

“GO TO JAIL – DO NOT COLLECT \$200”¹

Drug Promotions and Physician Compliance

Charlene L. McGinty and Sandra K. Herron
Powell Goldstein LLP, Atlanta, GA

I. Introduction

Physicians and pharmaceutical manufacturers have traditionally enjoyed a mutually beneficial relationship. In its most simple form, this relationship involves the exchange of value for value: through traditional drug sample programs, manufacturers furnish physicians with the newest medications and educate the physicians on their use, while physicians treat their patients with the new drugs and furnish the manufacturers with consumers—the patients—for their products. This relationship may become contaminated, however, through practices designed to obtain a competitive advantage by one pharmaceutical manufacturer over another, or to take advantage of favorable payor practices for prescription medications.

According to regulators, however, these competitive practices can improperly influence a physician’s therapeutic conduct, disadvantage consumers, or result in increased medication costs; consequently, relationships between pharmaceutical manufacturers and physicians are subject to intense scrutiny. The reasons for this scrutiny are readily apparent. Healthcare costs continue to rise, and rightly or wrongly, the cost of drugs has been targeted as a major contributor to the high cost of care. As government payment for prescription drugs continues to grow, most recently with the enactment of the Medicare

Prescription Drug, Improvement, and Modernization

Act of 2003 (Medicare Modernization Act),² so will the government’s interest in curbing activities perceived to increase fraud, waste, and abuse in its programs. Moreover, government enforcement activities have resulted in exorbitantly high settlements with pharmaceutical companies based, in part, on their relationships with physicians. These

high-dollar settlements further motivate the so-called *qui tam* relators who can receive a significant portion of any settlement or judgment against the companies they report. As a result of these and other factors, pharmaceutical manufacturers are, and will remain, in the regulatory enforcement spotlight, and their relationships with physicians will remain at the forefront of government activity.



In the last several years, the federal government has increasingly focused its enforcement lens on reported fraud and abuse in the pharmaceutical industry. Large awards have been paid to *qui tam* relators for reporting activities of pharmaceutical manufacturers, especially with regard to payments to physicians. These *qui tam* relators are most often current or former employees of the companies or the physicians with whom the companies have done business. Recently, TAP Pharmaceutical Products, Inc. (TAP) paid out more than \$875 million to settle charges against it of manipulating Average Wholesale Price (AWP) and providing free samples of the drug Lupron® to physicians, who then billed Medicare for the cost of the drug. Combined with other high-profile settlements, pharmaceutical manufacturers have paid out billions in the last several years.

While much of the focus of these investigations has been on manipulation of the AWP charged to government programs, and on switching arrangements, marketing the spread and other high profile marketing activities, other less high profile activities have been uncovered in these same investigations. Included among the identified improper activities are fraudulent consulting arrangements between the pharmaceutical manufacturers and persons in a posi-



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tion to refer business, particularly physicians. Pharmacists and pharmacy benefit managers have also been in the spotlight because they may often influence which drugs are prescribed or dispensed.

Many of the practices uncovered and labeled by the government as “fraudulent” have been standard business and marketing practices for years. In fact, in an industry other than health care, they would be considered good and legitimate business practices. Now, however, pharmaceutical companies and physicians must alter the way they conduct business, and must implement effective compliance plans to avoid any improper conduct and thereby prevent the costly investigations that might ensue. There is a legitimate need and valuable benefit to preserving pharmaceutical companies’ ability to engage healthcare providers, the natural experts for the industry, as consultants. Yet, because these natural experts are often also the pharmaceutical companies’ customers, the intent behind the relationship is always open to question. The regulatory framework can be complicated and confusing; there are, however, safe ways to structure these relationships and avoid the pitfalls of both actual and apparent noncompliance.

In this article we will discuss the relationship between pharmaceutical manufacturers and physicians, examining the characteristics that make this one of the most common, yet high-risk, relationships into which these parties may enter.

II. Applicable Law

Pharmaceutical manufacturers’ relationships with physicians can come within the ambit of two chief legal schemes when the relationships include marketing and development activities: the Federal Anti-Kickback Statute (Anti-Kickback Statute) and applicable state consumer protection laws and state anti-kickback laws. State laws vary and we have not addressed those laws in this article, but any such relationship between pharmaceutical manufacturers and physicians should be reviewed for compliance with such laws, as applicable. With respect to Stark law considerations, the government made it clear in the preamble to the Stark regulations that pharmaceutical manufacturers are not generally subject to the Stark laws because they do not furnish “designated health services.”³ Therefore, the ordering, prescribing, and dispensing drugs would not constitute a referral by a physician to the manufacturer for designated health services. Our discussion will concentrate on the Anti-Kickback Statute and enforcement actions under same.

A. The Anti-Kickback Statute

The Anti-Kickback Statute broadly prohibits activities that can foster increased costs to federal healthcare payment programs, including Medicare and Medicaid. Violations of the Anti-Kickback Statute carry both criminal and civil penalties. State anti-kickback laws often go further, prohibiting remuneration to induce referrals for all payer sources.

