When is a Kickback a Kickback?

Navigating the perilous road of marketing incentives in the pharmaceutical industry

By Ronald J. Friedman

In January 2010, the federal government filed a civil action under the False Claims Act accusing drug manufacturer Johnson & Johnson ("J&J") of orchestrating a massive unlawful pharmaceutical monetary kickback scheme. This action by the U.S. Department of Justice serves as a reminder to all in the healthcare industry, be they pharmaceutical companies, pharmacies, medical providers or healthcare facilities, to review and examine their financial arrangements with others in order to ensure they do not contain unlawful remuneration agreements, and to be vigilant in their efforts to avoid market conduct that may be viewed by others — especially the government — as involving an unlawful kickback.

Johnson & Johnson Under Fire

The J&J case was filed as a civil action under the federal False Claim Act (Title 31 U.S.C. Sections 3729-33), seeking restitution, treble damages and civil penalties. If found liable, the action will cost J&J many millions of dollars. Omnicare, Inc., the alleged recipient of the kickback payments, has already settled with the government, agreeing to pay $98 million for participating in multiple unlawful kickback schemes, including the scheme with J&J. Omnicare is a well-established provider of pharmacy services to nursing homes and other long-term care facilities. The unlawful kickback schemes in which Omnicare is alleged to have engaged include Omnicare's receipt of kickbacks from multiple drug manufacturers, including J&J, and unlawful kickback payments from Omnicare to multiple nursing homes Omnicare was servicing. The payments to the nursing

homes were for “consultant pharmacist services” provided by Omnicare at rates below Omnicare’s cost and below fair market value, in order to induce the nursing homes to refer their patients to Omnicare for pharmacy services. In addition, Omnicare is alleged to have offered inflated prices to acquire business assets of the nursing homes as a disguised kickback for the nursing home’s utilization of Omnicare services. Civil complaints against some of these nursing homes have already been resolved with the homes agreeing to pay the government $14 million.

Criminal Unlawful Kickback Statute

While the actions against Omnicare and J&J were filed as civil actions, their liability is predicated upon alleged violation of the federal anti-kickback statute (42 U.S.C. Section 1320a-7b(b)), a criminal felony punishable by up to five years imprisonment and a $25,000 fine. While the government has at this juncture chosen to pursue the matter civilly, it should be recognized that the decision to file a matter civilly or criminally is often a matter of prosecutorial discretion and a person or business entity faces dual risks of both a civil action and criminal prosecution designed to deter such conduct. Indeed, there have been numerous criminal prosecutions in the healthcare industry for making or receiving kickbacks. Such prosecutions can be expected to increase in the future due to the healthcare reform bill (Patient and Affordable Care Act), enacted in March 2010, which lessens the burden on prosecutors by providing that the government is no longer required to prove that a defendant had knowledge of the law or specific intent to violate the anti-kickback statute.

The criminal anti-kickback statute is written in broad terms, and punishes equally those who offer to pay a kickback as well as the recipients. It also criminalizes the conduct of anyone who aids or facilitates the commission of the kickback scheme. The criminal statute makes it a crime to pay, or offer to pay, any remuneration — direct or indirect, overtly or covertly, in cash or in kind — to another person or entity in order to “induce” that person or entity to refer persons for services to be rendered under a federal healthcare program, such as Medicaid and Medicare, or to “induce” such person or entity to purchase, or to recommend the purchase of, a service or product funded by a federal healthcare program. In addition to the criminal fine and imprisonment, culpable individuals and entities are subject to civil

fines of $50,000 per violation and three times the amount of unlawful remuneration paid. Offending individuals and businesses also face exclusion from further participation in federal healthcare programs.

