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Courts crack down on drug marketing strategies

Researchers who agree to 'author' ghostwritten papers or conduct industry-sponsored clinical trials may find themselves in legal hot water now that courts worldwide are questioning the legality of some common pharmaceutical marketing tactics.

In the US and Europe, consumer groups and government prosecutors are pursuing civil and criminal cases against pharmaceutical companies. In June, the New York state attorney general charged GlaxoSmithKline (GSK) with fraud for withholding results of negative studies of the antidepressant Paxil. GSK and thousands of physicians are also the targets of an Italian investigation into the company's alleged practice of rewarding doctors for prescribing certain drugs.

In Massachusetts, pharmaceutical giant Pfizer pleaded guilty to fraud and agreed to pay the state and federal governments more than \$430 million in fines for aggressively promoting its blockbuster drug Neurontin. The US Department of Justice says the company illegally pushed the drug—approved to treat epilepsy—for a range of unapproved conditions including pain, bipolar disorder and attention deficit disorder.

The US Food and Drug Administration (FDA) approves drugs for specific disorders, but anecdotal or scientific evidence sometimes suggests wider applications. Until the FDA approves the new use, companies may not promote the 'off-label' uses, but the agency sometimes allows distribution of peer-reviewed journal articles endorsing such uses. Documents released in the Neurontin case detailed Pfizer's plan for 20 ghostwritten review articles with paid scientific authors, four-star travel junkets for consultants, and misleading continuing medical education programs.

Jeff Trewitt, a spokesman for the Pharmaceutical Research and Manufacturers of America, says the use of journal articles to specifically promote off-label use "is a gray area—we don't know if it's legal or not."

Critics charge that the FDA has always been lax about enforcing its own rules on drug promotion. In 1998, a US District Court further limited the agency's authority, saying its off-label marketing rules violate companies' First Amendment rights.

After years of being subject to those lightly enforced FDA rules, companies are scrambling to make sure they are in compliance with existing laws. They also face a new set of laws as state and federal lawyers evoke both FDA rules and the False Claims Act to recover some of the high cost of prescription drugs for public health programs.

The manuscript guidelines at most major journals prohibit ghostwritten reviews. But the practice is common and rarely exposed—

Kimberly Caesar

except in lawsuits like this one, says Drummond Rennie, deputy editor of the *Journal of the American Medical Association*.

Rennie says researchers routinely send him solicitations from drug companies. For several thousand dollars, the researcher is asked to take a cursory look at a review and agree to serve as the sole author.

"This is outrageous behavior," Rennie says. "This is taking money for one reason only and that is to act as a shill for the drug companies."

The practice may be reprehensible and turn up as an example of fraud in one of these cases, but it probably won't land a researcher in jail, says former US Department of Justice attorney T. Reed Stephens.

Industry insiders say the rules on drug promotion may become clearer as more cases make their way through the courts. In the meantime, says Stephens, researchers and companies are likely to remain confused about what marketing practices will get them in trouble with the law, especially when it involves an unapproved use.

Tinker Ready, Boston

Europe kicks off prion research network

The European Commission on 28 May launched the world's largest prion disease research network.

With 52 centers from 20 countries and a five-year budget of €14.4 million, the NeuroPrion Network aims to understand what causes prion protein modifications, how they develop in animals, and how they are transferred to humans to cause variant Creutzfeldt-Jakob disease (vCJD). A new prion research facility, to be launched at the Commissariat à l'Energie Atomique, a multidisciplinary research organization near Paris, will coordinate the network, identifying areas for applied research and greater coordination.

Researchers plan to develop early diagnostic tests for prion diseases in both animals and humans. The network will include national surveillance centers for vCJD

in the European Union. Institutes will share training programs, staff, genetically modified mouse strains, and tissue and fluid banks.

Since 1995, 141 people have died from vCJD in the UK. Results from direct analyses of human biopsies indicate that nearly 4,000 Britons between ages 10 and 30 may be harboring the prion protein that causes vCJD. The UK Health Protection Agency, a member of the new network, is collecting 100,000 tonsil samples to be tested for the disease.

The network "is a very interesting experiment," says Theodoros Sklaviadis, an expert in prion diseases at the Aristotle University of Thessaloniki in Greece. But, in light of the recent tissue survey results, he says, "additional funds should be allocated to cover basic research needs."

Xavier Bosch, Barcelona