



Letter to the editor: The Pundit Speaks
By Randolph M. Howes, M.D., Ph.D.
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"Off-Label Drug Use Can Be Dangerous"

The term "off-label" means that a drug is being used for some condition or symptom other than that for which it was FDA approved. Drug companies are legally barred from promoting their products for such uses but doctors can legally prescribe medicines for off-label uses. Actually, this is a very common practice in America and usually meets little resistance until law suits result from alleged off-label use.

Frequently, drug makers test drugs for many conditions and promote their results but they do not always seek FDA approval for the new proposed uses, especially, if the new studies are not convincing. Such appears to be the case with Pfizer's epilepsy drug, Neurontin. Pfizer is now defending against lawsuits requesting refunds on prescriptions paid for by insurers and consumers, who claim that, "Pfizer concealed evidence the epilepsy drug Neurontin didn't work for those unapproved uses, including nerve pain, migraines and bipolar disorder." Lawyers are seeking class action status for this case.

A dozen published studies found that reporting of the results was often misleading, indicating that the medicine worked better than internal drug company documents showed and that unfavorable study results were buried and replaced with something else positive, without disclosing the switch. The report against Pfizer was filed in the New England Journal of Medicine in November of 2009, which was only two months after Pfizer was fined \$2.3 billion for marketing other illegal blockbuster drugs. This fine included an unprecedented \$1.2 billion criminal fine.

The Public Citizen's spokesman, Dr. Sidney Wolfe, said, "It is the first comprehensive look at studies in which a company and people working for it so maliciously manipulated the data to make a drug look more effective than it actually was. In every instance, the published article made the drug look better than it would have. This results in harm."

Neurontin's potential side effects include suicidal tendencies and depression and it has been approved for over a decade to treat seizures and the pain of shingles but not for other conditions. Neurontin sales peaked in 2004 at \$2.7 billion and Pfizer disputes the report's findings.

In the America that I love, we will appreciate the fact that drug sales is a huge business and it can be significantly affected by the profit motive, while appearing to ignore patient safety. Drug manufacturers have been caught playing fast and loose with the facts and fines and convictions must be enforced upon guilty parties. This is similar to the antioxidant vitamin situation, which I discuss at www.iwillfindthecure.org. As always, do not take drugs unnecessarily and if in doubt, consult your physician.

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