The Anti-Kickback Statute reads as follows:

* * *

- (2) Whoever knowingly and willfully offers or pays *any remuneration* (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -
 - (A) to refer 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) to purchase, lease, order, or arrange for or recommend 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.⁴

Notably, courts have held that it does not matter under the Anti-Kickback Statute that an arrangement might benefit patients. Federal courts have held that if even a single purpose of the remuneration is to induce a person to engage in prohibited conduct for items or services payable under a federal healthcare program, the Anti-Kickback Statute is violated.⁵ Moreover, if a predictable result of the arrangement is increased market share for the company, at greater expense to federal healthcare payers, the risk is even greater since this is one of the outcomes the Anti-Kickback Statute was designed to prevent.

Because the Anti-Kickback Statute’s reach is so extraordinarily broad, it can prohibit activities that, while technically violating the Anti-Kickback Statute, present little risk of program abuse. Accordingly, Congress included in the Anti-Kickback Statute a requirement that the U.S. Department of Health and Human Services (HHS) establish certain “safe harbors” to protect such arrangements. HHS accomplishes this mandate through its Office of Inspector General (OIG). To date, the OIG has published 22 such regulatory safe harbors. If an arrangement

meets *all* of a safe harbor's requirements, the arrangement is fully protected, and will not subject the parties to sanctions under the Anti-Kickback Statute.

Many common arrangements do not fit squarely within a safe harbor. For those arrangements, the best practice if a company is to minimize its risk is to structure the arrangement to meet the requirements of the most closely applicable safe harbor, and to include sufficient safeguards to minimize any chance of federal healthcare program abuse. Provided that there is no intent to violate the Anti-Kickback Statute—that is, there is no intent to engage in activities prohibited by the Anti-Kickback Statute—structuring an arrangement in this manner should significantly decrease the parties' risk of adverse action by a government enforcement agency, and certainly should minimize the risk of a criminal enforcement action by the OIG.

Included among the regulatory safe harbors is one safe harbor that is of particular interest here: the safe harbor for personal services and management contracts. To qualify for full safe harbor protection, an arrangement must satisfy all of the following seven requirements:

1. The agency agreement is set out in writing and signed by the parties.
2. The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
3. If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
4. The term of the agreement is for not less than one year.
5. The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal healthcare programs.
6. The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

Physician Organizations Practice Group Leadership

Charlene L. McGinty, Chair

Powell Goldstein Frazer & Murphy LLP
Atlanta, GA
cmcginty@pgfm.com

Ann M. Bittinger, Vice Chair

(Publications)
The Bittinger Law Firm
Jacksonville, FL
ann@bittingerlaw.com

David J. Hyman, Vice Chair

(Research)
Boone Smith Davis Hurst & Dickman
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dhyman@boonesmith.com

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creisz@bassberry.com

Lisa D. Taylor, Vice Chair

(Educational Programs)
St John & Wayne LLC
Newark, NJ
ldt@stjohnlaw.com

7. The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.⁶

As noted above, the safest course for a manufacturer and a physician is to structure their relationships to fully satisfy the safe harbor. However, it may not always be possible to do so; and, even relationships outside the safe harbor may not violate the Anti-Kickback Statute. The government recognizes these realities; accordingly, the OIG has provided fairly extensive guidance on pharmaceutical activities and relationships.

B. OIG Guidance

Beginning in 1988, the OIG started to focus on drug marketing schemes as possible violations of the Anti-Kickback Statute. In 1991, the OIG published its report, *Promotion of Prescription Drugs Through Payments and Gifts*.⁷ Among other things, the OIG found that drug companies sometimes improperly offered cash and other remuneration.

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Alice G. Gosfield, Chair
Alice G. Gosfield & Associates PC
Philadelphia, PA
agosfield@gosfield.com

Charlene L. McGinty
Powell Goldstein LLP
Atlanta, GA
cmcginty@pogolaw.com

Michael F. Schaff
Wilentz Goldman & Spitzer PA
Woodbridge, NJ
mschaff@wilentz.com

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neration to physicians through a variety of means, including sponsorship of drug studies, speaking engagements, and payment for program attendance. The study identified specific problematic practices, including payments to physicians for sham services or payments out of proportion to services rendered by the physicians. For example, one program compensated physicians for their participation in a “research project.” Physicians were required to enroll patients in the program to collect data on the types of patients using the drug company’s products. Another program paid physician and spouse expenses for a trip to a Caribbean resort for a drug promotion seminar.

In its publication of the 1994 OIG Special Fraud Alert in the December 19, 1994 *Federal Register*, the OIG republished five previous special fraud alerts, including its *Special Fraud Alert: How Does the Anti-Kickback Law Relate to Prescription Drug Marketing Schemes?*⁸ The Alert stated that, in an “era of aggressive drug marketing . . . patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product.”

The 1994 OIG Special Fraud Alert focused on “product conversion” by pharmacies, “frequent flier” campaigns aimed at physicians, and “research grant” programs in which physicians were given substantial payments for *de minimis* recordkeeping tasks. The tasks performed by the physicians given “research grants” included administration of the pharmaceutical company’s drug to patients and making brief notes about the treatment outcome, sometimes a single word. Consistent with the discussion above for the Anti-Kickback Statute, the government noted that if one purpose of the scheme was to induce the provision of a prescription drug item reimbursable by Medicaid, then the Anti-Kickback Statute was implicated and no safe harbor would protect the conduct.

