Avoiding FDA Fire
Sample Accountability: Employing Compliance Measures


Don Schenker

COMPLIANCE WITH THE PRESCRIPTION DRUG MARKETING ACT (PDMA) HAS BECOME AN INCREASINGLY URGENT ISSUE FOR PHARMACEUTICAL SALESFORCES AND THEIR REPS. AS GOVERNMENT AND INDUSTRY MOVE TO HEIGHTEN ENFORCEMENT OF SAMPLE ACCOUNTABILITY, DRUG MANUFACTURERS AND THEIR SALES REPS FACE SEVERE CRIMINAL AND CIVIL PENALTIES FOR NONCOMPLIANCE, INCLUDING FINES OF UP TO $1 MILLION AND PRISON TERMS OF UP TO 25 YEARS. IN ADDITION, BOTH REPS AND THEIR DIRECT MANAGERS FACE MAJOR PERSONAL LIABILITY — EVEN IF ONLY THE FORMER IS AT FAULT.

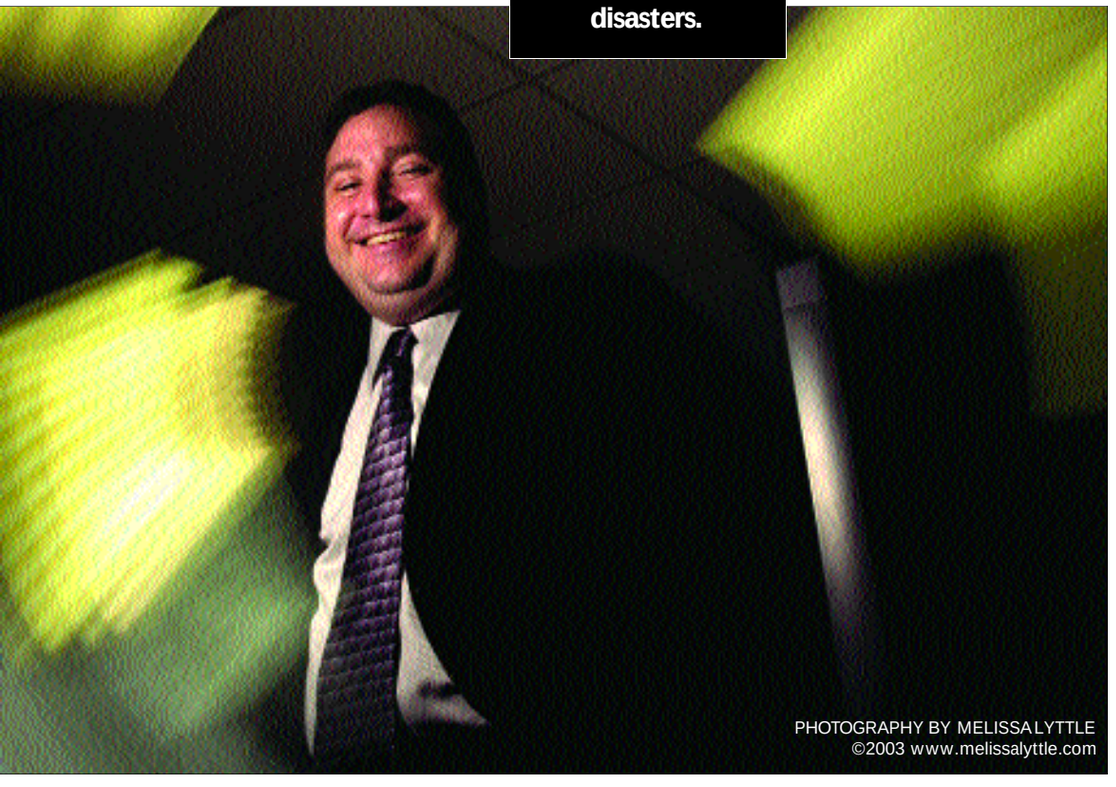
Don Schenker is president and CEO of Synergistix Data Solutions. Synergistix Data Solutions, based in Hollywood, Fla., builds and supports state-of-the-art workflow solutions using the most current and efficient technologies.

Ensuring FDA compliance starts with establishing standard operating procedures. Whether a company chooses to go with an electronic or paper-based solution for sample accountability, it must have procedures in place to prevent disaster.

