Case in Point: Pharmaceutical Fraud

Diluting Crooked Pharmacist' Drug Treatment Tampering

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Pharmacists who commit fraud by diluting prescriptions pose a serious threat to patients. Integrating new controls to stop these criminals in their tracks might save lives.

Nobody suspected that Robert Courtney was capable of committing fraud. After all, his father was a preacher; he spent his early years enveloped in a world of Christian values in Hays, Kan. His childhood was stable. His family was supportive. After high school, Courtney earned a pharmacy degree and eventually went on to own and operate the Research Medical Tower Pharmacy in Kansas City, Mo. By the time he was in his late thirties, he owned a second pharmacy. Courtney had achieved his lifelong dream of becoming a successful pharmacist and he displayed a lavish lifestyle to prove it.

His first indulgence was a Mercedes, a purchase that launched his grandiose obsession with owning "only the best." Next, he bought an enormous house in the upscale Tremont Manor Enclave, located in northern Kansas City. If material possessions indicate happiness, anyone would have believed that Courtney was in a state of perpetual bliss. However, his personal life told a different story as the emotional effects of committing an unthinkable fraud surfaced. Just prior to purchasing his second pharmacy in 1990, Courtney, then 38, divorced his wife and retained custody of his two daughters. Shortly thereafter, he used his ostentation to attract another woman and, after just four months of dating, Courtney proposed with a four-carat diamond engagement ring. They eloped just after Christmas in 1990, less than a year after his first divorce.

"As long as you are married to me, you'll drive a BMW," Courtney was said to have promised his new wife. He forced her to buy $600 dresses and prohibited her from gaining weight. He flaunted his money when he was around his church friends, while at other times he was stingy. Courtney complained that his parents were "squeezing him for money." At one point, he instructed his wife to find ways to pinch pennies. He soon became as obsessed with saving money as he was with flaunting it. His wife later recalled that when they would dine out, he wouldn't allow her to order her own food and insisted that she eat a small amount from his order.

Courtney began to display extreme mood swings, a possible indication of deception. He was verbally and physically abusive to his daughters. His frightened wife recognized the red flags and left.

Two years later, Courtney married for a third time and exhibited the same erratic behavior he had in the past. According to testimony, he didn't allow his wife to participate in the design of a spectacular new home in excess of 5,000 square feet. He maintained financial control over all the household financial affairs and decisions and forced his new wife to sign a prenuptial agreement. He became obsessed with "feeling needed." In 1999, Courtney pledged to donate $1 million to the building fund of his church. Throughout the 1990s, his outward appearance displayed a high income, but behind the scenes, he was under pressure.

Courtney's luxuries required a substantial level of income to support, much more than he could have possibly generated by his two pharmacies. So how was he making ends meet? Well, he had been diluting patients' potentially lifesaving cancer-treatment drugs for about eight years. But eventually a pharmaceutical sales representative discovered the fraud when he conducted a routine review of the pharmacy. Courtney confessed and was sentenced to 30 years in prison.

Courtney's scheme prevented patients from receiving proper treatment for their diseases. In some cases, he might have contributed to or caused their deaths, though it was never proven. It was a typical fraud triangle, complete with all three angles: opportunity, pressure, and rationalization. Courtney enjoyed a lifestyle that created a need, which generated an internal pressure to meet his financial obligations. He had no supervision, controls, or checks and balances, which allowed him the opportunity to commit this crime. Finally, Courtney rationalized his actions by believing that his patients were going to die anyway. Here, we examine the establishment of internal controls that might help reduce, eliminate, prevent, and/or detect future occurrences of the dilution of pharmaceutical medicines fraud.

GRAY MARKET AND BEYOND

The United States generates $236 billion of pharmaceutical industry's global revenue of approximately $550 billion. By owning two pharmacies, the size of the industry presented Courtney with an opportunity to capitalize on this market. His initial fraud involved buying prescription medications from a retired pharmaceutical representative through the "gray market" - pharmaceuticals for sale outside the authorized distribution channels of the pharmaceutical company that produces the product. According to attorneys Duncan Curley and Lisa M. Ferri, gray market goods, also known as parallel imports, are produced under intellectual property rights held by the owner (or its licensee) for legitimate sale in one market and are then diverted and distributed in a second market without the intellectual property rights owner's authorization.1 By purchasing legitimate

drugs through the gray market, Courtney was able to substantially increase the markup on those drugs and reap a huge profit. He often paid cash under-the-table for additional discounts. The pharmaceutical gray market is illegal and violators who participate in it are subject to criminal prosecution. This was his first departure from ethics and legitimate business practices. As with most schemes of this nature, Courtney's fraud grew. His next fraudulent activity involved diluting the drugs in the prescriptions he received from doctors regardless of whether he obtained the prescribed drugs from legitimate sources.