Then, in April 2003, the OIG published more comprehensive guidance, its *Compliance Program Guidance for Pharmaceutical Manufacturers* (CPG).⁹ The CPG tracks the Federal Sentencing Guidelines in its discussion of the fundamental seven elements of an effective healthcare compliance plan. Additionally, the CPG identifies three specific risk areas: (1) the integrity of data used by state and federal governments to establish payment amounts; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples. In its discussion of the second risk area, the CPG recommends a two-pronged approach: first, identify any remunerative relationship between the manufacturer or its representatives and persons or entities in a position to generate federal healthcare business *directly or indirectly* (emphasis added); then, determine whether any *one* purpose of the

remuneration may be to induce or reward the referral or recommendation of business payable in whole or in part by a federal healthcare program.¹⁰ The OIG recommends the use of safe harbors, including the personal services and management contract safe harbor discussed above,¹¹ the employment safe harbor,¹² and others as applicable.

Areas of focus in the CPG that relate directly or indirectly to consulting arrangements include selective “offers of remuneration” (i.e., offers made to some, but not all purchasers), contracts with purchasers for data collection services, relationships with formulary committee members, payments for educational and research grants, and personal services compensation arrangements. The OIG cautions that under the Anti-Kickback Statute, “neither a legitimate purpose for an arrangement (e.g., physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (i.e., the purposeful inducement of business).”

With respect to consulting and advisory payments, the CPG cautions that while in general, fair market value payments to small numbers of physicians for *bona fide* consulting or advisory services are unlikely to raise any significant concern, the following arrangements are suspect: (1) compensating physicians as “consultants” when they are expected to attend meetings or conferences primarily in a passive capacity, and (2) compensating physicians for services connected directly or indirectly to a manufacturer’s marketing and sales activities, such as speaking, certain research, or preceptor or “shadowing” services. In particular, the CPG mentions the use of healthcare professionals for marketing purposes in ghost-written papers or speeches, and “detailing,” or compensating physicians as consultants for time spent listening to sales representatives market pharmaceutical products.

The CPG advises manufacturers to review all arrangements for physician services to ensure that: (1) the arrangement is set out in writing; (2) there is a legitimate need for the services; (3) the services are provided; (4) the compensation is at fair market value; and (5) all of the preceding facts are documented prior to payment. In addition, manufacturers should structure the arrangement to fall within a safe harbor whenever possible.

It is important to note that governmental industry guidance in the form of compliance program recommendations is often followed by targeted enforcement initiatives. Indeed, according to the OIG’s 2005 Work Plan (found at www.oig.hhs.gov), payments to providers by pharmaceutical manufacturers will continue to be one of

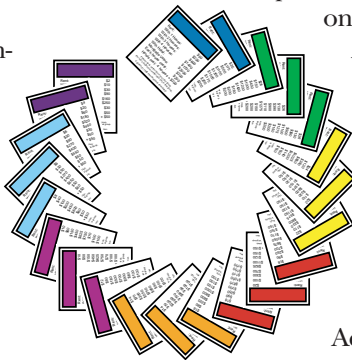
the OIG’s areas of focus, along with artificial inflation of AWP and rebates to Medicaid programs.

III. Industry Guidance

A. The Pharmaceutical Manufacturing Industry: the “PhRMA Code”

The pharmaceutical industry has not been idle through the course of this debate. In fact, the Pharmaceutical Research and Manufacturers of America (PhRMA), a pharmaceutical industry member organization, was one of the sponsors of the American Medical Association (AMA) educational program discussed below. Then, PhRMA published its own *Code on Interactions With Healthcare Professionals* (PhRMA Code), effective July 1, 2002.¹³ The PhRMA Code addresses interactions with respect to marketed products and related pre-launch activities, but not clinical trials prior to release by the Food and Drug Administration (FDA). It is very simple in its format and addresses subjects including:

1. Informational presentations by or on behalf of a pharmaceutical company: the presentations must provide educational and scientific information in an appropriate setting; occasional modest meals are permitted and structure of the activity should be conducive to scientific exchange, no inclusion of spouses or other guests;
2. Third party educational or professional meetings: financial contributions by drug companies permitted if paid to event sponsor but not directly to individuals (however, the sponsor has the ability to use funds to reduce registration fees for all attendees); no control by drug company over selection of content, faculty, etc.; no financial assistance can be used toward funding lodging, travel, or personal expenses of non-faculty attendees, and no compensation for personal time of physician attendees by drug company; modest meals acceptable; location must be appropriate;
3. Scholarships and educational funds to attend carefully selected educational or training conferences: individuals must be selected by the academic or training institution; must be major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations;
4. Gifts of educational or practice related items to physicians: not of substantial value (\$100 or less); no items for personal benefit of a physician;
5. Speaker training meetings: where physician is trained by drug company to provide a valuable service to the



drug company, reasonable compensation for time, travel, lodging, and meals is permissible if the training is on the company's drug products and FDA compliance for communications about products and the trainee meets the requirements for consultants; and

6. Consultants: reasonable compensation and reimbursement for travel, lodging, meals; must be bona fide arrangement as evidenced by written contract (state services provided and basis for payment), legitimate need for consultant identified prior to hiring consultant, criteria for selecting consultant related to purpose of consulting and selection of consultant by persons with expertise to evaluate criteria, number of consultants reasonable for purpose identified, records are maintained regarding appropriate use of services provided by consultant; and the venue/circumstances of any meeting are conducive to the consulting services, which are the primary focus of the meeting.

