Safeguarding The Boardroom
Avoiding Potential Criminal Liability

Preparing Your Sales Force
Legal Issues From Training To Trial
Dear Clients:

The first decade of the twenty-first century has been filled with more than its share of controversial events and ethical dilemmas, many of which have led to legal examination. From mass torts to the ramifications of business decisions, as well as increased attention to marketing activities, companies have faced new challenges and new exposures.

Becoming more common in this decade are “Lone Pine orders,” born in 1986 out of a New Jersey trial court in response to a suit brought by over 400 plaintiffs. Read *Putting the Horse Back in Front of the Cart: Lone Pine Orders in Multi-plaintiff Pharmaceutical Litigation* to learn more about why these orders are a particularly appropriate remedy for the inefficiencies inherent in multi-plaintiff pharmaceutical actions.

Today, we’re living in a post-Enron era, in an economy that is bringing even more scrutiny to executive and corporate conduct. A climate of increased corporate prosecutions is particularly relevant to healthcare companies because of the public welfare aspect these companies implicate. That’s why issues addressed in the article *Safeguarding the Boardroom Against Potential Criminal Liability* can be helpful in reducing risk, better understanding liability issues, and explaining the standards of criminal intent.

Also in this issue of *Pro Te: Solutio* is the first part of the two-part article, *Preparing Your Sales Force, Keeping Legal Issues in Mind, from Training to Trial*. In part one, *Preparing Your Sales Force on the Front End — Initial Training*, learn why plaintiffs’ trial strategies are evolving towards perceived marketing and promotional violations — and how a comprehensive training program is essential to limit your company’s exposure.

We hope you’ll be pleased with this second-quarter edition of *Pro Te: Solutio*, exclusively available to Butler Snow’s Pharmaceutical, Medical Device, and Healthcare clients. In this challenging economy, we feel it’s important to provide information that informs you about and helps to protect you from risk and litigation.

In return, we welcome your comments and questions as we strive to make a difference for those dedicated to making a difference in the lives of others.

Christy D. Jones  
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It’s human nature to share problems. But how often is someone willing to share solutions? Butler Snow wants to do just that — provide scenarios and the solutions that turned a client’s anxiety into relief and even triumph. That’s why we created this magazine, Pro Te: Solutio, which explores how real-life legal problems have been successfully solved.

That’s also why we at Butler Snow redesigned and expanded our unique health-oriented industry group, now comprised of two major sections that handle business and litigation. The Pharmaceutical, Medical Device, and Healthcare Industry Group has more than 50 multi-disciplinary attorneys who provide creative solutions for the complex issues of the healthcare industry. This group includes product liability and commercial litigators; corporate, commercial, and transaction attorneys; labor and employment attorneys; intellectual property attorneys; and those experienced in government investigations.

Pro Te: Solutio is a quarterly magazine available only to the clients of Butler Snow. If you have questions or comments about its articles, you’re invited to contact group co-chairs Christy Jones and Charles Johnson, as well as any of the attorneys listed on the last page of this publication.
PUTTING THE HORSE BACK IN FRONT OF THE CART

Lone Pine Orders in Multi-plaintiff Pharmaceutical Litigation
What Is A Lone Pine Order?

In 1986, a trial court in New Jersey entered a case management order requiring the over 400 plaintiffs who had sued a landfill operator over toxic exposure injuries and damage to property values to offer details regarding their alleged exposure, reports of physicians regarding causation, and specific information supporting claims of property damage. The plaintiffs were unable to meet the burden of the case management order, and the case was eventually dismissed. Thus, the “Lone Pine order” was born.

Since that time, Lone Pine orders have been implemented in state and federal courts in various types of actions and are becoming more common. Lone Pine orders are a particularly appropriate remedy for the inefficiencies inherent in multi-plaintiff pharmaceutical actions and can be an effective tool to streamline the defense of such cases.

Mass Torts Often Include Plaintiffs With No Legitimate Claim

The problems confronted by pharmaceutical manufacturers in defending mass tort claims are no secret. The sheer number of plaintiffs involved, sometimes in the thousands or even tens of thousands, results in an expensive and unwieldy process from the start. This is true regardless of the legitimacy of the underlying claims. In August of last year, six industry leaders — Eli Lilly, Johnson & Johnson, Merck, Novartis, Pfizer and Wyeth — sent a joint letter to the Financial Accounting Standards Board (FASB). The specific purpose of the letter was to address the equity of proposed changes in accounting rules regarding how pending lawsuits should be reported, and in explaining why mass tort cases are so difficult to predict, they illustrated the problems caused by the volume of these actions. The companies explained that:

[...] mass tort defendants often lack the most basic information about plaintiffs who are asserting claims. A mass tort may develop, multiply, diminish, or disappear based on a host of procedural or legal rulings, fact-findings, and other events, none of which can be predicted in advance.3

The manufacturers also zeroed in on the stark lack of information regarding the plaintiffs in such cases:

