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Structuring Marketing Joint Ventures

By **Mark Pohl**

Marketing joint ventures have created several successful products. For example, the stunning success of Lipitor® is attributed to a marketing joint venture that combined the marketing finesse of the marketing partner, Pfizer, with the scientific innovation of the compound's inventor, Warner-Lambert. Legal battles between marketing partners, however, underscore that such a marketing joint venture must be structured carefully, lest it be vulnerable to legal attack under Federal law.

In the following pages, I review the current scope of a law that regulates pharmaceutical industry joint ventures as well as discuss some examples of actual marketing joint ventures that have run afoul of the law.

The Law

Federal law prohibits a drug maker from paying another company to induce business that is reimbursable under a Federal health care program (e.g., the Veterans' Administration or Medicare). Prohibited deals include, for example, paying another person or company for recommending the purchase of any good reimbursable by a Federal health care program. A violation is classified as a felony.

This law was intended to address a perceived "growing problem" of fraud in Federal health care programs. The law combats this by prohibiting activities that may result in the over-prescribing or over-utilization of goods paid for by Federal health care programs. Thus, seemingly innocuous marketing joint ventures can violate the law.

Sales Representatives

The law is broad enough to literally cover payments to commission sales representatives, as commission sales representatives are paid, based on product sales, to induce another person to order the products.

The law, however, excepts employees. To qualify, an individual must meet the Internal Revenue Service definition of an employee. If the person meets this definition, pay for his or her sales activities are exempt from the law.

Bona fide employees are exempt from the law even if paid a sales-based commission, i.e., even if paid for inducement otherwise prohibited by the law. Further, a bona fide employee is exempt even if only a part-time employee, paid on a commission-only basis. Leased employees may also be exempted, under certain conditions. As long as a bona fide employer-employee relationship exists between the employee and the employer, the relationship falls within the scope of the employee exception.

In contrast to bona fide employees, independent contractors and third-party companies (such as joint venture partners) *do not qualify* for this exception. This is because of alleged widespread abusive practices by salespersons who are independent contractors and, therefore, who are not under appropriate supervision and control by the manufacturer. Thus, if salespersons are paid on the basis of the amount of business they generate, to be exempt from civil or criminal prosecution, the manufacturer "should make these salespersons employees."

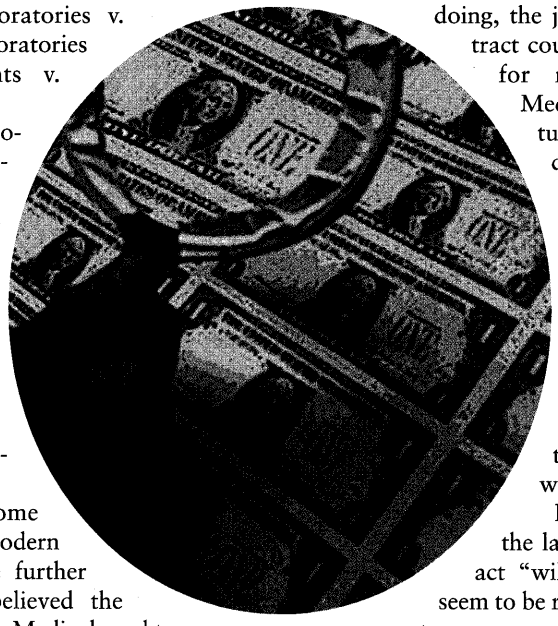
It has been argued that appropriate supervision and control of independent contractors can be had by including restrictive terms in the agency agreement. Further, certain pharmaceutical marketing activities are already controlled by other Federal statutes. See e.g., U.S.C.A v.21, §§ 331(k) (prohibiting material alteration or obliteration of drug labeling); 331(o) (prescription drug distributors must give government-approved packaging inserts to physicians, on request).

In the future, the exception for employees might be expanded to include independent contractor commission-sales contracts. This, however, will happen only after the government can predict, with reasonable certainty, that commission-sales contracts will not be fraudulent. For now, the definition of "employee" does not include independent contractors and marketing joint-venturers paid on a commission basis.