"It's not easy, especially for the almost 1,800 small and midsize pharmaceutical companies that represent the majority of firms in the industry," says Don Schenker, president and CEO of Synergistix Data Solutions. "Many of these firms have reps who are not company employees, making sample accountability even more difficult to monitor."

Companies must have procedures in place to prevent sample accountability disasters.

With penalties ranging from $250,000 to $1 million, the key is to establish procedures and put them in place as soon as possible to help ensure PDMA compliance. According to Mr. Schenker, the important thing to realize is that sample accountability is not something that can be "taken care of" once or twice a year. It is an ongoing process in which pharmaceutical firms must produce accurate information on demand.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SITUATIONS OF GROSS NONCOMPLIANCE

"Everyone in the industry has heard of the well-known pharmaceutical company that had to pay $875 million in penalties — the largest ever against a healthcare company," Mr. Schenker relates. "The firm agreed to plead guilty to criminal charges that it engaged in a kickback scheme with doctors in marketing its prostate cancer drug. What may not be known is that fully one-third of that penalty had to do with a PDMA violation. The company also agreed to plead guilty to one count of criminal conspiracy to violate the PDMA, for which it paid $290 million of its total fine."

Blatant noncompliance of PDMA exists. According to Mr. Schenker violations range in severity — from criminal acts to acts of omission.

For example, a rep may have a doctor sign for samples and then put fewer samples on the shelf than were signed for. The rep then takes the remainder and either keeps them or sells them for profit. Or, sometimes reps, doctors, and pharmacists are involved simultaneously in prescription drug fraud, each playing a vital role. A rep can have a physician sign for 100 samples, but instead — with the doctor's knowledge — give them to a pharmacy. The pharmacy sells the samples, and the rep, doctor, and pharmacist split the profits.

"There also is the scenario in which a rep from one pharmaceutical firm is given access to the physician's sample closet and ends up not just leaving his

or her own samples — but stealing samples from other companies," he says.

Yet not all cases are so blatant. Many cases of PDMA noncompliance, according to Mr. Schenker, could easily have been averted. For example, a rep may leave samples and simply forget to have the doctor sign for them. Still, it is a PDMA violation,albeit an innocent one.

In another scenario, a rep may leave samples for a doctor who no longer holds an active state license.

"Before the adaptation of the PDMA, the main source for validating physicians was to verify their Drug Enforcement Administration (DEA) number," he says. "With the finalization of the act, this method shifted to state-issued license numbers."

Today, each physician must have the appropriate license and paperwork in place to be given samples. Laws and regulations differ from state to state, and reps and their managers must keep track of these to avoid getting hit with PDMA violations.

"For example, in Ohio, reps cannot give samples to nurse practitioners and physician's assistants, while in Florida, it is perfectly legal," Mr. Schenker says.

Another scenario of PDMA violation, Mr. Schenker says, may be a result of a rep simply being lazy. Usually, a rep's job entails visiting a certain number of doctors each day. If the rep has failed by the end of the day to make all of the required sample calls, he or she may simply forge a doctor's signature and dispose of some of the samples.

"When it comes to PDMA compliance, more often than not it's not a matter of a rep with criminal intent, but rather not following the rules correctly," he adds.

SETTING UP A SYSTEM OF CHECKS AND BALANCES

To ensure ongoing PDMA compliance and avoid getting hit with a hefty fine, the pharmaceutical company needs a long-term strategy to meet regulations, implement programs, purchase and leverage technology, and maintain and monitor the program.