Plaintiffs and their counsel often have never met, and ‘client meetings’ may be nothing more than e-mail intake forms or phone calls to call centers. Typically, neither the plaintiffs nor their counsel have collected the relevant medical records, much less had them evaluated by an expert. Any particular mass tort plaintiff thus may never have ingested the defendant’s drug; if the plaintiff ingested the drug, the plaintiff may not have suffered any injury; if a plaintiff ingested the drug and suffered an injury, the injury may not have been related to the claimed defect.3

The problem is one known all too well to pharmaceutical manufacturers. Mass tort litigation takes on a vast, costly, and unpredictable life of its own before even the most basic information is known about the plaintiffs and the facts behind their alleged injuries. A single complaint filed on behalf of thousands of plaintiffs may state only the most basic allegations to substantiate the claims — that the listed plaintiffs ingested the drug at issue and that the plaintiffs suffered injuries therefrom. Traditional discovery requires interrogatories, requests for production, procurement and analysis of medical records, depositions of plaintiffs and treating physicians, and expert discovery in order to determine even the basic details of a given individual’s ingestion of a drug and the nature of the alleged injury. Often in the
context of mass torts, this long discovery process reveals that a substantial number of plaintiffs have no case. The time, money, and energy spent defending the baseless claims harms both the manufacturers, who have been forced to defend baseless actions, as well as plaintiffs with potentially legitimate claims but who have been forced to stand in a line crowded by illegitimate plaintiffs.

The inclusion of spurious plaintiffs has several causes. Ordinarily, plaintiffs’ attorneys have an incentive to pursue only legitimate claims, as those are the cases with actual value at the end of the day. However, in the mass tort context, the incentives change as a large number of plaintiffs may be seen in the early stages as a sign of strength. Additionally, just as it is costly and unwieldy for manufacturers to defend claims numbering in the thousands, it is likewise difficult for plaintiffs’ counsel to investigate and verify the validity of claims being filed in such numbers. Even sending a form letter to each plaintiff is a massive undertaking for plaintiffs’ counsel when so many plaintiffs are involved, as is gathering the details and documentation of each plaintiff’s medical history and alleged injury. Thus, a properly drafted and enforced Lone Pine order can force plaintiffs and their lawyers to do early in the process what often is left until years later: specifically set out medical records, medical testimony, and expert proof to support each individual claim of exposure and injury.

The Lone Pine order essentially places the horse where it belongs: in front of the cart; prior to full-scale discovery, the order requires plaintiffs to demonstrate the basic facts supporting a claim of ingestion of the drug, the fact that an injury was suffered, and a medical opinion to establish causation.

**The Practical Effect**

The practical value of Lone Pine orders may differ in each case depending on how stringently a court is willing to draft the order. In some cases, such as the original Lone Pine case, the order may result in all-out dismissal early in the life of the case. In other cases, the order may result in efficiently weeding out unsubstantiated claims early in the process, resulting in a smaller group of potentially legitimate claims for which full discovery is warranted. Even for plaintiffs’ claims that survive the order, the information provided pursuant to the order — evidence of ingestion, specific claims of injury, and medical opinions — allows defendants to hone their strategy earlier in the litigation. This information aids in prioritization of individual plaintiffs, targeted discovery, and overall strategy, whether toward exploring settlement or preparing for trial. Even if a given Lone Pine order does not result in the dismissal of a single plaintiff, the consistent and proper use of such orders in pharmaceutical cases may help create an environment in which plaintiffs’ counsel are motivated and expected to file complaints on behalf of plaintiffs for whom they are immediately prepared to give specific evidence of exposure and injury. Creating such norms in the world of pharmaceutical mass tort would help avoid the problems created by a morass of non-specific claims like those that necessitated the implementation of the Lone Pine order in the first place.

**Strategic Considerations**

Lone Pine orders, as case management tools, are within the discretion of the trial court. Thus, a party pushing for a Lone Pine order must succeed not only in convincing the court that the case warrants such treatment but also that the order should contain the “teeth” necessary to require plaintiffs to comply with meaningful requirements or face dismissal. Anyone with any experience in litigation has learned that rules and procedures may appear iron-clad but often are not strictly followed by the parties or enforced by the court. Courts tend to be hesitant to subject clients to what some may view as draconian punishments for failure to comply with procedural requirements. For this reason, getting a Lone Pine order entered is only part of the battle. The real utility comes with an order that is drafted with clear and enforceable terms, with all parties and the court understanding the requirements and consequences of failing to meet them. Then, it becomes the job of defense counsel to hold plaintiffs to the requirements of the order.

**Horse Of A Different Color: Plaintiffs’ Perspective**

Plaintiffs’ counsel in some instances may be willing to agree to Lone Pine orders but generally oppose them. While it may seem that such an order merely requires the plaintiffs to demonstrate the details of a good-faith claim with a reasonable degree of specificity, plaintiffs may argue that the burden the Lone Pine order places on them is far beyond what
it ought to be. After all, the argument goes, a plaintiff defending against a summary judgment motion need only demonstrate to the court that disputed issues of material fact exist. A Lone Pine order, on the other hand, essentially requires plaintiffs to defend against summary judgment immediately by setting forth a prima facie case within weeks of filing suit and prior to gaining any meaningful discovery from the defendants. Courts often may find such arguments persuasive.