The PhRMA Code overtly recognizes the potential for fraudulent or sham consulting arrangements. The PhRMA Code is referenced as a valuable tool by the OIG in the final version of the CPG. The CPG cautions, however, against legal reliance upon the PhRMA Code, and states that the PhRMA Code should be used as guidance only.

B. Medical Industry Response

Prior to publication of the CPG, the OIG's activities in investigating and punishing pharmaceutical manufacturers did not go unnoticed by the pharmaceutical and medical communities. Indeed, both recognized that it was in their best interests to develop and implement internal, appropriate guidance for their members to help avoid scrutiny and further regulation by the government. The guidance discussed below arose from that realization.

In the early 1990's, the AMA published its *Opinion E-8.061, Gifts to Physicians from Industry*,¹⁴ which discussed proper and improper gifts, but no substantial effort was made to reinforce and educate physicians. In fact, it had become commonplace for physicians to accept substantial gifts, lavish dinners, and tickets to expensive sporting events, as well as cash in the form of sham consulting fees and research grants.



By the mid-1990's, the FDA had expressed its concerns over pharmaceutical marketing practices to physicians and physician promotional activities on behalf of pharmaceutical companies. The FDA is not only responsible for drug approvals, but is also charged with regulating the way in which approved drugs are marketed and

advertised. In 1997, the FDA published its *Final Guidance on Industry-Supported Scientific and Educational Activities (Guidance)*.¹⁵ The Guidance narrowly addressed how drug companies could financially support scientific and educational activities without coming within the purview of the Food, Drug, and Cosmetic Act¹⁶ drug marketing provisions and the consequent oversight by the FDA. The FDA said that such financial support would only fall outside of its enforcement efforts if the scientific and educational activity were free of the influence of the sponsor and did not serve to promote the sponsor's products. The Guidance also suggested meaningful disclosure at the time of the program to the audience of the sponsor's funding of the program.

After almost a decade of constantly intensifying OIG enforcement efforts (discussed in more detail below), a number of self-policing and educational initiatives began to arise within the AMA. By the beginning of the 2000s, the AMA had begun an educational initiative for physicians on acceptance of gifts from the pharmaceutical industry. In June, 2001, the AMA published its rather generic *Principles of Medical Ethics*, along with a re-emphasis on its *Opinion E-8.061, Gifts to Physicians from Industry*.

Opinion E-8.061 (Opinion) deals with remuneration in the form of gifts to physicians including in the context of speaking engagements and other consulting arrangements at conferences sponsored by or subsidized by drug companies. The Opinion expresses, among other things, that the definition of a legitimate "conference" or "meeting" is an activity held at an appropriate location where the object is to promote scientific activities and discourse, and the furtherance of knowledge on the topics being presented, with appropriate disclosure of conflict of interest and financial support. No subsidies from the pharmaceutical industry should be accepted for the food, lodging or personal expenses of physicians attending the conference or to compensate for a physician's time, unless in the form of reasonable compensation of physician/consultants for speaking engagements. The Opinion noted that "[t]oken consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses."

IV. Investigations and Enforcement Initiatives

The government has been active during the past decade in pursuing investigations and enforcement initiatives against pharmaceutical manufacturers, primarily in the area of illegal promotional activities and improper reporting of discounts and inflation of AWP. Although state Medicaid programs cover a broad range of prescrip-

tion drugs, federal Medicare coverage of prescription drugs has been very limited, mostly covering injectables and drugs accompanying durable medical equipment. With the passage late last year of the Medicare Modernization Act, this will soon change.

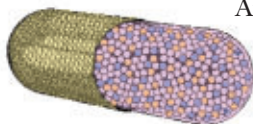
There have been a number of cases involving allegations that grants given to physicians were in fact kickbacks. Early cases set the tone for such allegations and their resolution, including the Caremark litigation which settled for \$161 million,¹⁷ and the Hoffman-LaRoche settlement for \$405,000.¹⁸ The most visible fraud enforcement initiative in recent years, and a case of significant import here, is the TAP case.

TAP is a joint venture between Abbott Laboratories and Takeda Chemicals of Japan. After four years of investigation by the government, on October 3, 2001 federal officials announced a settlement agreement wherein TAP agreed to pay \$875 million to resolve criminal and civil charges based on fraudulent drug pricing and marketing schemes. The payment included \$290 million in criminal fines and \$559 million in civil damages and penalties for False Claims Act liability and an additional \$25.5 million in civil liabilities to the States and the District of Columbia for false and fraudulent claims.¹⁹ In addition to the record-setting financial payment, TAP agreed to a sweeping 7-year corporate integrity agreement (CIA), which included a yearly review by an independent consultant of TAP's sales and marketing activities, to include a review of: speakers agreements and payments, agreements for consultation and other non-speaking arrangements, agreements relating to educational, clinical or research grants, and others.

