

# Over The Edge Brief



Late Breaking News For Northern California Chapter HFMA Members ♦ April 2002

## PROVIDER COMPLIANCE: FOCUS ON PHARMACEUTICALS

*Cary M. Adams, Esq.<sup>1</sup> Copyright © 2002.*

In 2001, TAP Pharmaceutical and various individual physicians and drug marketing representatives paid a steep price for not having had an effective compliance program in effect governing its marketing and pricing of its prostate cancer drug Lupron. The price for TAP:

\$875 million in total fines and penalties, including:

- a \$290 million federal criminal fine in connection with a guilty plea to criminal charges of violating the Pharmacy Billing Act, by allegedly urging physicians to sell free samples distributed by sales agents,
- \$560 million to settle False Claims Act claims in connection with alleged fraudulent pricing schemes, sales and marketing misconduct and failure to provide the best price,
- \$25.5 million to settle related state claims
- a Corporate Integrity Agreement requiring careful compliance procedures overseen by the government in the future,
- five years probation.

In addition, a total of eleven individuals have been indicted in connection with the matter. Four urologists have already pled guilty, while another physician and six TAP marketing personnel have more recently been indicted. Two whistle-blowers, a high-level TAP marketing representative and a

physician and his group, will receive \$77 million and \$17 million, respectively, out of civil settlement proceeds.

The penalties arose in connection with TAP's marketing of Lupron to physicians. One set of alleged violations concerned free samples, which the government claimed had been given to physicians in quantity with encouragement to charge for them in violation of the Prescription Drug Marketing Act. Another set of alleged violations concerned selling to physicians at prices steeply discounted from the reported "average wholesale price" relied upon by Medicare under law for paying the physicians for the same drugs, along with promotion of the opportunity to profit from the substantial spread in prices. By promoting the large spread available to the physicians, TAP was alleged by government prosecutors and agents to have offered and paid a kickback to physicians for prescribing their drugs for Medicare patients. The physician whistle-blower claimed to have been offered a \$65,000 payment styled an "educational grant" but intended instead to compensate him for switching his patients from competing drugs to Lupron.

The size of the TAP settlement suggests that there could be other physicians implicated, although the decision and timing of further prosecutorial efforts are likely to depend upon the individual discretion of different federal prosecutors scattered around the country.

<sup>1</sup> Cary Adams is a partner with the law firm of Murphy Austin Adams Schoenfeld LLP in Sacramento. His practice focuses on corporate and regulatory matters particularly as they affect the healthcare industry. This article is not legal advice, and readers should consult legal counsel for application of the rules discussed herein to their own situations.

Of much greater concern is the potential for similar violations to have occurred with respect to hundreds of other drugs and devices marketed by pharmaceutical and device firms to individual physicians and groups by nationwide teams of sales representatives. Magnifying this threat is the fact that the OIG has now identified the pharmaceutical industry as one of its top priorities for compliance enforcement during the current federal fiscal year. In addition to whatever investigations may be ongoing, this priority includes the planned publication of pharmaceutical industry guidelines for corporate compliance programs, and the recent solicitation by the OIG of comments from the industry regarding what should be included in such guidelines. It is also probable, if past practices are followed, that the OIG will issue a number of “fraud alerts” identifying specific problem areas that it is investigating and encouraging those with information to call one of its hotlines.

Very recent activity by the OIG has been summarized by March 14, 2002, testimony by inspector Janet Rehnquist (daughter of the Chief Justice), before Congress. The OIG has repeatedly and emphatically pointed out to Congress that Medicare’s method of payment for the few drugs that it covers, is flawed. Medicare reimburses 95% of the “Average Wholesale Price” or “AWP.” In the cases of Albuterol and Ipratropium Bromide, two common generic drugs, the OIG determined that Medicare could save in excess of \$200 million per year each, if Medicare would pay only what wholesalers typically pay, which bears no relationship to AWP, a price published for other purposes. Congress apparently adopted AWP for use in setting Medicare payment, without fully comprehending the relationship between AWP and other prices. Alleged abuses of AWP were also a prominent part of enforcement settlements against TAP and an earlier, smaller settlement with Bayer.

Large-scale compliance efforts have been commonplace for a number of years in other sectors of the healthcare industry, including clinical laboratories, hospitals, large physician groups,

skilled nursing facilities and home health care agencies. In each sector, very large financial settlements paid by a leading firm caught in compromising circumstances, followed by a series of fraud alerts, compliance guidelines tailored to the industry, and then a large number of smaller, less news-worthy “mopping up” settlements, has been the pattern. Previous nine figure settlements have paid by National Health Laboratories, National Medical Enterprises (psychiatric hospitals), Columbia/HCA (hospitals), and First American Home Health.