Admittedly, Lone Pine orders may increase the burden and costs on mass tort plaintiffs and their attorneys, but the question, of course, is whether they do so appropriately. After all, Rule 11 requires that claims made in the course of litigation be warranted by law and evidence. The question presented to the trial court is this: In a case with thousands of plaintiffs that have been widely solicited by plaintiffs' counsel who may not have had the opportunity to research each individual's claim, who should shoulder the burden and expense of separating the legitimate claims from the spurious ones? The concept behind the Lone Pine order is that the burden, heavy though it may be, should be placed in large part on plaintiffs and their counsel.

**LONE PINE ORDERS**

**In Pharmaceutical Actions**

While such orders are not routine, courts have entered Lone Pine orders in several pharmaceutical actions. Most recently, in August 2008, a California federal court entered a Lone Pine order in the Celebrex litigation requiring that within forty-five days an expert report be produced for each plaintiff, detailing the specific dates the drugs at issue were taken and specific references to the medical records as to adverse conditions. Lone Pine orders have been implemented by federal and state courts in the Rezulin litigation and a Lone Pine order was entered in conjunction with the Vioxx settlement as well. The continued application of Lone Pine principles to case management in pharmaceutical actions has the potential to build a body of law enabling a more equitable allocation of the burdens involved in pharmaceutical mass tort cases — a welcome development for manufacturers, their counsel, and the legal system at large.

**Conclusion**

Pharmaceutical manufacturers and their defense counsel should petition courts to enter Lone Pine orders in appropriate cases, work to ensure that the orders contain reasonable and enforceable terms, and seek to enforce the terms of the order. The willingness of courts nationwide to enter such orders will be a topic of interest to pharmaceutical manufacturers and their counsel for years to come.

3. Id.
Ever since corporate accounting scandals shocked the financial world at the turn of the 21st century, corporate executives have been on the radar of prosecutors and regulatory officials. Corporate officers and directors are reminded continually of the potential consequences of their management decisions each time a peer makes headlines for alleged criminal misconduct. In view of the current economic state of the nation and the new pronouncements in the 2009 Economic Stimulus Package, executives are likely to be scrutinized even more closely in the future.

Of course, healthcare companies are in no way immune to criminal investigations. In fact, it was the former CEO of HealthSouth, Richard Scrushy, who was the first chief executive charged with violating the 2002 Sarbanes-Oxley Act. Because of the public welfare aspect that healthcare companies implicate, they are often at or near the top of the list of companies susceptible to criminal prosecution. Because healthcare executives could violate a wide range of criminal statutes, from fraudulent financial reporting to misbranding a product, executives must be cognizant that the day-to-day decisions they make not only have civil implications, but can lead to criminal charges as well.

In the post-Enron era corporate prosecutions have increased. In 2007, U.S. Attorneys’ offices alone opened 878 new criminal healthcare fraud investigations involving over 1,500 potential defendants. In view of the increased emphasis on combating corporate misconduct, executives need to stay informed of what may be an indictable offense and take proper steps to prevent even an allegation of criminal activity. It might be clear to an officer or director that his or her individual business decisions have potential ramifications. What might not be apparent, however, is that liability may be imposed for acts the officer did not even know were illegal, or may be imposed based on actions of subordinates working under the direction or control of management.

I. The Ever-Changing Standard of Criminal Intent

Though corporate officers are vulnerable to charges under some common law crimes, most corporate prosecutions involve crimes that are established by federal or state statute. The majority of criminal statutes require evidence of “knowing” conduct; that is, they are general intent crimes that require that the defendant acted with knowledge or awareness of the facts involved but do not require proof...
Although criminal intent is a crucial element a prosecutor must prove with regard to most crimes, be aware that an officer or director may face criminal liability for acts of which they have no direct knowledge.
that the defendant was aware he or she was violating a specific law or regulation. Additionally, some laws mandate that the defendant have “willfully and knowingly” committed the alleged criminal conduct. An act is willful if it is done voluntarily and intentionally with specific intent, and again, ignorance of the law is typically no excuse.5 These terms have often been applied inconsistently by the courts, and much debate has arisen over what intent requirement to apply when corporate criminal liability is an issue.

For instance, in 1995, the Court of Appeals for the Ninth Circuit held in Hanlester Network v. Shalala that a healthcare network had not violated certain Medicare and Medicaid anti-kickback prohibitions.4 The Ninth Circuit interpreted the knowing and willful requirements of the applicable statute to mean the government had to prove the defendants knew the conduct was unlawful and acted with specific intent to disobey the laws at issue. Hence, the Ninth Circuit sided against the general jurisprudence that recognizes ignorance of the law is not an excuse.5 The United States Supreme Court also has held specific intent to be the proper standard in cases involving willful violations of tax laws, holding that, because of their complex nature, such tax laws were “highly technical statutes that presented the danger of ensnaring individuals engaged in apparently innocent conduct.”6 In direct contrast to Hanlester, the Eighth Circuit in United States v. Jain did not allow a defendant charged under the Medicare anti-kickback statute to assert a defense based on ignorance of the law.7 Instead, the court upheld the conviction of a psychologist where the government merely proved that the defendant doctor knew the conduct was “wrongful,” and held the government was not required to prove the defendant knew he violated “a known legal duty.”8 The Jain court held Hanlester was distinguishable because it involved an administrative debarment proceeding.9

Ultimately, the meaning of the term willfully “is often dependent on the context in which it appears.”10 Thus, the language used in each criminal statute can lead to different results. It would be impractical to require an executive to be aware of every potential statutory law that could be implicated as a result of his or her actions. It is practical, however, to be aware of the patently obvious regulations that are applicable in the healthcare arena and to take proper steps with legal counsel to ensure that decisions undertaken in the name of the company are done so with criminal liability issues in mind.

