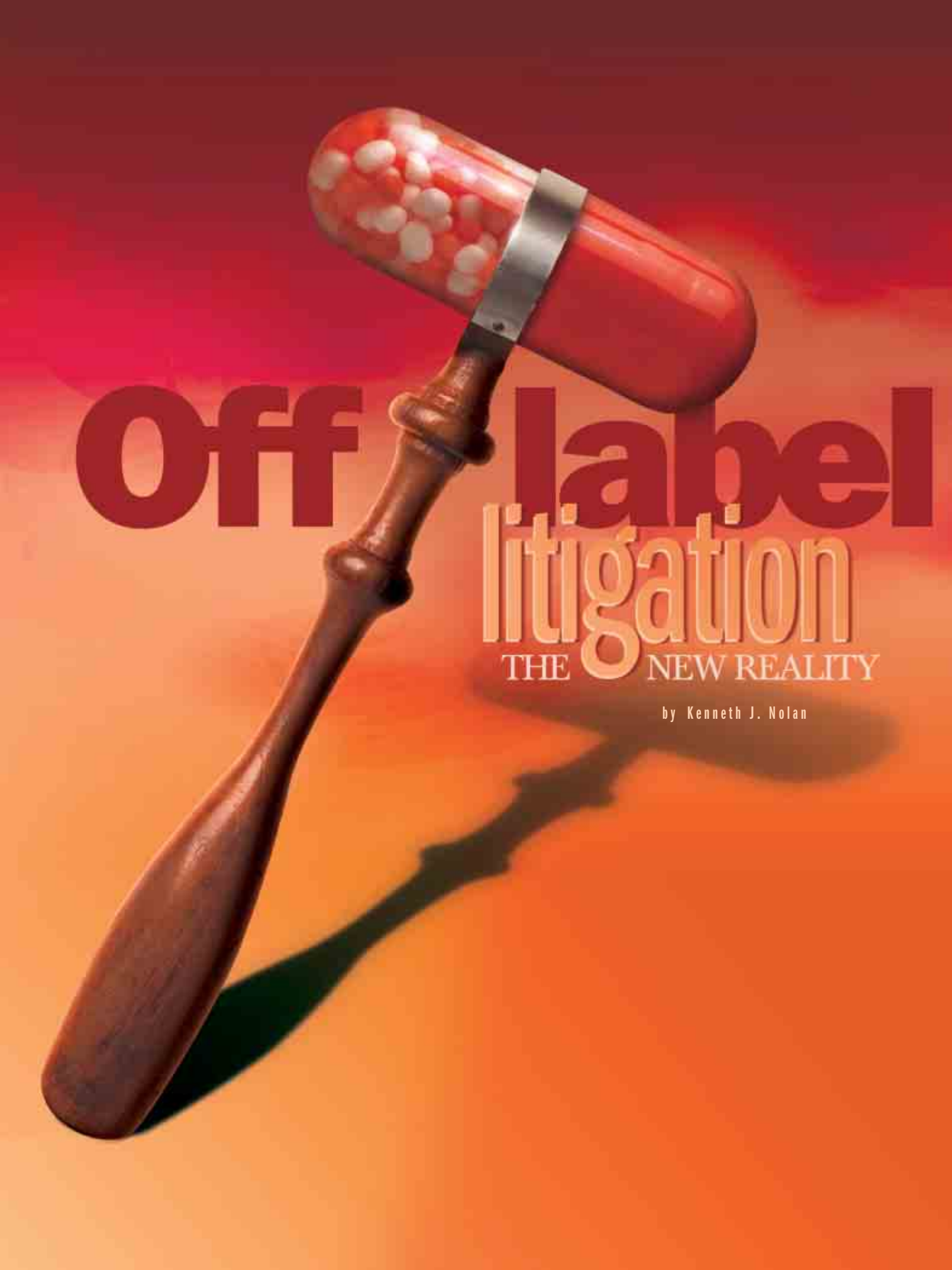

Off label litigation

THE NEW REALITY

by Kenneth J. Nolan

Ask anyone what pharmaceutical sales representatives do, including representatives themselves, and you're likely to hear: "Sell the product." What you could also have heard from management in charge of selling a product with an off-label market as recently as last year was: "Make the market." Given the increased number of civil suits the pharmaceutical industry is facing because of off-label marketing, however, "Make the market" is not a phrase you will hear in this context anymore.

As every sales representative knows, *off-label* is the term used to describe the prescribing of a drug for a use other than that for which it has been tested and approved by the Food and Drug Administration. Prescribing drugs off-label is generally accepted in the medical community and is recognized as having benefits for patients and providing flexibility for doctors. Sometimes, the off-label use is better than the drug's FDA-approved use, and when drug companies and their sales representatives provide legitimate information about off-label use within FDA guidelines (which only allow accurate and truthful dissemination of information in the form of peer-reviewed journal articles), doctors are better off because they don't have to rely on anecdotal information from colleagues about potential alternative uses for the drugs in question.