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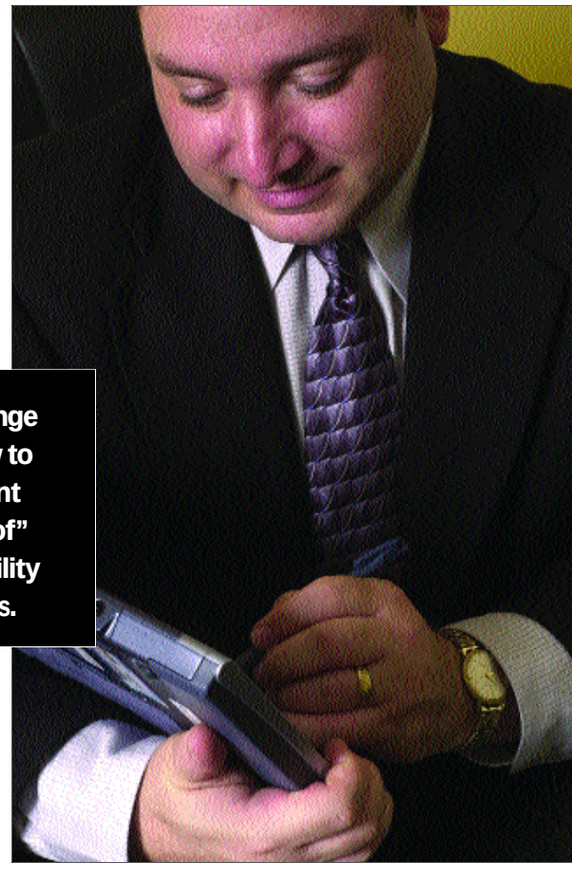
According to Mr. Schenker, the challenge lies in how to implement "fool-proof" accountability programs that will ensure that each sample is accounted for, gets into the correct hands, and is used correctly.

"This requires setting up a system of checks and balances that is either paper-based or automated," he says. "For example, PDMA requires firms to 'balance their checkbooks' at least once a year — verifying sample calls and accounting for all samples left with physicians. To truly ensure ongoing compliance, this 'checkbook balancing' should be done monthly, or at least every quarter.



"Every time a pharmaceutical company gives away samples, it's a lot like writing a check," he says. "The amount on the check and the amount of money taken from the account must match. Likewise, the number of samples signed for and the number of samples actually given to physicians must line up. When such checks and balances are made, it will be easy to see if a physician who writes only 10 prescriptions a year for a certain drug is somehow receiving 1,000 samples annually. Those 'red flags' are exactly what the FDA will be looking for."

USING PAPER-BASED SAMPLE ACCOUNTABILITY TOOLS

Many companies already may have a paper-based sample accountability system in place. A paper-based system does not require a large initial investment, and no training time is needed as most employees are already familiar with how to use and store paper documents. However, Mr. Schenker warns that the paper-based system must be organized to perfection.

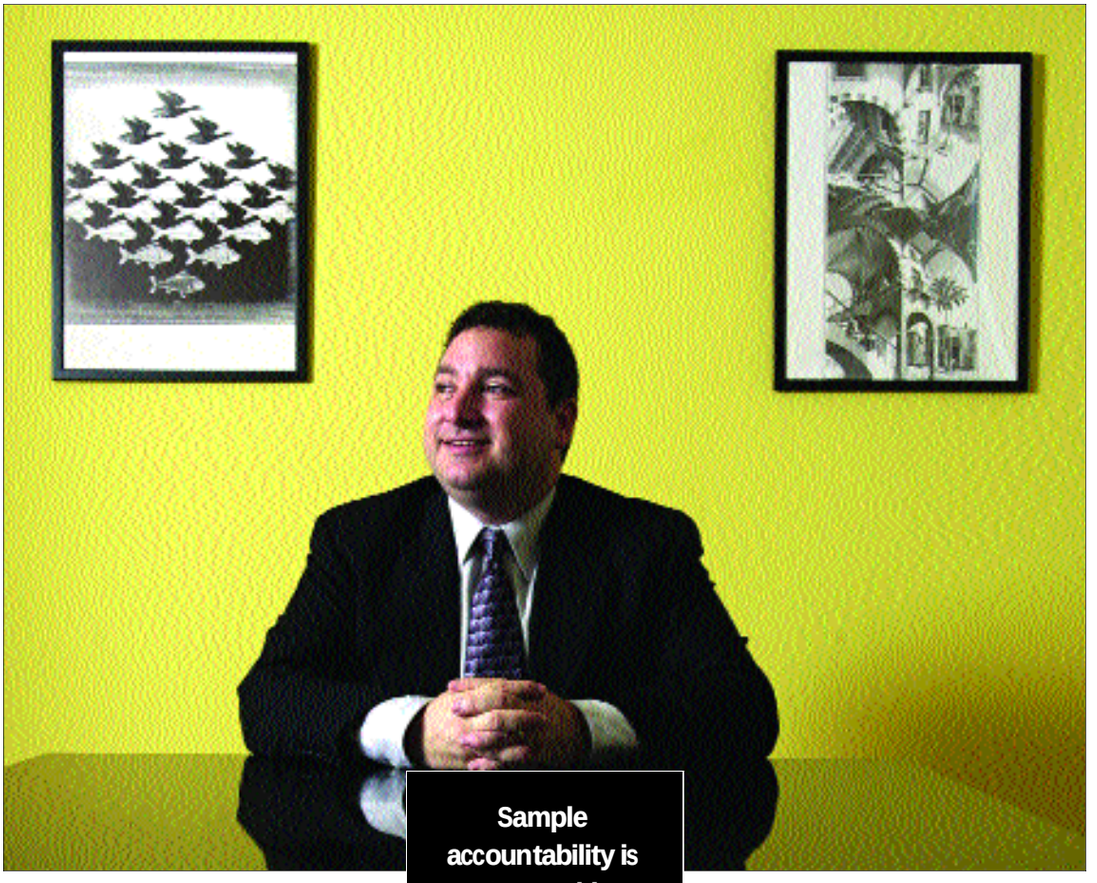
"One of the most ominous aspects of PDMA noncompliance is the personal liability faced by drug reps who fail to comply with the regulation and managers who do not assure compliance within their sales organizations," he says. "That is why proper tracking and recordkeeping, including appropriate classification and storage of documents, is so important."

