

## Pfizer pleads guilty, but drug sales continue to soar

Jeanne Lenzer *New York*

Pfizer, the world's largest drug maker, pleaded guilty on 13 May to numerous civil and criminal charges for illegally promoting the off-label use of gabapentin (Neurontin). It has agreed to pay a \$240m (£136m; €200m) criminal fine and \$152m to state and federal healthcare programmes. The fine is the second largest given in the industry.

Meanwhile, off-label sales of gabapentin continue to soar, despite evidence that the drug is not effective for some of the problems it is used to treat.

David Franklin, 42, a microbiologist and former Harvard research fellow who worked as a "medical liaison" expert for Warner-Lambert before it was bought by Pfizer in 2002, filed a whistleblower suit under the False Claims Act in 1996, charging the company with using "fraudulent scientific evidence" to promote off-label uses of gabapentin.

Dr Franklin's suit detailed how the company suppressed study results, planted people in medical audiences to ask questions intended to put gabapentin

in a good light, lavished perks on doctors, used ghostwriters, gave generous "consultation fees" to "thought leaders," and used psychological profiling of doctors in its successful bid to move gabapentin to so called blockbuster status (annual sales in excess of \$1bn) (*BMJ* 2003;326:620). Dr Franklin said that off-label uses accounted for more than 90% of the drug's \$2.7bn sales worldwide last year.

Gabapentin is approved for use as adjunctive therapy only for partial seizures and for post-herpetic neuralgia. But the company trained staff to promote it for at least 11 off-label uses, including as monotherapy for seizures, restless leg syndrome, bipolar disorder, migraines, and alcohol withdrawal seizures.

"A lot of people say it's a benign drug," said Dr Franklin. "But it's dangerous when patients are [taken off other] drugs that are effective."

Dr Matthew Keats, assistant professor of clinical psychiatry at Eastern Virginia Medical School, agrees, citing the case of a

16 year old man who committed suicide in May 2002 while taking gabapentin. "The shocking aspect of the story is that the manufacturer funded a study and knew as early as 1998 that Neurontin didn't work in bipolar disorder. But they didn't publish the results until two years later. Yet we still see it prescribed for bipolar disorder."

As part of the settlement agreement, Dr Franklin will

receive \$24.6m under whistle-blowing legislation.

The settlement is not a major setback for Pfizer, whose worldwide sales of gabapentin rose from \$1.3bn in 2000 to \$2.7bn in 2003.

The company's promotional efforts, Dr Franklin said, were "profoundly effective." He added, "A huge majority of people taking [gabapentin] now are taking it for the wrong reasons." □



CHRISTOPHER SUZUKI/AP

Whistleblower David Franklin said that Pfizer's efforts to promote gabapentin were "profoundly effective"

## GPs to check on patients' residency status to stop "health tourism"

Zosia Kmietowicz *London*

General practitioners will need to vet new patients for their residential status before treating them, under new rules to be drawn up by the government in a bid to cut the cost of so called health tourists seeking medical care in the United Kingdom.

The new proposals come just six weeks after hospitals introduced a system of charging overseas visitors for medical care other than emergency care.

Under the new proposals, which are under consultation

until 13 August, any patients who are not long term UK residents could be charged for GPs' services as private patients.

Failed asylum seekers would lose their right to free treatment as soon as a decision was made against them. But they would continue to receive free treatment for any conditions that existed before their residency was rejected.

Similarly, family members of people from overseas who reside permanently in the Unit-

ed Kingdom would be stopped from briefly visiting the country for free medical care. For example, pregnant women whose husbands work abroad would no longer have the right to give birth in an NHS hospital free of charge.

John Hutton, the health minister, argued that the new regulations will bring clarity to primary care staff as to who is eligible for free treatment. "These changes are necessary if we are to protect NHS resources from possible abuse," he said.

However, doctors' and managers' groups are concerned that NHS staff are being asked to take on the government's responsibility of policing who is eligible for free

NHS treatment, even though there is still no evidence of the cost that overseas visitors place on the system.

Rosey Foster, acting chief executive of the Institute of Healthcare Management, said: "We are concerned that practice managers and GPs should not be expected to become a hidden arm of the immigration services."

Dr John Chisholm, chairman of the BMA's General Practitioners Committee, said the impact of the proposals on certain groups, such as failed asylum seekers, needs to be carefully considered.

"We will be studying and responding to the consultation document." □