Industry compliance guidelines have already been published with respect to these other healthcare industry sectors. All of the guidelines are based upon a seven part structure identified in the Federal Sentencing Guidelines, including appointment of a compliance officer and compliance committee; establishment of written policies, procedures and standards of conduct; training; effective lines of communication; internal monitoring and auditing; internal enforcement; and effective response to detected offenses. In general, they have reflected a far more conservative perspective regarding compliance than was common in the industry prior to the government’s compliance focus, and the drug industry should expect the same.

In its notice of its intent to publish pharmaceutical industry compliance guidelines, the OIG solicited comment and suggestions from interested parties. There were eight written responses received. These ranged from comprehensive comments offered by the pharmaceutical industry through its association including a complete set of draft guidelines prepared by a major Washington, D.C., law firm in collaboration with one of the Big Five Accounting firms; comments by the physician director of an integrated health care system concerned over various pharmaceutical industry marketing practices; an association of drug store chains; a state Medicaid program; and the 340B Coalition (an organization of safety net providers that benefit from a particular drug pricing program not available to other providers).

Discussed below are a number of healthcare regulatory programs compliance with which is likely to be important as the drug industry takes its turn in the spotlight of concerted federal enforcement efforts.

**Antikickback.** Federal antikickback rules prohibit any person from knowingly offering or paying, soliciting or receiving, any thing of value in exchange for or to induce the referral of patients for which payment may be made under government payment programs. In drug marketing cases, one thing of value illegally offered, in the government's view, is a steep discount from Medicare's payment level, or the free samples provided with the encouragement that they be illegally resold, or the "educational grant" intended to reward a physician for switching his patients from other medications to Lupron. While the pharmaceutical industry has taken the position that AWP was developed for other purposes and should not be used against drug companies who are not prohibited from selling to physicians at whatever price they decide upon, in many cases concerning chemotherapy agents, it is the knowing marketing of the discount as an opportunity for the physician to make a substantial markup from Medicare on the drug that has led to focused attention from prosecutors and other enforcement personnel. It is also likely that Medicare's method of payment for drugs will be altered further, although anyone familiar with pharmaceutical pricing must acknowledge that it is already overly complex. It is fair to observe that past government efforts to regulate such pricing have had many unintended consequences.

Numerous other kickback problems can arise in connection with pharmaceutical sales and things of value given by sales representatives or the company to physicians. Gifts including free food, tickets to events, golf or other minor entertainment, given by sales personnel in an effort to gain time with physicians in order to educate them on the benefits of their products, research stipends given to physicians for services not provided or not needed, travel and entertainment given in connection with

seminars or consulting agreements, even stock options given by biotech companies to advisors to the development of new products, all need to be scrutinized under the federal kickback laws.

There are a number of existing safe harbor regulations that protect specified arrangements, including personal service agreements, and there is the possibility that additional safe harbors will be structured with the pharmaceutical industry in mind. Any arrangement that can fit entirely within the requirements of a safe harbor is likely to be protected from any kickback problems. If not within a safe harbor, however, then the arrangement is within a gray area that should be carefully scrutinized and possibly avoided. The kickback statute is violated if a knowing purpose of the arrangement is to induce or compensate for referrals of patients. Cases have held that if *one purpose* is to induce referrals, then the statute is violated, even if there are other legitimate purposes present.

Gift giving is a basic technique common to many forms of relationship building. In sales, it is accepted that the giving of small gifts can enhance the likelihood that a sale can be made, not because the gift creates a contractual obligation, but that it fosters a personal sense of relationship on behalf of the recipient, a subtle inclination, which can be exploited by the sales person to advantage. The more thoughtful and personal the gift, the greater the effect. Some foreign cultures recognize such gift giving as a formal obligation and expectation of doing business, and indeed, it is customary in many lines of business in the United States, witness the large and growing corporate gift industry. The kickback rules in contrast seek to prevent those in a position to determine or influence the treatment decisions of patients from being unduly influenced by things of value received from those who stand to profit from referrals.