II. The Responsible Corporate Officer Doctrine

Although criminal intent is a crucial element a prosecutor must prove with regard to most crimes, be aware that an officer or director may face criminal liability for acts of which they have no direct knowledge. Under the “responsible corporate officer doctrine,” an officer may be subject to criminal liability for corporate violations of laws that affect the public welfare, even if the officer did not personally participate in the wrongful acts. While such a standard may be hard to reconcile with the previous discussion of criminal intent, the standard is akin to the common law standard of strict liability, which disregards the state of mind of the culpable defendant. The responsible corporate officer doctrine has been firmly established by two United States Supreme Court decisions.

In the first, United States v. Dotterweich, the Supreme Court held that a corporate officer could be held personally liable for the corporation’s violation of strict liability provisions of the Federal Food, Drug, and Cosmetic Act (FDCA). The Court held that the defendant officer had a “responsible share in furtherance of the transaction which the statute outlaws.”11 The Court found that the purposes of the FDCA “touch the lives and health of people which, in circumstances of modern industrialism, are largely beyond self-protection.”12 Finding the defendant could be convicted of a crime even absent involvement or knowledge of the conduct, the Court emphasized that the public welfare component of the FDCA statute at issue mandated imposing strict liability on the officer.13

In United States v. Park, the Court elaborated on this “responsible relation” test. In Park, a case involving mislabeled drugs, a corporate board of directors was found criminally liable for acts of which they alleged they had no knowledge. Finding liability was warranted; the Court held that the executives had “a duty to implement measures that will insure that violations will not occur.”14 The Court noted that while these were demanding requirements, “they are no more stringent than the public has a right to expect of those...
who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.”15 In summary, the Court held that strict liability under the FDCA may be imputed to a corporate officer where it is found that the officer had, “by reason of his position in the corporation, responsibility and authority either to prevent the violation complained of, and that he failed to do so.”16 While this doctrine proffers a harsh result, Dotterweich and Park somewhat restrict the rule.

While a corporate officer may have overall responsibility for the duties and obligations of the corporation and thus is responsible to ensure compliance with the law, the doctrine imposes criminal liability only upon officers who are directly responsible or accountable for the corporation’s compliance. In any potential case, the determination of whether an officer is directly responsible for the conduct is a matter left to the discretion of prosecutors prior to indictment or by judges post-indictment. The question of responsibility, “depends on the evidence produced at the trial and its submission — assuming the evidence warrants it — to the jury under appropriate guidance. […] In such matters[,] the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted.”17 Thus, for the responsible corporate officer doctrine to apply, there must be sufficient evidence to show that the officer had a “responsible relation” to the corporation’s obligation at issue.

As an additional note, Dotterweich and Park involved sections of the FDCA that contained strict liability provisions. While not all criminal statutes contain such provisions, it is important to be conscious of those that do impose strict liability, especially for those operating in an industry where public welfare is of paramount concern.

III. RELEVANT CRIMINAL STATUTES

To take precautionary steps to avoid criminal liability, it is important to be aware of the statutes prosecutors use most often. While numerous state criminal statutes are also applicable to healthcare concerns, the following is a non-exhaustive list of criminal statutes that the federal government may invoke against healthcare executives:

- The provisions of the Federal Food, Drug and Cosmetic Act regarding misbranding and the introduction of unapproved drugs. Further, since there is no statute specifically stating that off-label drug promotion is a crime, prosecutors often use the misbranding statute to prosecute manufacturers that engage in off-label drug promotion beyond the uses described by the FDA-approved label.
- The False Claims Act. The FCA is a civil statute that allows the United States to bring charges against individuals attempting to defraud the government. There is also a criminal counterpart that allows for criminal penalties against anyone who knowingly presents, or causes to be presented, to the U.S. government a false or fictitious claim for payment.
- Numerous provisions of the Social Security Act
- Criminal statutes enacted under HIPAA
- General Criminal Statutes

Officers and directors are advised to consult with counsel to obtain the specific provisions of criminal statutes and regulations that could come into play in their line of business. Information and awareness are crucial to structuring a corporate environment that is shielded from criminal misconduct and potential liability for such conduct.