Thus, it has been argued that independent contractors should be given specific protection for commission sales arrangements, because they merely replicate with an independent contractor an economic arrangement which is valid with an employee. The government, however, has expressly rejected this approach, concluding that there is no reason for treating commission sales agreements differently under these regulations from other types of contracts for personal services performed by independent contractors.

Several Companies Have Violated the Law

Two publicly disclosed legal cases have held that certain marketing agreements violate the law. These two cases are Modern Medical Laboratories v. Smith-Kline Beecham Clinical Laboratories and Nursing Home Consultants v. Quantum Health Services.



Modern Medical involved a "Co-Operative Management Agreement." Under the agreement, Smith-Kline was paid to market, manage and operate Modern Medical's clinical laboratory business and facilities. Work was performed, and payments were made, according to the terms of the Agreement. Such work included, per the Agreement, marketing Modern Medical's laboratory services.

Performance occurred for some time. Then, SmithKline advised Modern Medical that it would not make further payments, because SmithKline believed the Agreement could be illegal. Modern Medical sued to collect the accounts receivable that SmithKline had refused to pay.

The judge, however, held that the Agreement violated the law. He said the law covers, inter alia, taking a physician's "order" and arranging for another to supply the goods or service. The court found that Modern Medical arranged for the Medicaid reimbursable goods or service to be purchased from SmithKline, and was paid for that service.

In Quantum Health Services, Inc., Quantum supplied reimbursable medical equipment and supplies to nursing home patients. To broaden its sales in a certain geographic market area, Quantum enlisted the services of a marketing partner, Nursing Home Consultants ("NHC").

NHC marketed medical supplies and equipment to nursing home residents on behalf of other companies. NHC thus acted as marketing intermediary between nursing home residents (who were covered by Medicare), and medical suppliers, whose products were paid for by the residents' Medicare coverage.

Under the contract with Quantum, NHC identified nursing home residents who needed Quantum's medical supplies and put these nursing home residents in contact with Quantum. Quantum then sold its products directly to the nursing home, on behalf of the residents.

The Marketing Contract detailed the sales procedures to be followed, and said that all orders were to be made directly with Quantum. NHC could thus only provide the appropriate documents, but could not otherwise assist a resident in connection with his placing of an order. The Contract mandated that if either party breached the order taking procedure and service guidelines, the other party could terminate the Contract. NHC thus had no direct involvement in the actual sales of the medical supplies to nursing home residents. As with the SmithKline case, Quantum refused to pay its accounts payable to NHC. As with SmithKline case, NHC sued to collect.

The judge held that the contract was illegal. In so doing, the judge discussed two ways the contract could be illegal. First, NHC was paid for referring persons who needed Medicare-covered supplies to Quantum. In turn, Quantum sold the residents those supplies (via their nursing homes). The court found this type of relationship to fall squarely within the kind of inducement prohibited by the law.

Second, NHC could be viewed as paid for recommending to Medicare recipients that they purchase their Medicare-reimbursable supplies from Quantum. As such, the relationship with Quantum would similarly violate the law.

In addition to payments to induce, the law expressly requires that the actor act "willfully." Thus, this element would seem to be required for the government to prosecute a person under the law. Willfulness, however, is apparently not required to make a contract illegal under the law, and thus void and unenforceable.

For example, in Modern Medical, there is no mention of either party's "willfulness." Rather, the court's opinion implies that both parties were completely unaware of the law on signing the Contract, and continued to be so until Smith-Kline discovered the possible violation. The court nonetheless found the contract illegal. In doing so, the court noted that performance of the contract after the ruling would definitely constitute a knowing and willful violation and thus, future performance would be illegal.

Similarly, in Quantum Health Services, it was not clear that anyone willfully violated the law. The judge thus could not say that anyone was criminally liable. Even without culpable intent, however, the court held the Marketing Agreement illegal (and thus unenforceable). The court noted that the subject matter of the Marketing Agreement was contrary to the public policy of the law. The court also noted that this remained true irrespective of whether anyone could have been prosecuted by the government in connection with that Agreement.