Be Careful What You Write

In the J&J case, the government alleges J&J violated the kickback statute numerous times by entering into written agreements with Omnicare through which J&J agreed to pay Omnicare quarterly “rebates” in return for Omnicare recommending, promoting and selling various J&J drugs to nursing homes, including the anti-psychotic drug Risperdal and antibiotic Levaquin. In making its allegations, the government relies upon written documents obtained from J&J and Omnicare, including numerous e-mails written by company insiders discussing the pecuniary motives for the financial arrangements between J&J and its customer, Omnicare. While the written agreements utilized marketing-incentive language, characterizing the payments as payments for Omnicare’s “Active Intervention Program” and “Appropriate Utilization Program,” the government contends that these were merely disguised words for what were ordinary kickbacks in return for Omnicare recommending and selling J&J products. In addition, the complaint alleges J&J violated the kickback statute by making payments to Omnicare allegedly for the purchase of Omnicare “data” consisting of the names of physicians who could prescribe J&J drugs but were, in essence, rebates for recommending its drugs. Often times, according to the complaint, J&J never bothered to collect the data or was already receiving it for free. Finally, the government alleges that J&J paid disguised kickbacks through “grants,” “education funding” and “meeting sponsorship fees” to Omnicare as a subterfuge for rebates with the purpose of inducing Omnicare to recommend J&J drugs, which ended up costing the government millions of dollars in claims upon federal programs.

An Endless Variety of Kickbacks

Conduct that has been deemed to violate the anti-kickback statute includes consulting fee agreements between pharmaceutical companies and physician groups designed to induce medical providers to prescribe the

company's drugs, providing free drugs in order to induce providers to prescribe drugs or encourage the recipient providers to bill Medicaid for the samples or even to sell the samples, and providing weekend retreats, conference attendance fees, lavish meals, free rental space and other benefits in order to induce prescribers to prescribe drugs. Further, these cases reflect a willingness by the government to examine the internal documents of a company and its customers in order to see through any alleged justification for a financial arrangement and conclude that the true purpose of the arrangement is the unlawful remuneration for referring, recommending or selling drugs and services. Such investigations can be expected to continue as government and policy-makers pay close attention to the profits being earned by drug companies, pharmacies, medical providers, and healthcare facilities, and the concomitant costs being incurred by the Medicare and Medicaid programs. While there are certain "safe harbor" provisions for remunerative arrangements, set forth in the anti-kickback statute (42 U.S.C. Section 1320a-7b(b)(3)) and by federal regulation (42 C.F.R Part 1001), that offer protection for certain types of financial arrangements, these "safe harbor" exceptions are narrowly circumscribed and must be strictly adhered to in order to avoid having the arrangement considered a violation of the anti-kickback statute.

Compliance Instruction

In 2003, the Office of Inspector General ("OIG") of the U.S. Department of Health and Human Services released its Compliance Program Guidance for Pharmaceutical Manufacturers, designed to assist pharmaceutical companies in avoiding financial arrangements amounting to kickbacks. The Guidance directs that nothing of value should be offered or provided by a pharmaceutical company under conditions that would tend to influence a provider's prescribing practices. This Guidance is reflective of the view that the only proper consideration by a provider in deciding whether to prescribe a drug should be the effective care of the patient, not any financial consideration, direct or indirect, the provider receives as a result of prescribing the product.

The OIG has passed similar Compliance Program Guidance for Nursing Facilities and Physicians, and American Medical Association guidelines specifically counsel healthcare professionals to reject gifts and benefits

from drug manufacturers and care facilities other than those of “nominal value and those with direct educational or patient benefit.” Plainly, the concern is that the judgment or prescriptive pattern of the medical care professional will be impacted by the receipt of benefits, and the federal government will be left paying the bill for this impact.

Assessing Marketplace Arrangements

While it is difficult to generalize or comment upon a financial arrangement without direct reference to it, those arrangements apt to draw the most scrutiny from regulatory authorities are any business arrangements between persons and entities in the healthcare marketplace that have the tendency to skew or weight prescribing decisions made by practitioners with no corresponding benefit to patient care, as well as those arrangements that appear to be increasing the costs of federal healthcare benefits programs due to the volume of drugs or services ordered. This is when the collective antennae of regulatory authorities tend to perk up, and one needs to ensure that such arrangements do not violate the statute or that they fit within a recognized “safe harbor” exception. For example, any rebates or price discounts by drug manufacturers need to fit with the “safe harbor” for group purchasing organizations, managed care and risk-sharing arrangements, or some other legally authorized mechanism.

Moreover, it is not always the drug manufacturer or pharmaceutical company that is promoting the unlawful kickback. There are repeated instances where it has been the physicians and physician groups that were leading the way to extract from the pharmaceutical companies and medical device makers remuneration for promoting and prescribing their products. Nevertheless, there has been ample misconduct on the part of pharmaceutical companies involving kickbacks within the last few years.