The TAP investigation itself concerned marketing practices for the prostate cancer drug, Lupron®. The most visible part of the investigation involved manipulating AWP, underpaying Medicaid rebates, and providing kickbacks in the form of free samples of Lupron® to physicians who then billed Medicare full price for the drug. Other practices investigated include paying physicians sham consulting fees for speaking and other advisory arrangements, sponsoring speaking engagements, meeting, and questionable educational and research grants. In fact, the probe began when a physician/medical director of Tufts Health Plan in Boston was approached and offered a large sum in grant money to be used for any purpose if he would include Lupron® in the Tufts' formulary instead of the lower priced substitute, Zoladex®. Initially, the medical director was offered \$20,000 in grant money, but on the second visit from TAP marketing personnel, he was offered \$65,000 in unrestricted

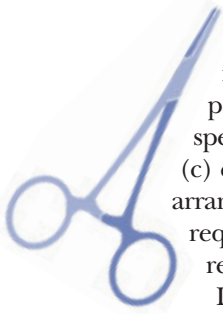
funds accompanied by \$100,000 in discounts on other TAP products.²⁰

In addition to TAP as an entity, six TAP executives and one physician were named in the indictment. Just prior to the indictment, four other physicians had been charged and pled guilty. The actual civil and criminal charges in the case were conspiracy to defraud Medicaid programs in a number of states, conspiracy to violate the Prescription Drug Marketing Act (which forbids billing for free samples), and violations of the Anti-Kickback Statute and False Claims Act. One physician (an Oregon urologist) caught in the TAP net recently settled with the federal government and agreed to pay \$213,198 to resolve allegations of improper billing of Medicare and Medicaid for free drug samples received from TAP.²¹ As part of TAP's settlement with the Oregon Medicaid Fraud Unit, it gave the Fraud Unit a list of all physicians to whom TAP representatives had provided free samples of Lupron®.²² According to industry sources, other pharmaceutical companies are under investigation by the same prosecutors as in the TAP matter.²³ They also warn of "heightened scrutiny" in the area of marketing and promotion of drugs: "Practices subject to review likely will include disease management programs, advisory panels involving physician input, grants to customers and referral sources, and marketing that targets individual physicians."²⁴ Of course, AWP and drug pricing will continue to be of concern.



Another pharmaceutical company, Schering-Plough Corporation, announced in November, 2002 news of a letter from the U.S. Department of Justice stating that its subsidiary, Schering Corp., was the target of a grand jury investigation of its clinical trial practices. In later updates, the company reported that the investigation included sales of misbranded or unapproved drugs (off-label uses of drugs), submitting false pharmaceutical pricing information to the government for the purpose of calculating rebates to Medicaid programs, providing remuneration (free drug samples and sham clinical trial grants) to managed care organizations and physicians to induce the purchase of company drugs, and document destruction and obstruction of justice relating to the government's investigation.

Other recent CIAs have included in their provisions audits of marketing practices. For example, Bayer Corporation, which entered into an initial CIA in 2001 for its drug pricing practices, entered into an Addendum to Corporate Integrity Agreement effective April 24, 2003, again concerning its pricing practices. It is interesting to note that the government has added a require-



ment for independent review of non-rebate payments Bayer has made to include: (a) speaker agreements; (b) honoraria requests; (c) consulting and other non-consulting arrangement agreements; (d) educational grants requests; and (e) charitable contribution requests. In addition, in July of 2003, Abbott Laboratories entered into a CIA that included an independent review of sales and marketing practices, including “consulting, speaking and other advisory fee-for-service agreements” and product trials. Pharmaceutical companies should take note that pricing practices scrutiny by the government seems now to include, among other things, indirect rebates in the form of consulting agreements, speaking fees, and payments for published articles if they are found not to be legitimate arrangements.

Finally, in mid-May of 2004 the government announced settlement, along with what it called a “groundbreaking” CIA, of a *qui tam* suit against Warner-Lambert and its Pfizer arm. This *qui tam* suit alleged, among other things, that the company employed a “publication strategy” for off-label uses and efficacy using physicians to perform the work normally performed by the company’s sales force; that is, physicians were paid to recommend to providers the prescription of Neurontin® for off-label uses. Other activities targeted as improper included payments to physicians (1) through “consultant’s” meetings, where physicians were paid to listen to speakers about off-label uses of the drug, (2) in the form of grants to physicians who were demonstrated advocates of the drug’s off-label uses, (3) in the form of honoraria for the use of their names on scientific articles intended for publication, which were actually ghost-written by company agents, and (4) for speaker fees in large amounts for making presentations wherein they advocated the off-label use of Neurontin®. Pfizer will pay \$430 million to settle these charges, including \$240 million in criminal fines. Perhaps more significantly, though, Pfizer agreed to restructure its marketing and promotions activities, and to submit to Independent Review Organization (IRO) oversight of those activities.²⁵

Government enforcement of the anti-kickback laws against pharmaceutical manufacturers and the physicians with whom they do business has thus been highly lucrative. Continued enforcement activity, including close scrutiny of relationships with physicians, is likely to continue for some time. Indeed, in considering physician relationships with pharmaceutical manufacturers and the importance of including these relationships in physician compliance activities, it is important to remember that the Anti-Kickback Statute criminalizes and punishes conduct on *both* sides of a knowing transaction; that is, both

the party who pays remuneration and the party who receives remuneration. Accordingly, in any of the above-noted relationships involving physicians, the physicians are potentially subject to liability. However, there remain legitimate reasons to continue those relationships, as discussed below.

