Legal Matters

Litigation Threatens Off-Label Pharmaceutical Sales

By Kenneth J. Nolan, for HealthLeaders News, Jan. 21, 2004

SUMMARY (full story below)

The pharmaceutical industry reaps an estimated $13 billion a year in off-label drug sales. But HealthLeaders member Kenneth J. Nolan says those sales may be in jeopardy if the pharmaceutical industry does not pay more heed to the federal False Claims Act.

FULL STORY

Because a few companies have egregiously violated FDA rules and regulations in marketing their drugs for off-label uses, spoiling it for the majority, the pharmaceutical industry is on a collision course with the Federal False Claims Act (FCA) that may jeopardize its $13 billion in annual, off-label pharmaceutical sales. In addition to what has already been filed, expect an increasing number of qui tam lawsuits and crippling fines against specific companies, as well as unwanted government regulation--unless industry leaders develop standards to curb abuses.

The FCA is the U.S. Government's most powerful and most utilized tool to fight fraud. The FCA was originally enacted by Congress in 1863, as a response to widespread abuses by government contractors against the Union Army during the Civil War. The Act was scarcely used in the interim years until 1986, when Congress enacted amendments to the Act which strengthened the law and increased monetary awards.

A company that violates the FCA is liable to the United States Government for a civil penalty, plus three times the amount of damages which the Government sustains. For example, if a drug manufacturer causes the submission of false claims of $10 million to the Medicaid program, it is potentially liable for damages of up to $30 million, plus a civil penalty of up to $11,000 for each patient claim for reimbursement submitted.

The Act also authorizes qui tam enforcement. The qui tam provisions allow any citizen, called a "Relator," who has knowledge of fraud that has taken place against the government to bring a civil action in Federal Court in the name of the United States. In return for his/her and his attorney's efforts, the citizen is entitled to share in the proceeds of the recovery.

In a case that is currently being litigated, Dr. David Franklin filed a qui tam lawsuit back in 1996, on behalf of the United States, alleging that Parke-Davis engaged in the illegal marketing and off-label promotion of Neurontin, causing physicians to prescribe it for uses that the FDA had not approved. The lawsuit also alleges that Medicaid programs have been wrongfully paying for these off-label uses, resulting in millions of dollars of fraudulent payments.

In May, 1999, Genentech pled guilty to a criminal charge and paid a $30 million fine, admitting that it had unlawfully attempted to expand the market for Protropin for burns and certain kidney disorders, when the drug had only been approved by the FDA for long-term treatment of growth failure in children. In addition, it paid a civil settlement of $20 million to reimburse government expenditures under Medicaid and CHAMPUS.

In May, 2003, Schering-Plough disclosed that it received a letter from the U.S. Attorney's office for the District of Massachusetts, advising that it is the target of a federal criminal investigation, in part because it allegedly promoted certain drugs for off-label uses. All of these situations have a similar ring to them: products approved by the FDA for a specific purpose or purposes were allegedly illegally marketed or sold for one or more unapproved conditions. Although the FDA approves a drug only for particular uses for which it has been tested, it does not regulate how the drug may be prescribed. So, based upon peer-reviewed medical literature, anecdotal information from colleagues, and other objective sources of information, physicians may prescribe a drug approved for one use for another, or "off-label," use. Off-label use is generally accepted in the medical community, and there are numerous examples of how patients have benefitted from the practice.

The catch is that, though physicians may prescribe drugs for off-label use, the FDA specifically prohibits drug manufacturers from marketing a drug for a use or dose that it

has not approved, nor can its sales representatives legally make unsubstantiated claims about the safety and efficacy of their products. To stay within the law, a manufacturer must not interfere in any way in a physician's decision to prescribe its product off-label. (If a manufacturer intends to promote a drug for new uses in addition to those already approved, any materials it produces describing off-label uses must meet certain stringent requirements, and the manufacturer must resubmit the drug to the FDA testing and approval process.)

Of course, violating federal law has not stopped a certain few pharmaceutical companies engaged in inappropriate off-label marketing from creating a complex array of monetary incentives for physicians to induce them to write prescriptions for off-label uses. Just to name a few, there were so called "consultants" meetings, at which physicians are paid to hear presentations about off-label prescriptions, there were honoraria paid to physicians to hear off-label promotion under the guise of Continuing Medical Education seminars, and there were so called "educational grants" provided to doctors who were high prescribers.

None of these incentives had anything to do with true scientific or medical research or learning. Physicians who receive such inducements have been typically selected by the sales and marketing departments based upon their ability to prescribe the drug and to influence other doctors to do so. Ultimately, the decision-making of a physician, the all-important element in healthcare coverage policy, is completely undermined by such improper off-label marketing.

What's more, such duplicity makes pharmaceutical companies liable to prosecution by the federal government - if the off-label use advocated by the company is not supported by legitimate science.

When a pharmaceutical manufacturer induces physicians to prescribe drugs for off-label uses that are not substantiated by objective medical review, the Federal False Claims Act is triggered if payment has been made by a government program, because claims for such off-label uses are not reimbursable, except under very limited conditions. Medicare limits its coverage to injectable and anti-cancer drugs and mandates that there must be at least some support for off-label use in major drug compendia or peer-reviewed literature. TRICARE allows for cost-sharing for off-label drugs when there is reliable evidence that such usage is safe and effective from clinical studies in referenced medical literature, formal technology assessments, published national medical policy organizations, and published reports of national experts. Medicaid will not reimburse for drugs unless their off-label use is included and supported in any one of three major drug compendia.

There are many examples of off-label uses of drugs that clearly have been safe and effective, and they are perfect examples of why off-label use is important to the practice of medicine and beneficial to patients. The past conduct of a small portion of pharmaceutical companies could threaten the reputations and viability of the vast majority, however. Had such companies not flouted the FDA, with its limited resources, hundreds of millions of dollars in drug costs, physician visits, and side-effect managent could have been

saved.

Moreover those companies that have abided by FDA rules and regulations, as well as federal law proscribing kickbacks, would have had a more level playing field on which to market and sell their drugs. Patients would have had physicians making medical decisions to treat their illnesses based upon sound science, not due to the mercenary, off-label marketing of drugs for uses supported by little or no legitimate scientific data.

Expect the most disadvantageous trend in Federal False Claims Act litigation for pharmaceutical companies to get worse before its get better--as the past misleading marketing activities of more pharmaceutical companies are exposed. And hope for a new trend to emerge--the pharmaceutical industry policing itself to head off unwanted government intrusion in its proprietary activities. All of the rules, regulations, and safeguards are in place. The industry just needs to find the collective will to reinforce implementing them as standard operating procedure.#

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