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Physician Off-Label Marketing

As physician reimbursement decreases, physicians are increasingly looking to other means to replace lost income and control more of the healthcare dollar. From television infomercials to highway billboards, physicians are entering the world of marketing to build and sustain a medical practice. Part of the marketing by physicians involves describing the nature and benefits of off-label use of medical devices and drugs. But physicians need to be wary of the many restrictions surrounding off-label marketing. While these restrictions generally apply to manufacturers, it is important for physicians to understand the extent of these restrictions and how they may apply to them. The extent to which the prohibition against off-label marketing applies to physicians is ambiguous. This article explores the ways in which physicians may engage in off-label marketing of drugs and devices, while noting the restrictions that may apply to such practices.

FDA Regulations Governing Manufacturers

Regulation of off-label marketing of drugs and medical devices is focused on governing the actions and behavior of those in the manufacturing process. The Food and Drug Administration's (FDA's) enforcement actions are premised on the theory that a drug or device is illegally "misbranded" under the federal Food, Drug, and Cosmetic Act[1] (FDCA) if it is marketed for a use inconsistent with the direction on its label.[2] Under 21 C.F.R. §§ 201.128 and 801.4, the "intended use" (or "on-label" use) is determined by the intent of those who are legally responsible for the labeling of the drug or device. Consequently, enforcement actions against off-label marketing have focused on manufacturers—those who are engaged in the "labeling" of drugs and devices.

Federal investigations are conducted jointly by the FDA and the Department of Justice (DOJ). The basis for the investigations and prosecutions is that off-label marketing by manufacturers causes the use of unapproved prescription drugs and medical devices, and therefore claims for federal reimbursement for off-label use are "false" under the federal False Claims Act[3] (FCA). The FCA provides for treble damages and an $11,000 penalty per claim. Additionally, the government can exclude individuals or entities from participation in federal government programs. Individuals and entities also are subject to criminal prosecution.

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121 U.S.C. § 301, *et seq*.

2*See* 21 C.F.R. §§ 201.128, 801.4; 62 Fed. Reg. 64074, 64075 (Dec. 3, 1997). For a discussion of enforcement actions against off-label marketing, *see* John N. Joseph, David Deaton, Houman Ehsan, and Mark A. Bonano, *Enforcement Related to Off-Label Marketing and Use of Drugs and Devices: Where Have We Been and Where Are We Going?*, J. Health & Life Sci. L., January 2009 at 73.

331 U.S.C. §§ 3729 *et seq*

Some enforcement activity involves fraudulent marketing of drugs or devices that have not been vetted by the FDA. For example, in 2007, the Purdue Frederick Company, as well as some of its top executives, pleaded guilty to charges of misbranding with intent to mislead under provisions of the FDCA. The government alleged company executives made false claims that OxyContin was less addictive, less subject to abuse, and less likely to cause withdrawal symptoms than other plain relievers. The FDA had approved none of these statements.

Even with its focus on manufacturers, the FDA's regulatory structure for off-label marketing is in a state of flux because of legal challenges over the government's ability to regulate commercial speech. Confusion over the regulations of off-label marketing became more pronounced with the U.S. Supreme Court decision last year in *Sorrel v. IMS Health*.[4] In *Sorrel*, the U.S. Supreme Court ruled that when a law restricts truthful, non-misleading commercial speech on the basis of content and the identity of the speaker, the law must be subject to heightened judicial scrutiny. The Court consequently struck down a Vermont statute that restricted pharmaceutical companies' access to information related to patients' prescription drug usage.

Application to Physicians

As physicians seek to promote their practices that may involve the off-label use of drugs or medical devices, they are confronted with the array of complex and confusing regulations discussed above. Although the FDA regulates the promotion of drugs and devices by manufacturers, as a matter of policy, the agency generally does not interfere with the practice of medicine. Once a drug or device has been cleared for sale for one purpose, physicians may prescribe it for any other purpose that is safe and effective in their professional judgment.

Unfortunately, aside from the FDA's published policy that it will not intrude upon a physician's medical judgment, there is little regulatory or other legal guidance for healthcare practitioners who want to market their practices that involve the off-label use of drugs or devices. It soon becomes clear that there is no basis to prohibit physicians from engaging in off-label marketing since the FDA's enforcement actions are premised on the FDCA's prohibitions against manufacturers. That does not mean, however, that physicians may promote or market off-label uses of drugs or devices without any restrictions.

Anti-Kickback Issues

The biggest concern that a physician faces when engaging in off-label marketing is exposure from the Anti-Kickback Statute (AKS).[5] Under the AKS, it is a felony to solicit, offer, or receive any remuneration in return for referring an individual for the furnishing or arranging for the furnishing of any item or service or for the purchasing,

4*Sorrell v. IMS Health, Inc*., 131 S. Ct. 2653 (2011). For a discussion of the impact of *Sorrell, see* John N. Joseph, Matthew T. Newcomer, David Deaton, David Leviss, and Caitlin Bair, *Is* Sorrell *the Death Knell for FDA's Off-Label Marketing Restrictions?*, J. Health & Life Sci. L., February 2012 at 1.
542 U.S.C. § 1320a-7(b).

leasing, ordering, or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal healthcare program. In the past, many promotional practices associated with off-label marketing included payments to physicians in amounts well above fair market value for the services the physicians performed. Many of these arrangements involved sham consulting fees where physicians did little or no work in exchange for compensation. Criminal liability under the AKS is possible, as well as civil penalties up to $500,000 for entities and $250,000 for individuals, restitution of government monies paid, possible imposition of a corporate integrity agreement, and imposition of civil monetary penalties. Individuals may be sentenced up to five years in jail for each healthcare-related kickback.