Pharmaceutical Company Misconduct

- In April 2007, Pharmacia & Upjohn Company, Inc. (acquired by Pfizer in 2003) pleaded guilty to violating the anti-kickback statute and paid more than $19 million to the government for paying a distribution

company an excess payment to recommend sale of its human growth hormone drug, Gentropin.

- In February 2008, Merck and Co. paid more than $399 million to the government to resolve allegations that it violated the anti-kickback statute by making payments to physicians to recommend its drugs, disguising such payments as “training,” “consultation” and “market research” fees.
- In September 2009, Biovail Pharmaceuticals pleaded guilty to kickback charges and was fined $22 million for paying medical providers to prescribe its drug, Cardizem.
- In September 2009, Pfizer paid more than $48 million to the government to settle a variety of claims, including allegations of illegal kickbacks to providers to purchase its various drugs.
- And in March 2010, Alpharma paid more than $42 million to settle kickback allegations involving inducements paid to physicians to prescribe its morphine-based drug Kadian.

Multiple complaints against additional pharmaceutical companies alleging unlawful kickback schemes are currently pending.

Avoiding Trouble

As the federal government continues to search for ways to fund a national insurance program and to root out fraud and abuse in existing health benefit programs, one can expect the pharmaceutical industry will remain in the cross-hairs of regulatory authorities. Whistleblowers have achieved great success, earning millions of dollars for exposing fraud, abuse and criminal conduct by pharmaceutical companies, their executives, pharmacies, care facilities and providers. Settlements have grabbed major headlines due to their large figures, attracting even more focus upon the industry. Pressure can be expected to mount for the public accounting of all relationships between pharmaceutical companies, pharmacies, providers and care facilities under the belief that casting sunlight on such relationships will further serve to expose and deter misconduct by all involved, including the physician with the easily-induced prescription pen.

Given the prevailing winds, pharmaceutical companies and those with

whom they interact — including pharmacists, providers and healthcare facilities — need to be especially vigilant to inspect and review their financial arrangements with others and examine those relationships with the same careful skepticism as will the government and other regulatory authorities should those practices be challenged as constituting unlawful kickbacks. No financial arrangement is worth paying a fine of millions of dollars, going to prison or risking the reputation of one's company. Moreover, the question one needs to always ask is a simple one: Are one's arrangements with vendors and customers "clean," or do they contain veiled remuneration and inducements, either in cash or in kind, for referrals or for the recommendation of medical services or products covered by a federal healthcare program? If inducement is present, careful examination must be made to ensure such arrangement falls within a "safe harbor" established by statute and federal regulation.

In the area of research, for example the OIG has stated a preference for having the educational and research grant components of the drug manufacturing firm segregated from the marketing branches, that any research for which there was compensation be research that was truly conducted, that any payment given constitute reasonable compensation for the research, and that such research not simply be a vehicle intended to influence the marketing decisions of the pharmacy, care facility or prescriber receiving the "grant" payment.

Although certain kickback schemes are easy to understand, others are more complex and involve difficult questions as to whether a business has unlawfully crossed the line or is engaging in fair actions in a highly competitive marketplace. Often times, the answer to this question turns upon an assessment of the subjective and objective reasons for acting and the impact and intended impact of the actors. The answer to these questions may challenge traditional ways of doing business in America. Sometimes it may be the operators of the kickback schemes themselves who are most surprised to find that their conduct is deemed to be in violation of law. For this reason, it is useful to proceed cautiously and to have counsel — skilled in the review of such documents and arrangements and highly conversant in the application of the "safe harbors" — examine such relationships to ensure compliance with the law and to avoid your company being the next one in an unintended, and perhaps unforeseen, spotlight.

Money spent paying judgments depletes funds that drug companies need to effectively compete, conduct research, and innovate. It keeps pharmaceutical companies and pharmacies, as well as medical providers and healthcare facilities, from focusing on the true mission at hand: The cost-effective practice of good medicine and providing drugs needed in the treatment of medical illness and disease. It is through a sober look at all of one's financial relationships with vendors that unwanted trouble can be avoided.

This article is presented for informational purposes only and is not intended to constitute legal advice.

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