The pharmaceutical industry is on a collision course with the Federal False Claims Act.

But creating a market based on unsound science or exaggeration, rather than on proven, legitimate studies, violates FDA guidelines as well as decency and common sense. Feeling pressure to sell drugs off-label to meet their quotas and make their bonuses, some sales representatives (and their managers) have gone along with their companies' illegal practices to save their jobs. These practices have ranged from managers requiring quotas on off-label calls to reps arranging off-label continuing medical education events. Putting aside safety and effectiveness, companies realized that many doctors would not take any significant independent action to consider whether the science was legitimate. As a result, off-label uses have been successfully marketed based on studies of limited merit – like a study conducted with less than ten subjects or outside of the United States.

No more rule bending

This permissive atmosphere has changed. Now, sales representatives are finally being told by their companies, almost industry-wide, not to disseminate off-label information unless the physician's specialty is within the drug's indication. They are also being told that bonuses will no longer be paid on off-label sales, and that training will no longer include off-label education advocacy. But the changes cannot undo what has been done.

The pharmaceutical industry is on a collision course with the Federal False Claims Act that is likely to jeopardize its $13 billion in annual off-label pharmaceutical sales. Under the *qui tam* provision of the False Claims Act (see sidebar on page 19), individuals can sue on behalf of the government if they think their company has defrauded the government. Many individuals who are aware of inappropriate off-label marketing are beginning to come forward, and as a result, the industry can 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. This potentially catastrophic trend is already clear.

In May 1999, South San Francisco-based Genentech Inc. pleaded guilty to a criminal charge and paid a $30 million fine, admitting that it had unlawfully attempted to expand the market for Protropin® (somatrem for injection) 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 TRICARE, the healthcare program of the Department of Defense.

In 1996, David Franklin, a physician employed by Parke-Davis (now a part of New York-based Pfizer Inc.) filed a *qui tam* lawsuit on behalf of the United States, alleging that Parke-Davis engaged in the illegal marketing and off-label promotion of Neurontin® (gabapentin), causing physicians to prescribe

Free speech infringement?

■ In January of 2000, the pharmaceutical industry won an important legal battle when the Food and Drug Administration told a federal appeals court panel that it was abandoning restrictions on the dissemination of truthful information about off-label uses of pharmaceuticals and medical devices. The FDA's promise came after six years of battling with the Washington Legal Foundation (in *WLF v. Henney*) over whether off-label information from peer-reviewed journals and textbooks was speech or conduct. While the WLF's battle with the FDA may have been mostly won (the group still monitors the FDA's enforcement actions for free speech infringement), the trend toward false claims lawsuits is raising alarm for some in the WLF's Washington offices.

"If these suits are allowed to go forward, they certainly will result in truthful speech being suppressed, and that is worrisome," says Richard Samp, lead counsel at the WLF.

In 1996, David Franklin, a physician employed by Parke-Davis (now a part of New York-based Pfizer Inc.), filed a lawsuit alleging that Parke-Davis illegally marketed Neurontin® (gabapentin), causing physicians to prescribe it for uses not approved by the FDA. The lawsuit, which is still in litigation, also alleges that Medicaid programs have made millions of dollars of fraudulent payments for these off-label uses.

The case against Parke-Davis is particularly distressing to some because some of the judgments that have already been issued point to the possibility that pharmaceutical companies may need to avoid any and all off-label speech if they don't want to be sued in the future.

"The reason [the Parke-Davis case] is troubling is not that the suit was brought, but rather one or two of the preliminary decisions that have been issued by the federal district judge hearing the case," says Samp. "He has issued opinions that seem to suggest that there is something inherently false about some of the manufacturer action in saying things that encourage off-label use of drugs. Who knows how far that theory will get, but to the extent that there are judges out there who seem to believe that, that is certainly worrisome."

Continues Samp: "His basic claim seems to be that it is somehow a false claim for somebody to seek Medicare reimbursement for off-label use of a drug, even though the off-label use is one that is relatively well-accepted and doctors as a matter of course would prescribe a drug for that particular use."

While a decision by a federal district court judge alone doesn't create any binding authority, once a case gets to the appellate level the decisions have substantially more weight. "It's only when the cases get up to the appellate level and an appellate decision comes down that the decisions can be extremely troublesome," says Samp. "If the case ever reaches the court of appeals, one thing we would do would be to file a friend of the court brief with the appeals court trying to demonstrate why the district court decision was wrong-headed."

Because the financial incentive is so great in *qui tam* cases, a large judgment in one could encourage other attorneys to file suits regardless of merit. "It is certainly not my claim that a company has a right to do all sorts of off-label promotions, but [Franklin is] going about it the wrong way," says Samp. "The correct way to do it is, if you think a company is doing something improper that FDA should know about, you report it to FDA and FDA can bring an enforcement action, but if you're a plaintiff's lawyer that doesn't do you a lot of good, because you can't cash in by getting a lot of fees and a lawsuit the way you can if you do it under the False Claims Act."