IV. AVOIDING LIABILITY

Preventing a criminal indictment is certainly easier than attempting to cure one. Prevention starts with a suitable corporate compliance program. Such a program can prevent and detect criminal conduct and minimizes the chance that an executive may be found criminally liable for acts committed by subordinates. Because a prosecutor often uses his discretion to charge individuals in corporate cases, the more preventive measures that an executive can point to that demonstrate an intent to limit criminal conduct, the better.26

The Department of Health and Human Services has cited eight factors that are fundamental to an effective compliance program. While these factors refer to a program involving federally funded research, they are applicable to most any business or industry. An effective program must involve: 1) implementing written policies and procedures, 2) designating a compliance officer and compliance...
Because healthcare executives could violate a wide range of criminal statutes, from fraudulent financial reporting to misbranding a product, executives must be cognizant that the day-to-day decisions they make not only have civil implications, but can lead to criminal charges as well.
committee, 3) conducting effective training and education, 4) developing effective lines of communication, 5) conducting internal monitoring and auditing, 6) enforcing standards through well-publicized disciplinary guidelines, 7) responding promptly to detected problems and undertaking corrective action, and 8) defining roles and responsibilities and assigning oversight responsibility. 27

Such a program will not only help deter and detect criminal actions, but can also be strong evidence of the intent of the parties involved if a criminal investigation is pursued against the corporation and its officers and directors.

Finally, an officer should seek the advice of counsel before proceeding with any decision that seems questionable. Not only can counsel direct an executive as to the legal ramifications of corporate acts and decisions, but advice can provide an affirmative defense. The advice of counsel defense allows officers and directors to protect themselves from liability when they have relied on the reasonable advice of informed counsel and done so in good faith.

This defense negates the element of willfulness, as it demonstrates that the party fully reported the facts to a competent attorney and followed the advice received from that attorney. The evidence must also show that the attorney directed the conduct based on pertinent information and that the party was directed based on sound legal principles. 28

Thus, healthcare officers should involve legal counsel on most major business decisions where liability issues are unclear and should document all information considered, advice offered, and what actions were taken. In most cases, these steps will prevent the “advice of counsel” defense from ever having to be applied, given that taking these steps provides an excellent source of prevention.

The time to consider these issues is not after an officer or director is served with a government subpoena. Being able to point to an effective compliance program and advice from counsel taken on the front-end seriously reduces the chance of a criminal prosecution. In the event that an executive finds himself subject to a criminal investigation, having these procedures in place in the corporation provides a means to argue a good faith affirmative defense. When a corporation effectively implements these measures and the measures are taken seriously, legitimate concerns about criminal liability are significantly reduced.


3 See generally U.S. v. Gregg, 612 F.2d 43, 50-51 (2d Cir. 1979).

4 51 F.3d 1390 (9th Cir. 1995).

5 But see United States v. Mittal, 36 Fed. Appx. 20, 21 (2d Cir. 2002) (recognizing lack of unanimity among circuits as to whether prosecution of the Medicare anti-kickback statute required proof defendant knew of and intended to violate that specific statute).


7 93 F.3d 436, 441 (8th Cir. 1996).

8 Id. See also United States v. Starkes, 157 F.3d 833 (11th Cir. 1998) (Willfully, as used in anti-kickback provision of the Social Security Act, only required knowledge that the conduct was unlawful, not that the conduct violated the specific statute at issue).

9 Id.


12 Id. at 280.

13 See also United States v. Cordoba-Hincapie, 825 F. Supp. 485, 508 (E.D.N.Y. 1993) (“In cases involving matters traditionally within the public welfare realm — dangerous food, misbranded pharmaceuticals, toxic substances and the like — the strong public interests in enforcing the regulations at issue may arguably be viewed as justifying imposition of a strict duty of supervision and control upon corporate officers.”).


15 Id.

16 Id. 673-74.

17 Id. at 669 (quoting Dotterweich, 320 U.S. at 284-85).

18 21 U.S.C. §§331(a) and 352.

19 21 U.S.C. §§331(d) and 355(a).


22 18 U.S.C. §927. Note also that a conviction for submitting false claims to the government almost certainly will bring about civil penalties, as a conviction forecloses any questions relevant to civil liability based on the same underlying acts. See United States v. Diamond, 657 F. Supp. 1204, 1205 (S.D.N.Y. 1987) (“a prior criminal conviction establishes the facts underlying the conviction conclusively for purposes of a subsequent civil proceeding instituted by the federal government on the basis of the same facts.”) See also Photopulous, Todd P., “The (Un) Enforceability of Qui Tam Claims, Pro Te Soluitio, 1, 2, 2.

23 See 42 U.S.C. 1320a-7b(a) (felony to make any false statement or representation in an application for payment or benefit under a Federal healthcare program); 42 U.S.C. 1320a-7b(h) (Federal anti-kickback law that makes it a felony to solicit or receive funds for inducing involvement in a federal healthcare program); 42 U.S.C. 1320a-7b(c) (illegal to make misrepresentations concerning certification to participate in Medicare or state healthcare programs).


25 See, e.g., 18 U.S.C. 286 (conspiracy to defraud the government); 18 U.S.C. 1001 (criminal liability for knowingly and willfully making false statements to the government); 18 U.S.C. 1341 and 1343 (mail fraud and wire fraud); 18 U.S.C. 1516 (obstruction of a federal audit).

26 Note that prosecutors also have the power to enter into deferred prosecution agreements, a somewhat controversial measure that allows a corporation to admit criminal wrongdoing and submit to terms set by the prosecutor in order to avoid indictment.