THE FRAUD SURFACES

The first indication of wrongdoing was in May of 2001. A pharmaceutical sales representative visited a doctor's office and told the staff that Courtney's pharmacy had only purchased approximately one-third of the amount of the cancer-treatment drug Gemzar, which Courtney supposedly provided and billed to that doctor's office.2 The doctor averaged about 100 patient treatments per month, and according to the office records, the doctor was billed and paid Courtney's pharmacy approximately $100,000 per month.3

Based on the sales representative's information, the doctor sent a sample of a prescription ordered from Courtney's pharmacy for the drug Taxol, a cancer treatment drug, to an independent lab for testing to determine if the actual amount of the drug agreed with the prescription. The lab testing revealed that the prescription contained less than one-third of the drug prescribed by the doctor. The doctor then took several samples from the prescriptions received from Courtney's pharmacy and gave them to the U.S. Food and Drug Administration's special agents, who forwarded them to the FDA's Forensic Chemistry Center for testing. The test results confirmed that the samples contained substantially less of the drug prescribed by the doctor than would be required to constitute a full dose. The samples tested contained from 17 percent to 39 percent of the drugs prescribed by the doctor. The doctor's office obtained a second sample of three chemotherapy treatments from Courtney's pharmacy and the results from the independent lab revealed that the amount of drugs prescribed in each of the samples were zero percent, 24 percent, and 28 percent, respectively. To put the fraud into monetary terms, the prescription containing only 24 percent of the required drug netted Courtney $779.37 of profit on just that prescription.4

On Aug. 10, 2001, the FBI and the FDA obtained a search warrant to investigate Courtney's pharmacy. During an interview prior to the search, Courtney confirmed that he was personally involved in and responsible for mixing, assembling, labeling, and distributing at least some of the prescriptions that were tested by the U.S. Food and Drug Administration's Forensic Chemistry Center, according to the district court criminal complaint.5 Courtney couldn't explain why the chemotherapy treatments didn't contain the amount of drugs that had been ordered and was identified on the labels on the chemotherapy bags, the complaint read.6

On Aug. 15, Courtney, with his attorney, voluntarily appeared for an interview with an FBI special agent. During the interview, Courtney admitted to diluting several chemotherapy drugs. He stated that greed motivated him and that he limited the dilutions to the patients of one doctor -- 156 chemotherapy treatments for approximately 34 of the doctor's patients. Courtney was explicit that he hadn't done anything improper with any other drugs and/or anything with any medications/treatments for any other doctor's patients.7 However, further investigations showed that Courtney had, in fact, diluted other drugs and had improperly billed insurance companies for drugs not given to patients. Also, his dilution of the prescriptions caused the doctor unwittingly to submit fraudulent Medicare claims.

INTERNAL CONTROL REALITY

During the process of examining this fraud, two fundamental concepts of internal control came into sharp focus for us. First, there's no guarantee that internal controls or any system of controls can be completely preventative. Auditors, managers, and fraud examiners are all familiar with the concept of reasonable assurance. The American Institute of CPAs' SAS 104 has expanded the concept of reasonable assurance to "the high, but not absolute assurance level of assurance."8 However, when faced with a fraud committed by someone like Courtney, an individual who was aware of the consequences of his actions, the concept of reasonable assurance appears to pose a dilemma because it attempts to provide a level of protection while at the same time acknowledging that there are limitations to any system of internal controls. As unsettling as this thought may be, it's a fundamental environmental attribute of any internal controls system.

And, secondly, the general rule when evaluating internal controls is that the benefit of a control should exceed its cost. However, this cost/benefit analysis concept might be difficult to accept when dealing with life-threatening situations. Also, when you're dealing with the cost of obtaining and providing medical treatments to save lives, cost becomes a significant factor, and measuring the actual cost of establishing a control that provides a high level of protection becomes very complex and involves much subjectivity.

PREVENTING AND DETECTING PHARMACEUTICAL FRAUD

As part of our research for this article, we visited a pharmacy school to discuss Courtney's fraud and possible ways to prevent or detect similar schemes. We concluded that to make the process transparent and traceable, controls over the sale of cancer-treatment drugs to pharmacies (which include accounting for these drugs when they're in the pharmacist's inventory) and prescription preparation need to be better integrated among the other industry controls. A basic-level model (see chart above), shows the steps of supplying cancer-treatment prescriptions from the pharmaceutical companies to the pharmacist who prepares and provides the prescription to the doctor and the patient. (This

model is an adaptation of a standard, fundamental input, processing, and output process used to portray any system.)

Our analysis of the current process of providing cancer-treatment prescriptions shows that the existing system of controls might not provide a method to determine effectively if a prescription is being diluted.

