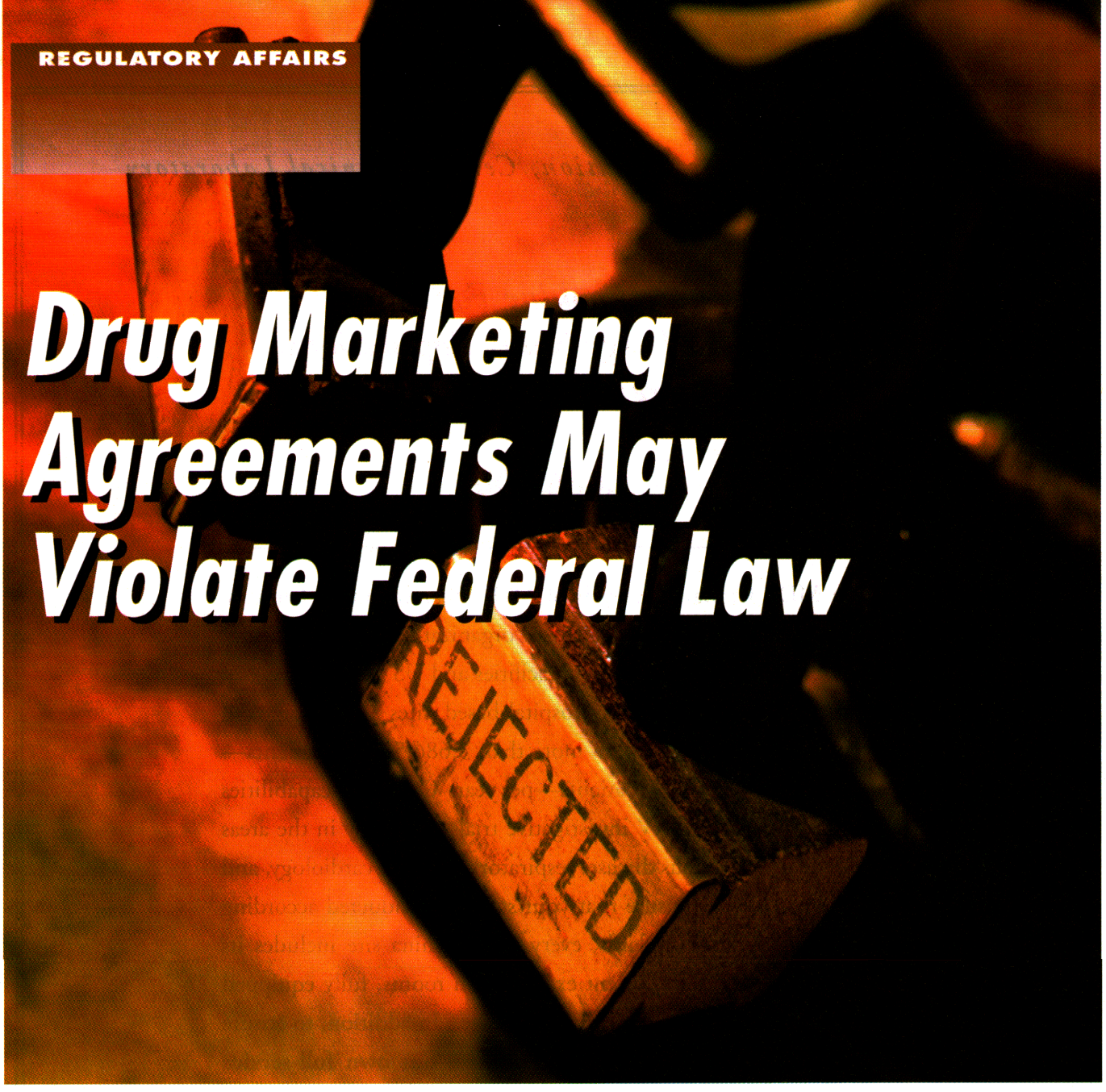

Drug Marketing Agreements May Violate Federal Law

Knowledge of the Medicare "anti-kickback" law can help companies avoid litigation for improper comarketing and copromotion arrangements.

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Pharmaceutical companies often have their products marketed by other companies or by contract sales organizations. In the United States, they must structure such arrangements properly to comply with federal law.

This article discusses the Medicare "anti-kickback" law, which has significant implications for marketing pharmaceutical products. Formally known as the Medicare-Medicaid Anti-Fraud Abuse Amendments of 1984, the anti-kickback law prohibits many types of copromotion, comarketing, and joint-venture marketing arrangements with which companies should become familiar.