28 See United States v. Cheek, 3 F.3d 1057, 1061 (7th Cir. 1993) (in order to establish the defense, “a defendant must establish that: 1) before taking action, 2) he in good faith sought the advice of an attorney whom he considered competent, 3) for the purpose of securing advice on the lawfulness of his possible future conduct, 4) and made a full and accurate report to his attorney of all material facts which the defendant knew, 5) and acted strictly in accordance with the advice of his attorney who had been given a full report.”)

WRITTEN by Robert G. Anderson and Jay K. McDaniel
With the increasing globalization of markets and soaring legal costs, firms are beginning to refine their business models for legal services to include legal process outsourcing (LPO) and utilizing international services for discrete projects such as document review and legal research. Benefits of LPO practices include significant savings and timely delivery, as LPO sites (in India, e.g.) typically have lower overhead and operate during American “off-hours.” However, LPO practices are not without potentially serious risks. At stake in LPO transactions are a lawyer’s ethical duties (ranging from competence and supervisory responsibilities to confidentiality and the prohibition against the unauthorized practice of law).

In August 2008, the ABA issued Opinion 08-451. Though permissive of LPO practices, the opinion noted several considerations a lawyer must weigh before engaging LPO services. Paramount among them, a lawyer must ensure that the individuals to whom she has delegated tasks are competent to perform them; and she must oversee the work appropriately. In addition to ABA 08-451, a developing body of ethics opinions speaks to similar issues. Below are ethics opinions, gathered across various jurisdictions, which either implicate LPO practices directly or speak to related issues (such as those governing non-lawyer assistants.) As such, these references may both guide attorneys in their current LPO decision-making and inform future LPO-specific opinions in those jurisdictions.

ALABAMA: Opinion Number 1990-04 (legal research services do not constitute the unauthorized practice of law).

ALASKA: Ethics Opinion No. 73-1 (an attorney may employ non-lawyers to do any task for her except counsel clients about law matters, engage directly in the practice of law, or appear in court or in formal proceedings a part of the judicial process, and so long as it is the attorney who takes the work and vouches for it to the client and is responsible to the client).

ARIZONA: Opinion No. 93-01 (prohibiting the association of a lawyer with a non-lawyer-operated business for the purpose of offering “attorney representation”).

CALIFORNIA: Los Angeles County Bar Association Professional Responsibility and Ethics Committee Opinion No. 518 (legal research and brief-writing are permissible if the attorney is competent to review the work and retains supervisory responsibility for the work product).

San Diego County Bar Association Ethics Opinion 2007-1 (LPO services permitted where lawyer is competent to supervise and client is informed).

COLORADO: Opinions 61 and 79 (extending duties of competence, supervision, and disclosure to clients to the use of non-lawyer legal assistants and prohibiting the unauthorized practice of law by such assistants through appearances in hearings or depositions).

CONNECTICUT: Formal Opinion No. 8 (prohibiting the creation of a partnership with non-lawyers for a consulting and research service limited to the area of taxation and estate and business planning. “The question of what constitutes the practice of law is a thorny question […] That these activities would be engaged in primarily for another attorney rather than directly for a lay client does not alter the fact that the purpose is to offer services of a legal nature, which, when performed directly for a client, can properly be performed only by a lawyer.”).

DISTRICT OF COLUMBIA: Opinion 227 (permits “migratory” paralegals to work for multiple law firms, subject to appropriate screening of conflicts and confidences).

FLORIDA: Opinion 07-2 (a lawyer is not prohibited from engaging the services of an overseas provider for paralegal assistance as long as ethical obligations of unlicensed practice of law, supervision, conflicts, confidentiality, and billing are satisfied).

GEORGIA: State Disciplinary Board Advisory Opinion No. 21 (extending delegable duties to non-lawyers including legal research and fact investigation, while prohibiting others, such as the rendering of legal advice or executing pleadings).

INDIANA: Opinion No. 4 of 1994 (provides for the temporary employment of non-lawyer assistants subject to attorney supervision).

Opinion No. 3 of 2000 (provides for contract employment of non-lawyer assistants subject to attorney supervision, maintenance of client confidentiality, and avoidance of conflicts of interest).

IOWA: Opinion No. 98-21 (permits legal research services for lawyers).

KENTUCKY: KBA E-142 (provides for non-lawyers to perform certain tasks, including legal research, as long as the lawyer remains responsible for and supervises the work).

KBA E-318 (provides that attorneys can establish legal research services for other attorneys, obligating them to preserve confidences).

MASSACHUSETTS: Opinion No. 75-8 (permits legal research services, including use of non-lawyer assistants where the lawyer maintains a direct relationship with the client, supervises the delegated work, and has complete professional responsibility for the work product).

MICHIGAN: RI-310 (permits temporary “leasing” of attorneys, subject to proper supervision and disclosure duties).

MINNESOTA: Opinion No. 8 (requires that non-lawyers be supervised by an attorney who is responsible for their work).
Mississippi: Opinion No. 177 (properly disclosed outsourced legal research is not prohibited).

Nevada: Formal Opinion No. 6 (permits an attorney to operate a collateral business of placing temporary secretarial and clerical help, as long as obligations of client confidences are preserved and disclosure of the attorney is made).

