

Recent Developments Leave Off-Label Marketing On Shaky Ground

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The U.S. Department of Justice's ("DOJ") prosecution of pharmaceutical and medical device companies for alleged off-label marketing and the Food and Drug Administration's ("FDA") recent attempt to provide parameters for such marketing means that now, more than ever, pharmaceutical and medical device companies must be wary of the promotional materials they send to doctors.

Currently, the DOJ is investigating more than 150 drug and medical device manufacturers for alleged off-label promotions. The consequences for manufacturers accused of off-label marketing can be significant. Last year, Pfizer Inc. paid nearly \$35 million to settle off-label marketing claims of its growth hormone Genotropin. Less than two years ago, Schering Sales, a subsidiary of Schering-Plough, agreed to pay \$435 million in criminal and civil fines as part of a guilty plea to a single count of off-label promotion. In 2004, Pfizer Inc. settled a case centered on the epilepsy drug Neurontin for \$430 million. These pale in comparison to the \$1 billion payout that Eli Lilly is reportedly considering for alleged off-label promotion of Zyprexa. Recently, Otsuka American Pharmaceutical, the U.S. subsidiary of a Japanese pharmaceutical company, agreed to pay over \$4 million to settle off-label marketing allegations brought by the DOJ. These settlements illustrate the risks pharmaceutical

companies face when they promote off-label uses of their products.

On February 15, 2008, the FDA issued draft "Good Reprint Practices" for industry use in the distribution of medical or scientific journal articles and reference publications discussing unapproved uses of FDA-approved drugs and medical devices. The FDA Deputy Commissioner for Policy explained the rationale behind this move: "[a]rticles that discuss unapproved uses of FDA-approved drugs and devices can contribute to the practice of medicine and may even constitute a medically recognized standard of care ... this guidance also safeguards against off-label promotion."

The FDA's "Good Reprint Practices" recommends principles that manufacturers should follow when they distribute scientific or medical journal reprints, articles, or reference publications. The principles are intended to ensure the transmittal of truthful and non-misleading information. For instance, the principles recommend the article or reference be published by an organization with an editorial board. Also, the principles recommend that the publishing organization divulge any conflicts of interest or biases for all authors, contributors, or editors associated with the article. Further, articles should be peer-reviewed and published in accordance with specific procedures. The draft guidance also recommends that manufacturers do not

distribute false and misleading articles. False and misleading articles would include those unsupported by credible medical evidence or publications that have been funded by one or more of the manufacturers of the product.

According to a 2006 analysis cited by the Wall Street Journal, an estimated 31% of psychiatric-drug prescriptions, including antidepressants, anti-anxiety and anti-psychotic medications, are off-label, and represented U.S. sales of about \$26 billion. The percentages were even higher

for other medications, such as asthma medicines. Thus, drug manufacturers benefit from providing doctors with off-label use data. However, due to the tension between the DOJ's surge of investigations into pharmaceutical companies for alleged off-label promotion and the FDA's new draft guidance on approved practices for distributing materials on off-label use, pharmaceutical and medical device companies must be wary of the promotional materials they provide to physicians.



If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers:

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