Rx for Industry Fraud

KENNETH J. NOLAN

Since the Enron debacle, whistleblowers have become America's new heroes, and more and more of them are likely to target the pharma industry. (See "Caught in the Crosshairs," *PE*, April 2002.) On their radar screen will be "kickbacks," rebate violations, average wholesale price (AWP) violations, and other fraudulent schemes. For that reason, pharmaceutical executives should work together to implement an industry-wide training program to stop fraud before it starts. Without such a compliance strategy, pharma companies will become increasingly vulnerable to lawsuits for at least four reasons.

First, whistleblowers have already exposed significant illegal pharma company activity through high-profile lawsuits—actions that suggest the industry is a lucrative place to look for more. A former TAP vice-president of sales and a physician exposed a TAP kickback scheme that was settled for $875 million: $290 million in criminal fines and $585 in civil damages. The doctor exposed a salesperson's attempt to bribe him to put Lupron back on his Medicare HMO's formulary. Eventually, he hired a lawyer, went to federal authorities, and filed a *qui tam* lawsuit in partnership with the government. Medicare recovered almost a billion dollars, and, together, the doctor and the former VP netted about $95 million.

In January 2001, Bayer agreed to pay $14 million to the federal government and 45 states to settle a *qui tam* lawsuit alleging that the company engaged in AWP manipulation practices that led to inflated reimbursement claims to Medicaid. Many more such settlements are expected to follow.

Second, more people now know, if they become whistleblowers under the federal False Claims Act and similar state laws, they may be able to earn as much as 15–30 percent of the settlement if the company is convicted of defrauding the government. More states are likely to follow the federal government's lead by enacting their own False Claims Acts, which will encourage even more litigation.

Third, pharmaceutical companies are especially vulnerable to whistleblowers, because they depend so heavily on person-to-person relationships for marketing and distribution. Those professional intermediaries—doctors, hospital administrators, HMO executives, pharmacists, and others—may not be above succumbing to illegal offers from company reps, or they may suggest some of their own. The pharma sector is only as strong as the weakest human link in its supply chain.

Fourth, the industry already has a bad public image, and any whistleblower who exposes it further is likely to gain widespread public support. People want their prescription medications, but they resent paying what they see as excessive costs. The same people who question why a little pill costs $15 dollars may jump at the chance to get even with companies they believe are gouging them.

Self-policing can head off everything from bad press to increased government oversight.

Fortunately, the industry's fate is in its own hands. It can minimize its exposure to whistleblowers, but only if executives are willing to develop an industry-wide, standardized compliance information and training program to avert fraud in each segment of its supply chain. Once in place, such a program may lessen the penalties that companies will face if violations occur. But executives must show that they are serious about regularly training and informing their employees about fraud and abuse and weeding out those engaged in kickback activity. Failure to implement such a preventive strategy could result in monetary penalties and government-mandated corporate integrity agreements, which are often expensive and burdensome to comply with—as Bayer and Abbott have discovered.

Self-policing can head off everything from bad press to lawsuits to increased government oversight. It can minimize the number of lawsuits and send a signal to whistleblowers that the industry is serious about protecting itself. Major clinical labs and other healthcare sectors have demonstrated that, with good results. As always, prevention is the best medicine. The only question is whether industry leaders will take it in the proper dosage—when it can do them some good. ▮

Kenneth J. Nolan is an attorney based in Fort Lauderdale, Florida. He can be reached at knolan@gate.net.