New Hampshire: Formal Opinion #1995-96/3 (permits employment agency to place lawyers, law school graduates, and law students to provide legal and quasi-legal services, as long as such employees properly avoid the unauthorized practice of law, disclose the nature of their employment relationship as appropriate, and comply with the rules regarding client confidences and conflicts of interest).

New Jersey: Advisory Committee on Professional Ethics Opinion No. 101 (prohibiting the creation and advertising of a legal research service by lawyers for use by other lawyers. “We hold that legal research and brief writing—the very foundation of all law practice—do constitute the practice of law”).

Advisory Committee on Professional Ethics Opinion No. 546 (holding as improper the hiring of a non-lawyer assistant in which the prospective employer is presently involved in matters adversarial to the prior employer).


North Carolina: 2007 Formal Ethics Opinion 12 (properly supervised LPO allowed for services such as “reviewing documents; conducting due diligence; drafting contracts, pleadings, and memoranda of law; and conducting legal research.” Client’s written informed consent required).

Ohio: Opinion No. 2005-1 (an attorney who performs research and writing on a contract basis to other attorneys but who is not engaged by, does not meet with, and does not offer advice to clients is not considered to be engaged in the practice of law).

Oklahoma: Ethics Opinion No. 319 (even though a licensed attorney in a supervisory capacity may delegate some law-related clerical tasks to non-lawyers, she must not delegate the professional function of an attorney which requires training, knowledge, and experience critical to effective representation of the client’s interest).

Oregon: Formal Ethics Opinion No. 2005-20 (a lawyer must supervise and control what is done in the lawyer’s name).

Pennsylvania: Informal Opinion No. 2006-04 (permits limited scope representation with the use of law school interns subject to twin responsibilities of reasonable limits and client informed consent; in addition, appropriate supervision is required).

Rhode Island: Provisional Order 18 to the Rhode Island Disciplinary Rules of Professional Conduct (providing that legal assistants are not to engage in services requiring independent legal judgment, shall be subject to the direction of lawyers who will be ultimately and directly responsible for the work product and all aspects of the attorney-client relationship).

South Carolina: Opinion 02-12 (invoking South Carolina judicial interpretation of the unauthorized practice of law and the proper role of paralegal in legal research, investigation, and the preparation of legal documents).

South Dakota: Opinion 2004-01 (permits non-lawyer employees to work for multiple law firms as long as client confidences are protected and the unauthorized practice of law is prevented by adequate supervision).

Texas: Opinion 508 (prohibits pooling employees under a non-lawyer leasing agreement among multiple law firms).

Utah: Opinion 02-07 (allows the association of an attorney with a paralegal outside the attorney’s firm, as long as the attorney’s independent professional judgment is maintained).

Vermont: Advisory Ethics Opinion 2002-02 (permits hiring of independent non-lawyer/paralegal service subject to attorney’s supervision and instruction to protect confidences and avoid conflicts of interest).

Virginia: ABA 08-451 (acknowledged in Virginia State Bar’s ethics database index).

West Virginia: L.E.I. 84-3 (permits operation of legal research service so long as the contemplated research service is limited to the legal profession and not to business or the public and is not advertised or held out in any manner to provide such services to the public at large or outside of the legal profession).

The following states’ ethics rules do not address LPO issues:

Arkansas
Delaware
Hawaii
Illinois
Maine
Missouri
Montana
New Mexico
North Dakota
Tennessee
Washington

The following states’ ethics opinions were not publicly available at the time of publication:

Idaho
Kansas
Louisiana
Maryland
Nebraska
Wyoming

Written by Mark Dreher
Part I of II
Preparing Your Sales Force on the Front End — Initial Training

To the learned intermediary, the face of your company is not the board of directors, not your Chief Executive Officer; not your scientists, physicians, and epidemiologists; and not the multitude of people with whom you may interact on a day-to-day basis, who address the regulatory, manufacturing, and distribution issues related to your products. Rather, to a physician using or prescribing your device or drug, the face he or she most often associates with your company is that of the sales representative. This face could be someone who has been with your company for twenty years or a young twenty-two year old, fresh out of college and working in a full-time job for the first time. Perhaps most importantly, this face may also be the one that a jury associates with your company at trial and whose testimony may be instrumental in securing a favorable defense result. The importance of training and preparing your sales representatives — from a sales perspective and testimony perspective — cannot, therefore, be understated. This article, while not exhaustive, provides a list of possible actions to take during initial training that will give your sales representatives the foundation to be successful in the field and ultimately may limit your company’s exposure.

Initial Training: Compliance

It goes without saying that sales representatives should be trained on anatomy and physiology, medical terminology, and pharmacology, and must undergo training tailored to the specific drugs or devices that the individuals may be detailing. Likewise, sales skills lessons are important to ensure that a consistent, focused message gets to the end user in the manner intended. From a legal perspective, compliance training — teaching the sales representatives what they can and cannot say, do, or use when calling on physicians or other healthcare providers — merits special attention. Educating representatives on the underlying rules and regulations which govern their sales activities and potential ramifications for failing to adhere to the federal, industry, and company mandates, provides context for their application of your company’s policies.