While the court in Quantum did not actually find will-

fulness, it was, however, potentially implicit in that fact situation. Prior to the execution of the Marketing Agreement, Quantum's President received legal advice indicating that the Agreement's per-item fee structure was likely in violation of the law. The judge said, however, that it was "far from clear" that Quantum's President thought that legal opinion was correct.

However, Quantum's President told NHC's President, while negotiating the Marketing Agreement, that the planned compensation scheme might violate the law. Thus, the judge noted that the principals knew that the arrangement might be illegal. The judge reasoned that, if people knew that, even if they execute an agreement prohibited by law, judges would nevertheless allow them to recover the benefit of their illegal bargain, what would deter them from entering into such arrangements in the first place?

Structuring Joint Ventures

Certain marketing joint ventures qualify for an exception to the law. The exception covers payments from a joint venture that are returns on an investment interest to an investor. An investment interest is a security issued by the joint venture or subsidiary. It includes shares in a corporation, interests or units of a partnership, and bonds, debentures, notes and other debt instruments.

Under the regulation, an investor is a person who holds an investment interest in the joint venture. An investor can hold this interest directly or indirectly. Indirect ownership includes, for example, holding a legal or beneficial interest in another joint venture (such as a trust or holding company) that directly holds the investment interest in the joint venture. The exemption exempts payments from a joint venture or other non-public company, to its investors, under certain conditions.

To qualify for the exemption, the joint venture needs eight ingredients. To qualify for the exemption, the joint venture must comply with several constraints on its operations. First, the joint venture must get at least sixty percent of its gross revenues from unrelated persons. The joint venture must obtain a minimum of its revenues from unrelated persons. In calculating this percentage of revenue, the joint venture need not use its public financial, nor its tax reporting results. The joint venture need not even use Generally Accepted Accounting Principles. Rather, the joint venture is free to use any internal accounting principles it chooses to adopt, so long as it uses such principles consistently over time, "so that it is not manipulating the data to obscure its noncompliance." Such accounting freedom allows for a certain, albeit limited, flexibility.

In calculating the percentage of revenues from investors, one must examine the investors in the joint venture, as well as the investors in the investors in the joint venture. Thus, if the joint venture investors are themselves owned by entities who refer business to the joint venture, such referral business must be included in evaluating the percent of related party referral.

This element might not be applied strictly, i.e., violation might not result in prosecution. It "is highly unlikely" that the government will pursue an investigation of a joint venture that complies with all the safe harbor's seven other elements, except the venture has obtained from investors over forty percent of its gross revenue (based on prior year fiscal data), if the venture is making a good faith effort to reach compliance. Such effort can be based on data showing compliance on a monthly basis for the most recent months of operation.

This element would not seem terribly difficult to comply with, for many marketing joint ventures. Such joint ventures are often made expressly to obtain sales from unrelated parties.

While the rule restricts the percentage of related-party revenues, it does not restrict the profitability of such business. This is because the rule does not require that the joint venture actually lower the costs to Medicare and Medicaid of the venture's products. This is because any meaningful analysis of the relative costs of goods is too complex to be achieved by exemption regulation. Thus, while the exemption restricts the percentage of related-party revenues, the exemption does not require that such revenues, or the joint venture generally, actually decrease Medicare expenditures.

The joint venture may seek business from passive investors. If it does so, however, the joint venture must promote and furnish its items or services to investors in the same manner as to non-investors. As with related-party revenues, this element may not be difficult to meet, for joint venturers aimed at unrelated third parties.

The exemption also restricts the joint venture's financing activities. Saliently, the exemption restricts the ability of investors to otherwise do business with the joint venture.

The exemption requires persons who are not able to generate business for the joint venture to hold a certain amount of ownership. This element focuses on the ownership of the joint venture, rather than on the process by which the equity was offered to potential investors. Thus, there is no requirement for the venture to undertake a "public offering" within the meaning of Federal Securities law. The joint venture's process for soliciting potential investors is not reviewed, nor even material, under the exemption.