STATUTORY EVOLUTION

Federal funds reimburse the cost of many pharmaceuticals under a variety of federally funded health care programs. Such programs include Medicare, Medicaid, and others at the state level. Because federal funds are used, the federal government has an obvious interest in ensuring that pharmaceutical purchases are not superfluous or unnecessary.

When federal funds are used to buy unneeded medicines, the purchases present a drain on the federal health care system. The anti-kickback law combats inappropriate use of federal drug reimbursement policies.

The law also regulates pharmaceutical marketing and promotional activity. It

reduces financial incentives for ordering medicines that patients do not really need. The anti-kickback law originally outlawed offering "bribes" and "kickbacks" to promote pharmaceuticals. A bribe involves payment for the breach of duty of trust to another party. A kickback involves a refund of a payment for the breach of duty of trust.

A company that pays another person to induce business with federal health care funds may be criminally liable.

Under the original version of the law, if the marketing or promoting activity did not entail paying a bribe or kickback, then the marketing activity was legal—even if it arguably encouraged purchasing superfluous or unneeded medicines. Thus, many marketing arrangements that the federal government found objectionable were found legal.

WIDER NET

To address a "growing problem of fraud and abuse in the system" and to remedy the law's perceived deficiencies, Congress changed the anti-kickback law in 1997. Today, the law still outlaws kickbacks and bribes. But it is now more general and also forbids paying certain types of "remuneration," even if the payment is not a bribe or kickback. Thus, innocuous marketing arrangements may violate the law.

As amended, the law now says (in part):

> . . . whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) . . . in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) in return for . . . recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

The law criminalizes both the receipt and the payment of certain remuneration. Thus, a company that knowingly and willfully pays another person to induce business reimbursed with federal health care funds may be criminally liable.

This law is extremely broad. It generally prohibits a pharmaceutical manufacturer from paying another company for recommending to others that they purchase the manufacturer's drugs, if the purchases are reimbursable with federal funds. In March of this year, the federal government said that a distribution contract with a marketing consultant broke the law. Similarly, several federal courts have said that certain copromotion agreements break the law. Before examining some court cases in detail, this article elaborates on several parts of the law.

First, the "gravamen" of the law, or basis for a formal complaint, is inducement. Second, the law is limited to "remuneration," or transfers of value between discreet legal persons. Third, the law covers any culpable person. Each of these points merits greater discussion.

Inducement. This term describes the intent of those who offer or pay remuneration. The law uses the dictionary meaning of "induce," to lead or move by influence or persuasion. Thus, the anti-kickback law applies if one party makes payments intended to influence or persuade a person to use a federally reimbursed health care good or service.

Actionable inducement is not limited to direct marketing contact with the patients themselves. Rather, inducing a physician or corporation to use or recommend a particular good or service can be illegal.

In the court case *United States v. Bay State Ambulance & Hospital Rental Service,* an ambulance company paid a member of a city hospital bid committee in Rhode Island to recommend to the hospital that it use the company's services. The person received remuneration not for actually referring patients to the ambulance service, but for using his position in the hospital bid committee to award the city and hospital ambulance contract to the particular ambulance company. Because he so "induced" the hospital bid committee, he was found criminally liable under the law.

Remuneration. The law is limited to transfers of value among discreet legal persons. Thus, it does not apply to funds being transferred within a single legal entity. However, it does apply to fund transfers among distinct legal persons. That remains true even if the payments occur between entities with common ownership. Thus, payments between wholly owned subsidiary corporations come under the law. Similarly, the law covers payments between a parent entity and its affiliated joint venture entities.

The law encompasses remuneration in any form, including cash and noncash payments such as purchase discounts. Consequently, purchase discount arrangements among the commonly owned subsidiaries of a single corporate family may be within the scope of the law, even when the entities have exchanged no cash.

The law is drafted so broadly that it applies even when a company pays its own sales staff. Such payment involves, in the words of the law, "receiving any remuneration . . . in return for . . . recommending purchasing" the employer's pharmaceutical products. That is not, however, the kind of activity that Congress intended to outlaw. Thus, the law provides limited exemption for employees. It exempts amounts paid to employees who have a bona fide employment relationship with the employer.

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That exemption is available only for persons who meet the Internal Revenue Service definition of employee. In contrast to employees, independent contractors such as contract sales organizations fail to qualify for the exception. That is because of alleged "widespread abusive practices by salespersons who are independent contractors and, therefore, who are not under appropriate supervision and control," as noted in the

Final Rule issued by the Office of Inspector General.

