra and other drugs (Garner Harris, *Pfizer Pays \$2.3 Billion to Settle Marketing Case*, NYT, Sep 3, 2009). Pfizer still makes Celebrex, another so called COX-2 inhibitor, for which commercials have returned to the air.

While this is the largest sum ever, the Department of Justice reports that it receives billions from health care fraud. In 2008 alone, health care fraud made up 83.5% of the US\$1.34 billion recovered (DOJ press release, <http://www.usdoj.gov>). Among the chief offenders: \$361.5 from Merck for violating Medicaid status and giving kick backs to physicians; \$258 from Cephalon for off label marketing; \$75 million from Kyphon Inc for causing the submission of false claims to Medicare. Last but not least, CVS paid \$21.1 million for switching Medicaid patient from generic ranitidine (\$17.10 per month) to brand name for \$79.80, making \$62.70 per patient per month.

Other pay outs remembered: in 2001, TAP Pharmaceuticals paid \$875 million for fraudulent drug pricing and marketing of Lupron®, a prostate cancer drug;

the 2006 Oxycontin® case, \$634 million for misleading consumers; the Neurontin® case in 2004, \$430 millions for illegal marketing; the 2003 \$355 million case concerning illegal payments to doctors for prescribing Zoladex®, another prostate cancer drug.

A somewhat bizarre web site is <http://www.officialvioxxsettlement.com/>, where you can calculate your share of the Vioxx settlement (valued \$4.85 billion), given as "points". The "point value" seems to have been close to \$1915, according to one source (Jere Beasley, www.jerebeasleyreport.com/).

Many if not all affected companies agreed to comply with corporate integrity agreements (Pfizer is now up to the second one after the Neurontin case) What is astonishing however is how little changes, despite assurances from the industry. Interestingly, Pfizer's share price seemed to take it well (on August 31, \$16.70, September 3 low \$15.98, at time of this writing \$16.52). Furthermore, profits are still high: Merck, the year of the settlement (2008) noted a \$3.275 billion profit (down 26%).

Vignette

Our office is well on the way to become "unbranded". The partners have not been seeing drug reps in the office for years and recently we have removed all "drug paraphernalia" from the office. No pharma sponsored talks happen in the office, no one drops off food. The remaining issue is samples. For us, it is important to give patients access to clopidogrel (Plavix®, ~\$150/month), which many of our patients cannot afford but need because they had stents placed. Our secretaries keep a list of patients who need clopidogrel and are often scrambling for samples. Not having access to the drug has led to the

dreaded effect of "stent thrombosis", which can be fatal and can happen many years after the stent was placed (especially for newer drug coated stents). Patient can apply for charity and receive the drug for free but many do not qualify. They thus become dependent on the drug rep to drop off the samples regularly. It puts them and us in an awkward position and in my mind has undoubtedly led to people missing doses and coming back with myocardial infarctions. But without insurance, what choice do we have?

From a large Cardiology practice

Pharma Spotlight

Cholinesterase Inhibitors for Dementia

Treatment of Alzheimer's dementia (AD) with this class of drugs has become quite common. Basically there are four approved drugs, although Tacrine is rarely used due to hepatic toxicity. The remaining ones are Donepezil (Aricept®, ~\$220/month), Rivastigmine (Exelon®, ~\$220/month) and Galantamine (former Reminyl®/now Razadyne®, ~\$210 to \$315/month). They are generally indicated for mild to moderate dementia. It has been shown for Donepezil that effects disappear once the drug washes out (Rogers et al, *Neurology*, 1998). According to Press and Alexander (UptoDate 17.2), a trial of donepezil is reasonable in advanced AD. Evidence seems less clear for the other agents. Furthermore, evidence for use in mild cognitive impairment also is scant, and use is not recommended.

Benefits of treatment should be weighed against risk. While GI side effects are most common, as patients are usually elderly, cardiovascular adverse events become important and occur in a few percent of patients (e.g. hypertension, syncope), as do CNS side effects (e.g. headache, hallucination, confusion, depression, aggression).

One important aspect then becomes patient selection. The Minimal Mental State examination is the most accessible test for dementia for the general clinician, but it is not sensitive for mild dementia and more comprehensive tests are probably best executed by Specialists. What seems to be indiscriminate use by some practitioners for "memory problems" without much assessment and follow up seems misguided and potentially harmful.



© Benjamin Schaefer, 2009