Applying these points to the model, the pharmaceutical representative represents the input stage and the doctor's interactions with the patients represent the output stage. Currently, there appears to be a deficiency in ongoing interaction between these two stages of the model, which illustrates the possible lack of integration among the controls. If there had been a way to compare the amount of drugs sold to Courtney's pharmacy to the number and potency of prescriptions ordered by the doctor, then an analysis could have compared the reasonableness of the amount of drugs sold to the number of prescriptions prepared. At the very least, this type of analysis would have exposed a red flag because the amount of drugs sold wasn't enough to fill the prescriptions supplied. However, this discrepancy wouldn't have automatically indicated that dilution had occurred, because it also could have indicated that the pharmacist was obtaining drugs from another source such as the gray market. Either way, that integration of the controls would have indicated the need for further inquiries into Courtney's case.

The model presents three distinct stages of the process of delivering prescriptions to patients: a company supplying drugs to the pharmacist, a pharmacist preparing and transferring a prescription to the doctor, and the doctor administering the prescription to the patient. Here we try to identify key control(s) and show how, by integrating them, a system is established that offers an overview of the entire process, and allows for the timely identification of potential problems. The two fundamental concepts -- reasonable assurance and cost/benefit analysis -- provide a high level, but not absolute assurance of finding every error.

The needed changes to the control process in supplying cancer treatments to patients begin with the last stage of the model -- the administration of the treatment to the patient. Typically, a patient receives treatments at a doctor's office or another medical facility such as a clinic or hospital. A patient interacts with a medical professional who records how the patient's body responds to the treatment. Several of the drugs have insignificant side effects, but Taxol causes 100 percent hair loss, a result that wouldn't occur in a diluted dose. This record is a key control point.

From our discussions at the pharmacy school, we learned that individual patient results might vary widely. Many factors determine how a patient reacts to a treatment: physical condition, the disease's stage, and even the patient's meal before the treatment. Therefore,

looking at just at the reactions in an individual patient's body might not yield information for control purposes. However, physicians' practices that specialize in cancer treatment, of course, care for more than one patient at a time. For example, Courtney was supplying prescriptions for more than 25 of one doctor's patients. Many of the cancer drugs have well-documented side effects. While individual results from a treatment to a particular drug might vary widely, any significant deviation from the expected side effects recorded for a group of patients might indicate a red flag. The discovery of a discrepancy would require a review of information from other parts of the system.

The next step in the process is to determine the origin of a particular patient group's treatments and, if possible, to test those treatments. This isn't simple. Obviously, it would have to occur after the fact and any testing of new treatments couldn't duplicate the circumstances of the original treatments' administration. However, the integrative approach to the controls comes into play here. In the model, the doctor ordering the prescriptions would have access to the pharmaceutical company's records of the drug sales to the pharmacist responsible for preparing the prescriptions. It's possible with these documents to determine if the pharmacist is purchasing enough drugs to fill the prescriptions ordered by the doctor. This approach might not be completely foolproof, but the system of controls now provides a method of comparing information from the beginning of the process with information from the end of the process. We can now review the system and evaluate the pharmacist's work. A side benefit is that everyone involved is aware that we're making these comparisons, which adds to the overall control.

Integrative controls within the pharmacy are also possible. From our discussion at the pharmacy school, we learned that hospital pharmacies often require that a second pharmacist review prescriptions and approve them if they're correct. The second-review system could become mandatory for all cancer-treatment prescriptions.

However, this control has problems. For example, many pharmacists work alone, and some of these treatments have a short shelf life after they've been prepared. Timing of the second review would be critical. We must consider the cost/benefit analysis of the control. Does the benefit of the second review justify the cost? Moreover, who will bear the cost of the review? These treatments are already expensive. Also, a smaller community might only have one pharmacy, so a second pharmacist review could be difficult but not impossible. Additionally, if a perpetrator knows an independent third party might be testing his or her actions he or she must accept the additional "perception of detection" risk or cease the fraud.

INTEGRATE THOSE CONTROLS

Pharmaceutical fraud poses a serious problem for consumers. The current process of providing drug therapy to a patient poses a glaring weakness: lack of integration of

controls. To maintain integrity in the prescription drug industry, our proposed solution provides a way to address the issue, while attempting to consider two fundamental attributes of any internal controls system -- reasonable assurance and the cost/benefit analysis.

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1 Duncan Curley and Lisa M. Ferri, "United States: Trademark Rights vs. Gray Market Drug Imports" www.mondaq.com/i_article.asp_Q_articleid_E_40096

2 United States District Court Western District of Missouri, CRIMINAL COMPLAINT case number 01-0141L-01, Aug. 14, 2001, page 6.

3 Ibid, page 7.

4 Ibid, page 14.

5 Ibid, page 15.

6 First Amended Complaint, United States District Court Western District of Missouri Western Division, Case No. 01-0923-CW-W-SOW, page 7.

7 Ibid, page 8.

8 AICPA, SAS 104 paragraph 2, Effective for audits of financial statements for periods on or after Dec. 15, 2006, Statements on Auditing Standards NO. 104-111.