

## Drug Companies and “Off-Label” Marketing

By Anique Gonzalez

Recently, pharmaceutical companies have come under fire for allegedly employing a practice known as “off-labeling,” whereby they persuade physicians to prescribe drugs for reasons other than the drugs’ developed purposes. As a result, Congress has launched an investigation into the practice, class-action suits have been filed, and large settlements have been reached.

It is important to note that doctors, in most cases, are not breaking the law when they prescribe medicine off-label. The legal implications present themselves when drug companies begin marketing these drugs for purposes other than their original intended uses.

Plaintiffs’ attorneys claim that drug companies will often conduct research to discover additional uses for a specific drug and then present the information to doctors in hopes that the number of prescriptions for that drug will increase. While many may not consider this ethical, it is legal. A fine line has developed, however, between drug companies *providing information* about possible off-label uses and drug companies *promoting* use in a manner not sanctioned by the Food and Drug Administration (FDA).

In several of the lawsuits filed thus far, plaintiffs include not only individuals who claim they were injured by inappropriately prescribed drugs but also insurance companies who are contesting the off-label prescriptions they were forced to cover.

Such suits include a 7,000-member multidistrict Florida case that was filed against AstraZeneca. The plaintiffs allege that the drug company not only encouraged off-label use of the drug Seroquel but also suppressed information about the drug’s side effects. *Welfare Fund of Teamsters Local 863 v. Pfizer Inc.* is a New Jersey case that involves the drug company Pfizer and its cholesterol drug, Lipitor.

Various insurance companies and unions allege that they lost billions of dollars as a result of being forced to cover drugs that were prescribed off-label. Insurance carriers in Massachusetts filed a similar suit against Pfizer, claiming that many of the prescriptions written for the drug Neurontin were off-label prescriptions.

Many of the plaintiffs’ lawyers argue that off-labeling has padded pharmaceutical companies’ bottom lines and is responsible for large portions of their revenues. Insurance companies are now watching for drugs that have high levels of sales but whose uses, as defined by the FDA,

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are extremely limited. Consequently, insurance companies are starting to file suit in instances where they believe the majority of prescriptions were off-label.

Such lawsuits can yield extensive monetary damages for the drug companies involved, even when the suits do not go to trial. In the past two years, for instance, the United States Department of Justice has negotiated settlements that have now reached more than \$1 billion.

Other large settlements have included those of Schering Plough and Serono, both of which were accused of marketing their drugs off-label. In 2005, Serono settled a lawsuit for \$704 million, and in 2006, Schering Plough agreed to pay \$435 million after it, too, negotiated a settlement.

According to a study entitled “Off-Label Prescribing Among Office-Based Physicians” published in the *Archives of Internal Medicine*, off-label prescriptions accounted for 21% of drugs prescribed in 2001. In addition to insurance carriers and individual drug users, this recent surge in off-labeling has also interested Congress, which recently announced that it was investigating three drug companies as a result of claims that they were marketing anti-psychotic and narcotic drugs for off-label purposes.

However, Congress is not the only arm of government taking action. The United States Attorney’s Office in Philadelphia and Connecticut’s attorney general are both examining claims that Cephalon, Inc.’s drug Actiq was primarily used by individuals who were suffering from back pain and migraines instead of being used by cancer patients as it was originally intended.

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*Archives of Internal Medicine*

[archinte.ama-assn.org/cgi/content/abstract/166/9/1021](http://archinte.ama-assn.org/cgi/content/abstract/166/9/1021)

U.S. Food and Drug Administration

[www.fda.gov](http://www.fda.gov)

Pfizer

[www.pfizer.com](http://www.pfizer.com)