V. Serving as a Physician Consultant in Promotional Activities

Certainly some consulting arrangements between pharmaceutical manufacturers and physicians could be characterized as “sham” agreements intended to induce prohibited referrals; however, there are many legitimate purposes for physician consulting arrangements. These purposes range from purely scientific endeavors such as research, to advising on the marketability of products. Healthcare professionals often are best qualified and positioned to provide needed research, sit on scientific advisory boards, advise on new product development, participate in focus groups and otherwise provide legitimate consulting services.

Additionally, pharmaceutical companies have legitimate needs for consulting services in connection with clinical research trials prior to approval of their new drugs. Indeed, because of the difficulty in recruiting and closely following the human research subjects in the setting of an academic medical center, there has recently been a switch from the performance of clinical trials in academic medical centers to the conduct of such research through field trials in actual physician practices. Moreover, pharmaceutical manufacturers do not have the advantage of dealing directly with patients and cannot easily access post-approval drug information on new products that might be derived from following these patients. This kind of follow-up can be useful in promoting a product, as well as in providing information needed for the development of new products. It can also provide information regarding a drug’s side effects or benefits not identified in clinical trials.

Consultants such as physicians and pharmacists are thus instrumental in providing needed information for the development of appropriate pharmaceutical products. They often sit on advisory panels and committees for pharmaceutical companies. This kind of representation is standard in the business world because it provides needed outside expertise.

Healthcare professionals are also used for educational purposes, for marketing drug products or for targeting a particular market for these products. When healthcare professionals are used by pharmaceutical manufacturers for educational and marketing purposes, either directly or

indirectly, navigating through the healthcare regulatory requirements can be a tricky business. By identifying legitimate purposes for the arrangements and structuring them appropriately, pharmaceutical companies and healthcare professionals can significantly reduce any risk of investigation by the government.

VI. Why the Benefits Outweigh the Risks

There are a great many potential pitfalls in relationships between the industry and healthcare professionals ranging from exposure to governmental investigations to actual governmental oversight pursuant to CIAs. Actual investigations, even if they result in no adverse findings, can be time-consuming and costly. Compliance with onerous CIAs over a number of years can stretch the resources of a pharmaceutical manufacturer or provider and is costly as well. Shareholder derivative suits are also a possibility, affecting stock prices as well as the bottom line.

On the other hand, the industry has a real need for the use of healthcare practitioners as consultants in providing a wide range of services ranging from research to education and development of new product lines. Relationships with healthcare practitioners are critical to achieving industry goals of ensuring that patients have access to the products they need and that the products are used correctly for maximum patient benefit. The benefits of legitimate consulting arrangements can thus far outweigh the risks when structured appropriately.

VII. Physician Compliance Activities and Pharmaceutical Marketing

Physicians must include regular monitoring of their relationships with pharmaceutical manufacturers in their overall compliance plans and activities. As is usual in the compliance process, it is helpful for physicians, or their staff members who are delegated the responsibility, to document in policies and procedures the acceptable parameters for these relationships, including the following guidelines:

1. *Consulting and Advisory Payments.* All payments for physician consulting services must be limited to fair market value for *bona fide* consulting or advisory services. If a physician is to be compensated for attending a meeting, the physician must participate at the meeting in an active capacity; that is, for example, the physician might teach a session at the meeting. Such compensation for a physician who attends, but does not present at a meeting, could subject the payment to scrutiny. If a physician is to be compensated for preceptorship, the arrangement should be structured to conform to the personal services safe harbor discussed above.
2. *Samples.* As discussed above in the TAP case, billing for medications that were received as drug samples is forbidden. According to the OIG, if a sample has monetary value to a physician and is used to treat federal healthcare program beneficiaries, giving physicians samples to sell or bill could subject a physician to liability under the Anti-Kickback Statute and the False Claims Act. Physicians should never bill any payer for medications obtained as samples.
3. *Gifts and Gratuities.* The furnishing to a physician or the physician's family of benefits in conjunction with educational or marketing presentations made to the physician can implicate the Anti-Kickback Statute. For example, if a pharmaceutical manufacturer presents drug information to physicians during a free or subsidized Mediterranean cruise, the activity implicates the Anti-Kickback Statute if any purpose of the benefit is to increase the physicians' use of the manufacturer's products. Physicians must ensure that any benefits provided fall within the guidelines set forth above in guidance for such activities from the PhRMA Code or the CPG. Moreover, as the PhRMA Code is generally more stringent in its requirements than the CPG, the most protective approach is likely to adhere to the PhRMA Code guidelines.
4. *"Marketing the Spread".* Drug prices are typically set for government payers using the concept of AWP. Profits, of course, arise from the difference between retail price and AWP; that is, the difference between the amount for which a customer can buy a drug from the manufacturer and the price the customer can sell the drug to consumers. The difference between these prices is known as "the spread." The lower the AWP, the larger the spread and the greater the profit for the end seller. Manufacturers establish the prices for their products and can therefore, to some extent, manipulate the spread. According to the OIG, such manipulation of the AWP for the purpose of increasing physician profits implicates the Anti-Kickback Statute. Therefore, physicians should avoid any relationship in which a pharmaceutical manufacturer's representative actively markets the spread.
5. *Switching.* This violation occurs if a physician receives payment or a benefit in return for changing a prescription from one drug to another, typically from one manufacturer's product or generic drug to a different manufacturer's or non-generic drug. Physicians should accordingly avoid any relationship in which a pharmaceutical manufacturer's representative offers payment in any form in return for changing from one drug to another.



