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Limiting Potential Liability for Off Label Drug Marketing Through Risk and Claims Management, *Contributed by Jonathan M. Cohen and Jenna A. Hudson, Gilbert LLP*

As plaintiffs' law firms and state and federal governments continue to scrutinize "off-label marketing," drug manufacturers may become increasingly susceptible to a wide range of potential liability. Since May 2004, the country's major drug manufacturers reportedly have paid billions of dollars in fines and penalties for allegedly marketing drugs for off-label use.1 Government law suits alone have cost manufacturers at least $1 billion in recent years.2

Off-label marketing is when drug companies advertise or promote their products for uses or in dosages other than those approved by the U.S. Food and Drug Administration (FDA). Although doctors often prescribe medications for off-label purposes and the federal government and some states even require health insurance plans to cover off-label prescriptions under some circumstances, the government and some plaintiffs have alleged that a company violates the law if it markets drugs for off-label use.

Risks Associated with Violating Off-Label Marketing Rules

Despite the restrictions on off-label marketing, off-label drug sales have been estimated to comprise as much as 20 percent of the market annually,3 and some drug manufacturers' profits are closely linked to the volume of off-label prescriptions. Manufacturers take a sizable risk if they step too close to the line of improper off-label marketing. The Department of Justice and several states have filed civil suits under the False Claims Act, asserting that drug manufacturers have deceptively marketed their drugs for unapproved uses and put citizens at risk for side effects not listed on the drugs' packaging. Private citizens also have filed personal injury claims for side effects from off-label drug usage. In addition to damage awards, these personal injury claims may lead to recall costs, just as manufacturers have borne recall costs following previous on-label personal injury claims. Health insurers also have filed civil suits against manufacturers, claiming that the insurance companies have been forced to overpay both because off-label prescriptions themselves cost more than the approved alternatives and also because patients may incur additional medical costs due to side effects not listed on drug labeling.

Manufacturers even have been convicted of federal and state criminal misbranding and marketing charges. Although these convictions have led only to fines, the government may have the power to penalize manufacturers by declaring their drugs ineligible for reimbursement under government health care programs. The scope of damages also can affect a company's stock price, which in turn can provoke securities actions and directors and officers suits.

Scope of Potential Liability

One prominent example of the potential scope of liability that manufacturers face from off-labeling marketing is Eli Lilly & Co. and its drug Zyprexa. The FDA has only approved Zyprexa for schizophrenia and bipolar disorder in adults, but the drug has been prescribed—and allegedly marketed—for elderly patients with Alzheimer's Disease and other forms of dementia, as well as for children and teenagers with disruptive behavioral disorders.4 Plaintiffs—including health insurers—have alleged that Eli Lilly should be liable for deceptive and fraudulent marketing related to Zyprexa.5 Off-label marketing suits also have alleged that Zyprexa causes several non-labeled side effects, including diabetes.6 As of February 2010, Eli Lilly had paid nearly $1.2 billion dollars to settle over 30,000 private lawsuits, $1.415 billion in government fines and penalties under the False Claims Act, and $18.5 million in state penalties.7

Although not all manufacturers are as large as Eli Lilly, even small manufacturers are potentially subject to liability. The increase in litigation against drug manufacturers for off-label marketing is likely to continue in coming years. Drug manufacturers can save expense in the long run, however, by taking steps to prepare for any off-label claims before these claims arise, and, if claims do arise, companies looking to their insurance program for protection must do so armed with a firm understanding of their insurance policies.

Managing the Risk of Off-Label Drugs

Many manufacturers may have existing insurance that will cover some potential liabilities for off-label marketing, but other claims may fall outside of a company's existing coverage portfolio. Because of the variety of insurance policies that may be available and the range of potential claims related to off-label marketing, it is critical for companies to understand how their multiple insurance policies work together to protect them against losses due to off-label marketing.

Most companies already have Commercial General Liability (CGL) policies, which likely offer some protection from off-label marketing suits. CGL policies provide broad coverage against third-party claims alleging that damages resulted from a company's products or corporate behavior, including bodily injury, property damage, and potentially mislabeling and marketing. CGL policies likely will not, however, cover all types of claims and may provide coverage for only limited types of economic harm.

Drug manufacturers also may find existing coverage through their directors and officers (D&O) liability policies. D&O policies typically insure a company and its individual directors and officers against liabilities resulting from "wrongful acts" allegedly committed by the directors and officers. D&O policies may be implicated by both direct suits for alleged off-label marketing and shareholder derivative suits based on the liabilities to which off-label marketing may subject the corporation. D&O policies also may provide some coverage for economic harms that CGL policies may exclude. For example, some D&O policies cover losses due to misrepresentations in the sale of a company's own products, a category that insurers argue that CGL policies exclude.