One of the comments sent to the OIG by a physician focuses on the fact that the vast majority of physicians who accept free lunches or snacks in connection with listening to informational

presentations concerning treatment using the pharmaceuticals represented by the presenter deny that such small gifts could influence their treatment decisions. The commenter's point of view, however, is that such physicians delude themselves, and that the pharmaceutical companies would not spend the money without hard evidence that the expenditures actually work to increase sales. It is possible that the OIG will publish new safe harbors that cover certain activities, such as educational seminars, to provide guidance for a common practice that can be defended both as a means of educating physicians, and as legitimate efforts to promote the sale of new drugs, while at the same time protecting against more abusive practices such as the payment of "educational grants" that are in fact kickbacks disguised as education.

**Stark Self-Referral Law.** Because the kickback rules require proof of intent to pay something of value in exchange for or to induce referrals, and because there were studies purporting to show that physicians who owned an interest in clinical laboratories, and later other ancillary service providers, tended to prescribe more heavily the ancillary services offered by their laboratories, Congress enacted the Stark self-referral statute. In its first iteration, this law made it illegal for a physician with a financial relationship (ownership or compensation) with a clinical laboratory to refer a Medicare patient to the laboratory for services, unless the financial relationship fit within one of several specific exceptions defined by statute and regulation. Stark II expanded this law to apply to eleven different designated health services, including outpatient prescription drugs, durable medical equipment, and prosthetics, among others. Recent final regulations are now in effect with respect to many of the exceptions, and a second phase of final regulations is expected in the future. Physicians and ancillary service providers that operate out of compliance with these rules run a serious risk that all services provided in violation of these rules will be treated as improper and the subject of false claims act violations, regardless of whether there is intent or harm to the program. In other words, it is the

referral where a prohibited financial relationship exists that constitutes a violation, and the parties' intent is not an element of the offense.

**Prescription Drug Marketing Act.** This statute imposes restrictions on the handling and distribution of sample drugs, and makes it a violation for providers to sell sample medications. It also seeks to regulate the re-importation of drugs exported from this country (frequently at big discounts from domestic prices), and takes other steps to guard against adulterated product and unfair marketing practices. Management of sample drugs should be an important part of drug compliance efforts by providers who receive them in substantial quantities.

**Getting Started.** Pharmaceutical companies and provider organizations that deal with them who do not have an existing compliance program focused on these and other regulatory programs should consider adopting one promptly, even before drug industry guidelines are published. Because there are already guidelines applicable to physician groups, and other classes of providers, these can either be applied directly, or used as a reference in creating a program. The governing body of the organization should adopt a resolution creating the compliance program and confirming the organization's commitment to ethical and compliant behavior. The resolutions should appoint someone as the compliance officer and create a compliance committee, which can then begin its work, with reference to the seven principle characteristics derived from the Federal Sentencing Guidelines. Review of the OIG's annual work plan as well as recent fraud alerts can help to identify priority items for the compliance committee's agenda. External resources, such as membership in or attendance at seminars put on by the Health Care Compliance Association, or similar groups, can also be of value. The core of compliance work, however, is always defined by the organization itself, its specific activities and the ethical and regulatory issues presented thereby. While large pharmaceutical companies can be expected to have had sophisticated

compliance plans in effect for years, notwithstanding TAP's recent experience, the many newer biotech companies just beginning to distribute their products may be surprised by what they do not know about regulatory restrictions on their marketing efforts.

**Dealing with problems.** The principal reason for having a compliance program, and the principal fear that an organization may have in implementing one, is the likelihood that some compliance problem will turn up. Indeed, an annual audit performed by OIG for 2001 showed that 6.3% of randomly sampled Medicare fee for service billings were out of compliance with applicable regulations, a slight improvement over prior years. While many routine problems are turned up and corrected with minimal harm to the organization, sometimes you find that people have been violating the law, and sometimes with corrupt purposes. There are guidelines published by the OIG for voluntary disclosures of overpayments, which can be made to the Medicare carrier for inadvertent or innocuous errors, to the OIG for more serious violations, and even to the Justice Department where criminal activities are suspected. The handling of such disclosures and repayments shows a lot about an organization and its ethics and compliance programs. Doing it the right way can in the long run bolster the organization's compliance and standing with government agencies. It can also reduce or eliminate exposure to potential whistleblowers. Doing it wrong on the other hand can do serious damage to the organization and to people's lives. For significant repayments and disclosures, professional advice and assistance is advisable.

*The author may be contacted at:*

*MURPHY AUSTIN ADAMS SCHOENFELD LLP  
1000 G Street, Third Floor  
Sacramento, California 95814  
Telephone: (916) 446-2300 ext. 218  
Facsimile: (916) 503-4000  
E-mail: [cadams@murphyaustin.com](mailto:cadams@murphyaustin.com)*