Any policies, procedures, and guidelines adopted by physicians for their practices to address these areas above should be periodically reviewed for compliance with applicable laws, including the Anti-Kickback Statute. Additionally, all physicians, staff, and employees must be fully trained on and understand these policies, procedures, and guidelines.

VIII. Conclusion

While there is now abundant guidance for physicians and the pharmaceutical industry, the best protection remains full compliance within an Anti-Kickback Statute safe harbor. Complying with the AMA Principles of Medical Ethics or the PhRMA Code does not protect physicians from legal investigation or prosecution. In its CPG, the OIG has stated that following the PhRMA Code may help reduce the risk of fraud and abuse and provide helpful evidence of a good faith effort to comply with the applicable federal healthcare program requirements. This type of evidence generally helps mitigate fines and penalties assessed against a company in government investigations and litigation.

It is interesting to note that the CPG, unlike the AMA and PhRMA, does not address the subject of *de minimis* gifts to healthcare practitioners, such as free pens, fruit baskets, free lunches, etc. The AMA and PhRMA both provide that *de minimis* gifts are acceptable under certain circumstances. The AMA, in Opinion E-8.061 states they are acceptable if minimal in value and they are related to the physician's work, such as pens and notepads. The PhRMA Code concurs with the AMA on minimal gifts related to a physician's work, but goes further in identifying acceptable practices and unacceptable gifts. Items primarily for the benefit of patients, such as an anatomical model may be offered to healthcare professionals if they are not of substantial value (\$100 or less). On the other hand, gifts that are personal in nature, such as artwork, floral arrangements, or tickets to sporting events, are not acceptable. While the CPG approves of the PhRMA Code, the actual letter of the Anti-Kickback Statute prohibits *any* remuneration intended to induce referrals.

These three sources have much in common. Their individual focus on educational endeavors and under what circumstances healthcare practitioners may accept payment for consulting, speaking engagements or expense reimbursement are in accord. Together, they define the circumstances under which the industry may fund educational endeavors for third-party sponsored continuing education events and for meetings sponsored by practice associations or boards such as the AMA. They also set forth rules for involvement of the industry in these meetings.

While the AMA offers scant guidance on consulting arrangements, it does state that all interactions between physicians and the industry should be structured in such a way that the focus is on improvement of patient care and on maintaining the independent judgment of physicians in interacting with their patients. The PhRMA Code and the CPG both agree with this focus, but they provide much more specific input regarding consulting agreements and practices that may form the basis for concern. Specifically, certain practices relating to marketing efforts of the industry, such as paying for shadowing arrangements, are highly suspect. Payment for detailing arrangements is also suspect; however, both sources recognize that there may be a legitimate need for such arrangements, and provide advice on how to structure them. Providing funding for grants and research can raise concerns, especially funding for projects after a drug's FDA approval is obtained. Again, however, there may be legitimate needs for such arrangements.

The CPG goes the farthest in giving advice on how to structure the arrangements and is particularly adamant, with respect to research and grants, that the industry separate these functions from their marketing divisions. The CPG also recommends that the industry pay particular attention to structuring arrangements to fall within the safe harbor provisions of the Anti-Kickback Statute, and gives advice on what factors are important when an arrangement cannot be structured to fit within a safe harbor.

In the present complicated legal and regulatory environment, few activities are risk-free; consequently, physicians and their pharmaceutical partners sometimes may face difficult business choices in connection with their relationships. Few activities, however, carry the penalties attached to an Anti-Kickback Statute violation, so that consideration of a possible kickback violation should assume primary importance in any new consulting endeavor. Indeed, many arrangements can be structured to fit within a safe harbor. When the arrangements cannot be so structured, the advisory opinion process under the Anti-Kickback Statute can be one way to obtain certainty of compliance with law or to be assured of freedom from prosecution. Even without such full protection, arrangements can be structured to minimize legal risks as long as the arrangement is set forth in writing prior to any payment, there is a legitimate need for the services which are in fact provided, and compensation is at fair market value (with independent documentation of fair market value).

Although many consulting arrangements between physicians and the pharmaceutical industry have been found or alleged to be illegal, such arrangements remain important and may be pursued under carefully struc-

tured arrangements. Where there is a legitimate need for services and no intent to induce prohibited referrals, proper structuring of consulting arrangements can keep both physicians and the pharmaceutical industry with whom they contract on safe legal ground.

Charlene L. McGinty is a partner and Sandra K. Herron is an associate in the Atlanta, Georgia, office of Powell Goldstein LLP. Ms. McGinty's practice concentrates on mergers and acquisitions, joint ventures, the operation of health care facilities and delivery of health services, professional services contracts, physician contracting, structuring of busi-

ness ventures and tax exemption issues in healthcare law. Ms. Herron's current practice includes representation of a broad spectrum of healthcare providers on a variety of issues including healthcare facility operations, physician and mid-level practitioner recruitment, and physician contracting. Ms. McGinty received her B.A. in 1981 from the University of Kentucky and her J.D. from the University of Kentucky College of Law in 1986. Ms. Herron graduated summa cum laude from Saint Joseph's College with a degree in Health Care Administration and was CEO of a health system before attending Georgia State University College of Law, where she earned her J.D. in 1999.