To ensure compliance, the pharmaceutical company must constantly and consistently account for every sample out there. That means conducting checks and balances on a regular basis.

"For example, a company can review the signatures of physicians chosen at random to verify their authenticity," he says. "This will take some knowledge of handwriting analysis, including examining such things as the curves in various letters. The company also may need to send copies of the paperwork associated with a call to a doctor to check that he or she did indeed receive the samples they signed for."

If a pharmaceutical company is subjected to an FDA audit, the inspector may request that the company go back to its records and produce signatures for the samples given to various physicians. This is the type of information pharmaceutical companies must be able to produce on demand when they fall under PDMA scrutiny.

A paper-based system can work, to a point, Mr. Schenker says. Keeping important records on paper and going back to these documents again and again can be very time-consuming and, unlike electronic records kept in a data warehouse, documents can be lost or misplaced. It is when the pharmaceutical firm is asked to produce accurate information of a specific nature on demand — which will be happening more and more, thanks to PDMA — that the flaws of a paper-based system become instantly apparent, Mr. Schenker warns.



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Mr. Schenker suggests that an automated sample accountability system allows the pharmaceutical company to quickly produce reports on demand, without having to dig through old files. It all but eliminates the human error factor that is so prevalent with paper-based records.

"An automated system can help monitor federally mandated and customer-defined business rules that provide for compliance in sampling to physicians," he says. "It offers a data-capture feature that documents key information, and a suite of Web-based reporting tools that enable managers to run sales productivity and system metrics reports via the Internet. A secure digital signature function assures that physician sign-off cannot be copied, duplicated, or breached."

System integrity assures sampling only to physicians with valid state licenses. Just as important, such a system's back-end data management capabilities allow managers to quickly review and assess physical inventories, monitor trends, variances and practices of individual drug reps, as well as identify any issues or concerns on a daily basis.

Sales reps can access an automated system via hand-held computers, pen-based sub-notebooks, and the new Tablet PC.

"The one drawback of automated systems is that they require training for the salesforce," he says. "However, such training usually only takes a day or so of the employee's time. The time efficiencies they will enjoy by using an automated system will more than make up for it.

THE NEXT STEP

"There's no question about it — PDMA is here to stay," Mr. Schenker says. "The sooner pharmaceutical companies develop a fail-proof system for sample accountability, the better protected they will be."

To find out more about PDMA compliance, consider attending one of the upcoming conferences on the topic. According to Mr. Schenker, the "best of breed" is the PDMA Sharing Conference, which will be held September 14-17, 2003, in Salt Lake City. Information on the conference can be found at pdmaconference.org. The International Narcotics Enforcement Officers Association (INEOA) puts on another valuable conference each year. The next one will be held October 19-25, 2003, in Fort Lauderdale, Fla. Information can be found at ineoa.org. Finally, for the latest news on PDMA legislation, visit fda.gov.

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