Thus, before engaging in any off-label marketing, the physician should carefully review any arrangements he or she has with a manufacturer to make sure the arrangement does not violate the AKS.

Conspiracy Claims

Even if the physician's arrangement with a manufacturer complies with the AKS, there are other issues that should be examined before a physician engages in off-label marketing. Though FDA regulations regarding off-label marketing apply uniquely to manufacturers, the government has taken enforcement action against others who participate in off-label marketing programs. In 2006, authorities arrested Dr. Peter Gleason, a psychiatrist, who was paid tens of thousands of dollars to give seminars to promote the off-label use of Xyrem, also know as gamma-hydroxoxybutyrate, or GHB. Dr. Gleason was charged with conspiracy charges related to the off-label marketing. FDA approved Xyrem for use only in treating cataplexy, a condition associated with narcolepsy. It was alleged, however, that Dr. Gleason was paid to make misleading statements to audiences regarding the drug, including saying that it was safe to prescribe to children and the elderly, minimizing the potential side effects and dangers of overdose, and claiming that it could treat fatigue, insomnia, chronic pain, weight loss, depression and bi-polar disorders.[6]

AMA Guidance

Physicians also should explore and study the possible risks to a patient of off-label use of a drug or medical device. Physicians often are left to rely on ethical guidance to determine when it is acceptable to subject a patient to a potentially unknown/unsubstantiated risk for a potentially unknown/unsubstantiated benefit. For example, the American Medical Association (AMA) has adopted a policy that provides in part:

> *A physician may lawfully use an FDA-approved drug product or medical device for an unlabeled indication when such use is based upon sound scientific evidence and sound medical opinion . . . .*[7]

6Dr. Gleason committed suicide in February 2011. His co-conspirator has contested the charges and that case is on appeal. *United States v. Caronia*, Case No. 09-5006-CR (2d Cir.).

The policy also encourages the use of peer-reviewed literature for determining the medical acceptability of unlabeled uses.

Payment Issues

The AMA also has adopted a policy on payment for items that are not used in accordance with FDA labeling requirements. That policy provides in part:

When the prescription of a drug or use of a device represents safe and effective therapy, third party payors, including Medicare, should consider the intervention as reasonable and necessary medical care, irrespective of labeling, [and] should fulfill their obligation to their beneficiaries by covering such therapy.[8]

Physicians must be careful in how they bill for off-label devices and drugs. In most instances, neither Medicare nor Medicaid will cover such services. Private payors may differ in their payment policies, with some payors likely to claim that off-label uses of drugs and devices are "investigational" and thus not covered.

IRB Issues

Good medical practice and the best interests of the patient require that physicians use legally available devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a marketed product in this manner when the intent is the "practice of medicine" does not require the submission of an Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB). However, the institution at which the product will be used may, under its own authority, require IRB review or other institutional oversight.[9]

Professional Liability Issues

Physicians face exposure from professional liability claims if there is a bad outcome connected with a prescribed off-label use of a drug or medical device. For example, if a patient experiences an adverse outcome from the off-label use, the physician may have difficulty establishing that the treatment was within the standard of care. However, physicians generally can point to good-faith reliance on peer-reviewed literature and FDA and AMA policies regarding off-label use as the basis for their actions.

7AMA Policy, H-120.988: Patient Access to Treatments Prescribed by Their Physicians, *available at* www.ama-assn.org

8AMA Policy, H-120.988: Patient Access to Treatments Prescribed by Their Physicians, *available at* www.ama-assn.org.

9FDA Guidance, *available at* www.fda.gov/oc/ohrt/irbs/offlabel.html

Conclusion

Because of the myriad of issues that physicians face when they engage in off-label marketing, they should follow the criteria outlined below to stay clear of legal and regulatory risks:

- The physician should ensure that he or she is not an agent of a manufacturer for purposes of off-label marketing, exposing him or herself to conspiracy claims.

- The physician should examine all of his or her financial arrangements with manufacturers to ensure they are for fair market value for services and cannot be construed as payments for referrals.

- The physician should ensure there is sound scientific evidence supporting the off-label use of the device or drug in treating the patient. This should include peer-reviewed literature for determining the medical acceptability of unlabeled uses.

- The physician should ensure that any statements he or she makes are truthful and can be verified.

- The physician should disclose to the patient that the treatment involves an off-label use of a device or drug.

- The physician should investigate whether payors will pay for the services, and be careful that he or she properly and accurately bills for the services provided. The physician should not try to manipulate coding of the procedure to ensure payment by payors that do not cover the treatment.

- The physician should ensure that the off-label use of the drug or device is not "investigational" that requires the oversight of an IRB. If the physician's intent is the "practice of medicine," no IRB should be necessary.

- The physician should maintain records of the drug or device's off-label use and effects in patients.