End Notes

- ¹ Quote is from the game "Monopoly®," produced by Parker Brothers, a division of Hasbro, Inc.
- ² Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, Dec. 8, 2003, 117 Stat. 2066 (codified at various sections of Titles 26 and 42 of the United States Code, including 42 U.S.C. §§ 1395w (prescription drug benefit); 1395q (payments to Critical Access Hospitals); and 1395w (prescription drug pricing).
- ³ See Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase I); Final Rule, 66 Fed. Reg. 855, 920 (Jan. 4, 2001) (codified at 42 C.F.R. Pts. 411, 424).
- ⁴ 42 U.S.C. § 1320a-7b(b) (emphasis added).
- ⁵ For example, see *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985).
- ⁶ 42 U.S.C. § 1001.952(d).
- ⁷ OEI-01-90-00480.
- ⁸ This 1994 OIG Special Fraud Alert can be found at www.oig.hhs.gov/fraud/docs/alertsandbulletins/121994.
- ⁹ 68 Fed. Reg. 23731 (May 5, 2003), found at www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.
- ¹⁰ We recognize, from a business perspective, the tension between compliance with the stringent requirements of the Anti-Kickback Statute on the one hand, and the inherent purpose of any business venture to increase business and profits for the sponsoring company. Unfortunately, the Anti-Kickback Statute and its regulatory provisions make no allowance for business purposes outside the confines of a safe harbor. The issue remains frustrating, but the answer is straightforward: if a company wishes to avoid the significant risks attendant to a kickback violation, relationships must be structured to fit within the four corners of a safe harbor.
- ¹¹ 42 C.F.R. § 1001.952(d).
- ¹² 42 C.F.R. § 1001.952(i).
- ¹³ This document may be found at www.phrma.org.
- ¹⁴ Issued June 1992 based on the report "Gifts to Physicians from Industry," adopted December 1990 (JAMA 1991; 265: 501 and Food and Drug Law Journal, 2001; 56: 27-40); Updated June 1996 and June 1998.
- ¹⁵ 62 Fed. Reg. 64,074 (Dec. 3, 1997).
- ¹⁶ 21 U.S.C. §§301 et seq. (1994).
- ¹⁷ *In re: Cavemark Int'l, Inc. Derivative Lit.*, 698 A.2d 959 (Del. Ch. 1996).
- ¹⁸ See Paul E. Kalb & I. Scott Bass, *Government Investigations in the Pharmaceutical Industry: Off-Label Promotion, Fraud and Abuse, and False Claims*, 53 Food Drug L.J. 63 (1998).
- ¹⁹ See Dept. of Justice Release #513 (October 3, 2001).
- ²⁰ HomeCare, Dec. 1, 2001.
- ²¹ *Oregon Urologist Settles with Government on Allegations of Free Drug Sample Billing*, BNA E-Mail Alert: Health Care Fraud Report (Nov. 17, 2004).
- ²² *Id.*

- ²³ For example, see BNA Health Care Fraud Report, Vol. 7, No. 17, at 619 (August 20, 2003) discussing government subpoenas received by Johnson & Johnson, Merck & Co. and Bristol-Myers Squibb Co. regarding their respective marketing practices.
- ²⁴ HomeCare, Dec. 1, 2001.
- ²⁵ The mandated changes to Pfizer's marketing and promotions activities are extensive, as follows:
 1. IRO review of Pfizer's systems, policies, processes, and procedures relating to consulting arrangements, including a review of: (a) the criteria used to determine whether, how many, and under what circumstances and venue such contracts will be entered and performed; (b) the processes and criteria used to identify and select which HCPs with whom Pfizer enters consultant or other contractual arrangements; (c) Pfizer's tracking or monitoring of services provided or the work performed by the consultants (including the receipt of the consultants' work product, if any); (d) the uses made of work product received from consultants or other contractors, if any; (e) Pfizer's processes for establishing the rates paid to HCPs and the reasons or justifications for any differentials in the amounts paid to different HCPs; (f) whether and in what manner USP Sales tracks or monitors the prescribing habits or product use of individuals or entities with whom it enters consulting or other contractual arrangements, if any; and (g) the budget funding source within Pfizer (e.g., department or division) for the consulting or contractual arrangement.
 2. IRO review of Pfizer's systems, policies, processes, and procedures relating to grants or charitable contributions, including a review of the following items: (a) the processes and procedures used to approve grants or charitable contributions that are followed by personnel in Cluster A and Cluster X of USP Sales and the Grants Committee; (b) the criteria used to determine whether and under what circumstances the funding will be provided; (c) the processes and criteria used to approve recipients of the funding from Pfizer; (d) Pfizer's policies and procedures for requiring the recipient or the recipient's agent to disclose Pfizer's support of the funding and any financial relationship Pfizer may have with the speakers, faculty or other participants; (e) Pfizer's policies or procedures for seeking and memorializing the amounts paid to funding recipients and the purpose or justifications for the amounts paid; (f) Pfizer's policies and procedures relating to the independence of the programs sponsored through the funding; (g) Pfizer's policies and procedures relating to the content and balance of the programs sponsored through the funding; (h) whether and in what manner USP Sales tracks or monitors the prescribing habits or product use of individuals or entities receiving the funding, if any; and (i) the budget funding source within Pfizer (e.g.© Copyright 2004 by Powell Goldstein LLP