– G. Hradecky

it for uses that the FDA had not approved. Still in litigation, the lawsuit also alleges that Medicaid programs have been wrongfully paying for these off-label uses, resulting in millions of dollars of fraudulent payments.

These are not likely to be the only cases brought against the industry for inappropriate off-label marketing.

When a pharmaceutical manufacturer induces physicians to prescribe drugs for off-label uses that are not substantiated by objective medical review, the False Claims Act is triggered if payment has been made by a government program, because claims for such off-label uses are only reimbursable under certain 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 prescriptions 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 four major drug compendia. Under the Federal False Claims Act, penalties are severe – three times the amount of damages (for fraudulent billing), plus fines of $5,000 to $11,000 for each false claim submitted, with 15% to 30% of the amount recovered going to the whistle-blower.

What this means for reps

In none of the cases that have been publicized so far have sales representatives been specifically targeted, and it is unlikely that they will be, based solely on past conduct of off-label marketing. But now that the government has made it clear that off-label promotion (based on misrepresentations) will not be tolerated, and responsible companies have heeded such warnings, a sales representative who continues to do so will be out on his or her own.

The past conduct of a small portion of pharmaceutical companies has changed the industry as we know it. But there is a silver lining – sales representatives whose companies have always abided by FDA rules and regulations will now have a more level playing field on which to market and sell their drugs. Physicians will make medical decisions to treat patients' illnesses based

The history of *qui tam* law

■ *Qui tam* actions have been used as far back as the 13th century in England, where they were popular as a way for private citizens to gain access to royal courts. In the United States, *qui tam* actions have been around since 1776, although they were seldom used until 1986. In 1863, during the Civil War, congressional hearings disclosed widespread instances of military contractor fraud that included defective products, substitution of inferior material and illegal price-gouging of the Union Army. At the urging of Abraham Lincoln, Congress enacted the Civil False Claims Act, including the *qui tam* provision, as a weapon to fight procurement fraud. This law has also been known as the Lincoln Law and the Informer's Act.

The False Claims Act, as enacted in 1863, was designed to entice whistle-blowers to come forward by offering them a share of the money recovered. Even though this act was enacted to combat military contractor fraud, it was applicable to all government contractors, federal programs and any other instances involving the use of federal revenue.

Between 1863 and 1986, very few people took advantage of the law, primarily because of many difficult obstacles built into the act that whistle-blowers had to overcome in order to be successful and many judicial rulings making it difficult to enforce the law. Also, a problem for anyone who desired to file a lawsuit under the 1863 act was the provision that all relators (which is what *qui tam* plaintiffs are called) had to bear all the costs of the lawsuit and the government could take over the suit at any time, at its discretion. However, if a relator was successful, the 1863 act allowed him or her to recover a maximum of 50% of any amount recovered.

In 1943, Congress amended the act so that if the government had prior knowledge of the allegations, the relator had no jurisdiction over the lawsuit, even if the relator had independent and direct knowledge of the allegations. Also, the 1943 amendments reduced the award to the relator from 50% to a maximum of 25% if the government did not take over the case, and a maximum of 10% if it did.

In 1986, again as a result of serious concern over rampant procurement fraud, inadequate efforts of regular law enforcement to control the fraud, and the obstacles making it difficult for whistle-blowers to bring *qui tam* actions, Congress passed amendments to the act increasing the whistle-blower's share of the recovery to a maximum of 30%, increasing the powers of relators in bringing *qui tam* lawsuits, and increasing the damages and penalties that can be imposed on defendants. Important to relators, the 1986 amendment provides that even if the government joins the lawsuit and has primary responsibility for prosecuting the action, the relator shall have the right to continue as a party to the action. Also, prior government knowledge of the allegations does not automatically prevent a relator from filing a *qui tam* action.

As a result of the 1986 amendments, *qui tam* actions have increased dramatically and have been the most effective and successful means of combating procurement and program fraud. Since 1986, *qui tam* recoveries have exceeded $1 billion, with most of the successes involving fraud in defense and healthcare programs.

Source: www.quitam.com, *The Bauman & Rasor Group Inc.*

upon sound science, not the mercenary, off-label marketing of drugs for uses supported by little or no legitimate scientific data.

Expect the disadvantageous trend in Federal False Claims Act litigation for pharmaceutical companies to continue – and to get worse before it gets better – as the previous misleading marketing activities of more pharmaceutical companies are exposed. Expect sales representatives to be largely untouched for this conduct alone. But be careful – all of the rules, regulations and safeguards regarding off-label marketing are now in place, including a zero-tolerance policy from all responsible pharmaceutical companies. Sales representatives who now decide to cross the line for themselves or for a manager may find themselves standing alone. PR

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