Off-Label Drug Campaigns Unlikely To Disappear

Written On September 8, 2009 By Bob Kraft

As written by the Associated Press, the huge fine levied last week against Pfizer is unlikely to stop pharmaceutical companies from the profitable practice of off-label marketing of prescription drugs. Drugs are approved by the government for particular uses, but obviously drug manufacturers can make more money if they can promote their drugs as the solution for as many different diseases as possible. So the temptation is for drug companies to try to convince doctors to prescribe medications for purposes other than those approved by the FDA. This is a potentially dangerous practice, simply because the regulating agency has not tested the drugs for these off-label purposes. Here are excerpts from the article:

Pfizer Inc. was slapped with a record $2.3 billion in fines for illegally marketing some drugs, but critics say even that eye-popping total is unlikely to end the sometimes dangerous practice of promoting drugs for unapproved uses.

The penalty pales compared with the billion dollars or more in annual revenue that blockbuster drugs generate, and new government guidelines stir worry that the marketing of medicines for unapproved uses will become easier.

“Drug companies will continue to market off-label unless the financial downside makes it unprofitable,” said Dr. Adriane Fugh-Berman, a Georgetown University associate medical professor.

Off-label marketing is a tricky issue. Doctors say prescriptions for uses not noted on a drug’s package label – the fine-print insert that comes with the prescription – play a crucial role in treating patients, especially those with deadly illnesses and few treatment options.

Kraft & Associates
2777 Stemmons Freeway
Suite 1300
Dallas, Texas 75207
Toll Free: (800) 989-9999
FAX: (214) 637-2118
E-mail: info@kraftlaw.com

However, the Food and Drug Administration prohibits companies from promoting their drugs for uses it has not approved.

Huge fines for those caught violating these rules usually just nibble at drug company sales totals.

Pfizer’s fine is the largest health care fraud settlement in U.S. Justice Department history. But that $2.3 billion total stands small compared with the $44.2 billion in pharmaceutical sales that the world’s largest drug maker rang up last year.

Prosecutors said Pfizer promoted four prescription drugs, including the discontinued painkiller Bextra and the blockbuster Lyrica, for epilepsy and nerve pain from fibromyalgia, as treatments for medical conditions not approved by federal regulators. Lyrica alone registered $2.6 billion in sales last year.

Authorities also accused the drug maker of plying doctors with free golf, massages and resort junkets.

Pfizer hasn’t been the only target on off-label marketing. Earlier this year, Indianapolis-based Eli Lilly & Co. agreed to pay $1.42 billion to settle a case over the marketing of its top seller, Zyprexa, an anti-psychotic drug.

Fugh-Berman said fines alone will not end off-label marketing, but they can curb the practice when coupled with corporate integrity agreements such as the one the Justice Department imposed on Pfizer. These can force companies to disclose doctor payments or other information they’d rather keep under wraps.

“Our sense is that companies fear corporate integrity agreements more than fines,” Fugh-Berman said.

Kraft & Associates
2777 Stemmons Freeway
Suite 1300
Dallas, Texas 75207
Toll Free: (800) 989-9999
FAX: (214) 637-2118
E-mail: info@kraftlaw.com