In calculating the percentage of ownership, the joint venture is free to use any internal accounting principles it chooses to adopt. As with calculation of related-party revenues, however, the joint venture must use such principles consistently over time, so that it is not manipulating the data to obscure its noncompliance.

Investors in a position to "generate business for the joint venture" include all those who do business in any manner with the joint venture. This includes investors who refer customers to the joint venture or who otherwise generate business for the joint venture. It also includes investors who furnish goods and services to the joint venture. For example, if a drug manufacturer and a contract sales force form a co-marketing joint venture to furnish the manufacturer's drugs to patients serviced by the contract sales force, both the manufacturer and the contract sales force are "doing business" with the joint venture joint venture.

This category includes those merely in a position to generate business. It is not limited to investors who actually

make referrals. Rather, the focus is on the ability to make or influence the joint venture's level of business activity.

The ability to influence the joint venturer's business activity is an issue deserving consideration wherever the joint venture joint venture is owned by entities which are themselves involved in the health care industry. Where the joint venture has investors in a position to do business with it, the investors may thus need to negate this ability. Properly negating this ability may directly impact the structuring of the venture, and the allocation of duties between investor and venture. For example, consider a marketing joint venture owned by two drug manufacturers. The venture might not be legally able to process orders for the investors' products, if the venture also promotes these products. Such distribution might entail "doing business" with the venture's investors.

An investor can waive the ability to do business with the joint venture by written agreement. Such an agreement must be in writing. It must stipulate that the investor will not generate business for the joint venture for the life of the investment—that is, for so long as the investor remains an investor.

In calculating percentage ownership, special attention must be paid to cases where the joint venture is owned by other business entities, which are in turned owned by other persons. Such indirect investors' ability to influence business interests is attributed to the direct investors. For example, consider a situation where passive investors own parent joint venture P, and P is the active investor in joint venture joint venture V. In this situation, all of V's direct and indirect investors must comply with the exemption. Thus, joint venture P must meet the active investor requirements, and the investors of joint venture P must meet the requirements for passive investors in joint venture V.

Minor violations of the percentage-ownership element might not be prosecuted. It is highly unlikely the government will pursue an investigation of a joint venture which complies with all seven of the safe harbor's other elements, but has over forty percent insider ownership (based on prior fiscal year data), if the joint venture is making a good-faith effort to reach compliance with the standard.

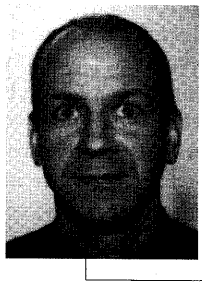
Such effort can be based on data showing compliance on a monthly basis for the most recent months of operations. How many months of compliance suffice to excuse noncompliance is, however, unclear. Similarly, whether actual compliance in fact is the only way to establish a good faith effort to comply is unclear. The safe-harbor rule is intended to provide an objective, bright-line test. Thus, some kind of objective data would seem to be required. Whether objective data which demonstrates, for example, a trend toward becoming compliant in the future is material to establish a good faith effort to comply is unclear.

For example, in Modern Medical, the agreement mandated that the marketing agent would take a fixed percentage (90%) of the total revenues obtained, remitting the remainder to the facility owner. The agreement thus gave the marketing agent a percentage of all Federal health care program revenues obtained. The court held that this arrangement for compensation took into account the value of the referrals or business generated between the parties, and thus failed to qualify for the exemption provision.

Similarly, in Quantum Health Services, the marketing agent's compensation was based on the number of sales made by the principal, rather than based on a predetermined annual fee. The court held that, the Marketing Agreement, by virtue of its compensation scheme, fell directly within the class of transactional relationships prohibited by the law. Because the compensation was based on sales volume, the agreement did not qualify for the exemption. The court noted that the Marketing Agreement may not, in the purest sense, be a commission sales agreement. Since the marketing agent received a flat fee for each item sold, however, it effectively received a percentage commission on those sales, the percentage being the fee divided by the item's total cost.

Summary

Business transactions in the pharmaceutical industry must comply with many industry-specific laws, including the Medicare anti-kickback law. Business arrangements allowable in other industries may be more complex in the pharmaceutical industry.



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