In their risk management review, companies should look not only to whether they have applicable CGL and D&O policies, but also to the extent to which those policies may limit or exclude coverage for off-label marketing claims. For instance, insurers might assert that off-label marketing is intentional misconduct, and thus falls outside of coverage. But, often policyholders are unaware or do not intend their statements to constitute marketing for an off-label purpose, and so the intentional misconduct provisions might not apply. Companies should be aware that policies from past years may cover later-asserted claims. Companies should therefore maintain copies of all of their insurance policies until well after policy periods have expired.

What to Do When a Claim Arises

In addition to engaging in risk management before claims arise, drug manufacturers must be prepared to manage claims that ultimately are filed against them. Once a claim arises, a company's early actions can significantly affect the extent to which the company can recover under its insurance policies. Drug manufacturers therefore should keep a few points in mind from the moment they become aware of an off-label marketing suit in order to maximize their potential insurance recovery.

Early Decisions Matter

Most insurance policies contain an array of procedural requirements that can serve as preconditions to coverage, so it is important that manufacturers are aware of the requirements of every insurance policy that may be implicated by a claim against them. This is particularly important when claims potentially trigger more than one insurance policy because different policies may contain]overlapping and possibly contradictory requirements.

One of the most significant early decisions companies must make is whether and when to provide their insurers with notice of claims against them. Companies must again look to the requirements of every policy that may apply. Prompt notice may be particularly significant under D&O policies, where a claim might be covered only if it is made and reported to the insurer during a specified time.

Other policy terms may apply when a manufacturer plans to look to its insurer for defense costs. Insurers often argue that their policies give them the power to participate directly in the defense and settlement of third-party claims, and insurers may argue they have a right to limit the insured's choice of defense counsel. Such policies also may require the policyholder to cooperate with the insurer even where the insurer has no right to control the defense. Policyholders should address the insurers' role in the defense early to ensure that, if necessary, the policyholder and its insurers agree on defense counsel. In some cases the interests of the policyholder and the insurer may diverge, such as where the insurer is defending under a reservation of rights or where the insurer and insured disagree about whether to accept settlement demands. In those cases the insured may be entitled to have the insurer pay for independent counsel. Focusing early on these issues may help to ensure maximum protection against off-label marketing claims.

Coordinate Defense and Insurance Strategies

As soon as an off-label marketing claim of any type is filed against a manufacturer, the manufacturer should immediately consider how its insurance and defense strategies interact. Companies must fight the temptation to focus first on their defense and later on insurance coverage. The way in which a company describes a claim in its defensive pleadings can significantly affect how much coverage is available. Conversely, policy provisions can affect how a company opts to defend underlying claims. It is therefore critical that manufacturers act quickly to coordinate an effective insurance strategy with their defense and other business goals.

Do Not Be Discouraged By Insurers' Defenses to Coverage

Although it is important that drug manufacturers appropriately involve their insurers where necessary, drug manufacturers also should be mindful that their insurers frequently will be looking for ways to minimize or evade coverage obligations. Policyholders should not, however, be daunted by these attempts because policyholders often have strong arguments to counter their insurers' legal positions.

One common argument insurers make to avoid coverage is that a policy does not unambiguously cover underlying claims. This argument alone is rarely successful, however, because most states have clear case law holding that ambiguities in an insurance policy must be construed in favor of coverage. Insurers also may argue that the policy language excludes coverage. For example, insurers might argue that a D&O policy's language excluding coverage for fraud applies to claims that a drug manufacturer marketed its products for off-label use. Here, too, most companies and their executives have powerful counterarguments. First, most states place a high burden on insurers to prove that a policy excludes coverage and require courts to construe such exclusions narrowly in favor of coverage. Second, exclusions for fraud generally apply only if, in a final judgment, the court in the underlying case (not the court dealing with separate coverage litigation between the insurer and insured) found that fraud occurred. As a result, insurers must pay to defend and, in many cases settle, claims that the policy might otherwise exclude.

If only a portion of the claims asserted against a drug manufacturer are arguably covered by a policy, the insurer also may argue that it need only pay for the covered portion of defense costs. Under most states' laws, however, an insurer has an obligation to provide a complete defense if any portion of a claim is covered. At most, an insurer might be able to apportion defense obligations if it can prove that certain defense costs are attributable only to allegations that are not covered under the policy. When a claim is arguably covered by more than one policy, the insurance companies whose policies are implicated may similarly argue that defense and indemnity obligations fall on other insurers but not themselves. Here, again, policyholders should recognize that they have arguments in their favor. Some courts have recognized that insurers cannot in good faith withhold coverage solely because they dispute whether they, or another insurer, must cover the claim. That result is particularly compelling when the coverage at issue implicates the insurer's duty to defend the policyholder and to pay the policyholder's defense costs.

Off-label uses of prescription drugs present companies with an opportunity to increase their profits, but such uses also carry with them the risk of legal liability. By being mindful of potential liabilities and engaging in risk and claims management, drug manufacturers can protect

themselves from the potentially devastating economic consequences of off-label marketing claims.

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