Culpable actors. The original version of the law was limited to kickbacks and bribes. A "kickback" or "bribe" needs a breach of a legally cognizable duty of trust. Such a duty was, in older cases, often found in the physician–patient relationship.

The law is not, however, literally limited to physicians. Rather, it imposes liability on whoever performs prohibited acts. Therefore, the reported legal cases finding violations are not universally limited to physicians or others who have a direct role in the provision of health care services. Pharmaceutical manufacturers can violate the law with comarketing or copromotion arrangements and other kinds of management contracts.

DAYS IN COURT

The law imposes criminal culpability only on those who act "knowingly and willfully." As a result, many innocent—not knowing or willful—violations of the law have not been prosecuted criminally.

Even an innocent violation, however, is still a violation and therefore illegal. If a marketing or promotion contract is illegal, it is usually unenforceable in court. That means accounts receivable and other amounts payable pursuant to the contract—such as stock option grants—may be uncollectible. A judge may not send anyone to jail but may still invalidate the contract.

The federal court found marketing contracts illegal, and thus unenforceable, in two recent cases. These cases, known as *Quantum Health Services* and *Modern Medical Laboratories*, are worthy of greater discussion.

Quantum Health Services supplies medical equipment and supplies to nursing home patients. To broaden its sales in a certain geographic market area, Quantum enlisted the services of a contract sales organization, Nursing Home Consultants (NHC). NHC is a contract sales organization that markets medical supplies and equipment on behalf of other companies to nursing home residents. NHC thus acts as marketing intermediary between the nursing home residents and manufacturers or distributors.

Quantum and NHC entered a marketing contract under which NHC identified nursing home residents who needed Quantum's medical supplies, and put the residents in contact with Quantum. Quantum then sold its products directly to the nursing homes, which bought the supplies on behalf of its residents.

The marketing contract detailed the sales procedures for both parties to follow. It stated that the nursing home residents should place all orders directly with Quantum. NHC could provide the appropriate documents to residents but could not otherwise assist a resident with placing an order. The contract also said that if either party breached the order-taking procedure and service guidelines, the other party could terminate the contract. Consequently, NHC had no direct involvement in the actual sales of the medical supplies to nursing home residents. NHC performed its marketing services under the contract. Quantum refused to pay NHC, but NHC sued to collect payment for its accrued accounts receivable.

Even without criminal prosecution, violations can create bad publicity and economic loss due to contract invalidity.

The federal court held that the contract was illegal under the anti-kickback law. The judge discussed two ways the contract could create illegal "inducement." First, NHC was paid for referring residents to Quantum. Quantum then sold the supplies to the nursing homes, which bought the supplies on behalf of the residents. The judge found that the marketing relationship "falls squarely within" the law. Second, NHC could be viewed as being paid for recommending to residents that they purchase their supplies from Quantum. As such, the relationship, too, violates the law.

The court did not prosecute anyone criminally. But the judge noted that the marketing contract was illegal and therefore unenforceable. Consequently, NHC could not collect the accounts receivable due from Quantum under the contract.

Modern Medical Laboratories (MML) owned clinical laboratory facilities and retained a contract marketing organization (CMO) to market, manage, and operate those facilities. The two companies signed a "Co-Operative Management Agreement" under which MML agreed to pay the CMO 90 percent of the gross receipts of the laboratory business.

MML conducted business with the CMO for some time under the agreement. Then, the CMO was acquired by an affiliate of SmithKline Beecham (SKB). After the acquisition, SKB advised Modern Medical that the contract was illegal, so SKB would make no further payments under the contract. Modern Medical sued SKB to collect accounts receivable due under the contract.

The federal court found that the agreement was illegal under the anti-kickback law. The judge noted that the law reaches any activity whereby one entity is paid for taking a physician's order and arranging for another entity to supply the drug. As in the Quantum case, Modern Medical could not collect on its accounts receivable under the contract because the contract was illegal.

The anti-kickback law is broad—it affects any deal where one company hires another for drug marketing—and the exemptions to it narrow. The law is therefore easy to violate. Criminal prosecution for marketing contracts has, to date been minimal. The federal government, however, has said that it is seeking increased funding to pay for such enforcement. (See Washington Report, August 1997.)

Even without criminal prosecution, violations can create bad publicity and economic loss due to contract invalidity. For larger manufacturers' smaller partners, contract invalidity could be "material" under federal securities law, creating larger economic risk for smaller companies. ▮