I. Federal Regulations
A. The Approval Process

Although the approval history of a particular drug or device may not seem important on its face in training sales representatives, its purpose is twofold. First, it gives the trainees an appreciation and understanding of what has gone into developing the drug or device
From a legal perspective, compliance training — teaching the sales representatives what they can and cannot say, do, or use when calling on physicians or other healthcare providers — merits special attention.
and getting it to market; second, it offers a history of the development of the labeling—which will essentially provide the four corners within which the sales message must be contained. If applicable, a review of the development process should also include a background on the relevant clinical trials used by the company to prove the product’s safety and effectiveness to the FDA, knowledge which the sales personnel may find helpful in fielding questions from physicians. For a pharmaceutical product, the approval history would include a review of the investigational new drug (IND) application and the new drug application (NDA). For a medical device, this would include a review of the investigational device exemption (IDE), the Premarket Approval (PMA) application, or the Premarket Notification (510k) submission, depending on the device.

Furthermore, a review of the approval process exposes sales representatives to those regulations which form the background of their compliance mandates. Sales representatives are able to see, first-hand, that the FDA heavily regulates labeling and marketing materials. As a result, they may develop a better understanding of why certain things such as off-label promotion and undocumented sampling are off limits.

B. Key Regulations Regarding Sales and Promotion of Drugs and Devices

1. Regulations Regarding Off-Label Promotion

To secure FDA approval for a drug or medical device, the manufacturer must demonstrate that the product is safe and effective for its intended use as labeled.\(^5\) The Food, Drug, and Cosmetics Act defines labeling as “all labels and other written, printed, or graphic matters […] upon any article or any of its containers or wrappers, or […] accompanying such article.”\(^3\) The regulations define labeling as:

Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug, and references published (for example, the Physician’s Desk Reference) for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the FD&C Act.\(^4\)

Regardless of what promotional item individuals use when detailing, sales representatives should always provide and/or present a package insert with every promotional material given to or reviewed by a physician.

The FDA considers the approved product labeling to be adequate directions for use and adequate warning.\(^5\) The product’s uses that are approved by the FDA are sometimes referred to as “labeled” uses because they appear in the product’s approved labeling.\(^6\) Uses that do not appear in the labeling and that are not approved by the FDA are often referred to as “off-label” uses.\(^7\) Off-label uses can include a physician’s using an FDA-approved drug to treat a condition not indicated in the drug’s FDA approved labeling, using the drug to treat an indication but changing the dosing, or using the drug for a different patient population from that in the drug’s approved labeling.\(^8\) While it is clear that a physician may prescribe a drug for any means he or she deems appropriate, regardless of whether that drug has been approved for use for that purpose by the FDA, the same standard does not apply for off-label marketing of a drug or device.\(^9\) In fact, a manufacturer may promote a product only for its intended uses; to do otherwise would be considered “misleading,” and the product itself would be deemed “misbranded.” Some examples of marketing activities that would qualify as misleading under the regulations are:

- promoting a product by suggesting that a product is better, more effective, safer, or has fewer or less serious side effects than have been demonstrated by substantial evidence or substantial clinical experience;
- representing that a product is safer or more effective than another product when no such proof exists;
- using literature, quotations, or references for the purpose of recommending or suggesting conditions of use that are not permitted or approved in the package labeling; and
- using a pictorial or other graphic matter in a way that is misleading.\(^10\)

a. Penalties for Off-Label Promotion

Avoidance of civil and criminal liability, both for the company and individually, is a powerful incentive for employees to adhere to company policy and FDA regulations. As illustrated by a slew of recent enforcement actions, the government is committed to detecting and prosecuting off-label promotion. For example, in 2004, the federal government began investigating Eli Lilly for the off-label promotion of Zyprexa. By January 2009, Lilly was facing criminal prosecution by the U.S Attorney, a civil investigation by the federal government, and civil investigations brought by the State Medicaid Fraud Control Units of the states, all relating to the off-label promotion of Zyprexa. On January 15, 2009, Eli Lilly agreed to enter a global resolution of the criminal and civil action.
elements to consider which will minimize the potential for off-label promotion include the following: ***Draft Written Standard Operating Procedures/Codes of Conduct***

Enact written standard operating procedures (SOP) for promotion and marketing, and have your sales force trained and tested on the procedures. Enact and enforce a code of conduct based on the SOPs, and have your sales personnel sign a certificate stating that they have been trained on the SOPs and that they will pledge to follow them in the course and scope of their jobs. **Audit Your Sales Team**

Periodically audit your sales team, from the detail representatives all the way up to senior management. The audit should include a review of promotional materials, call notes, speakers, and sales team meeting agendas and minutes. **Assess Each Brand for Risk**

Some products will be more susceptible to off-label use by physicians than others. Identify which products may fall into this category and proactively train and retrain the sales personnel responsible for promoting these products. **Train, Train, and Retrain**

Sales personnel in the field should be constantly reminded of their detailing obligations and restrictions. Representatives should be promptly trained and retrained upon the issuance of new regulations or guidance.

**Establish a Written Protocol to Handle Off-label Questions**

Sales representatives expect off-label questions from their healthcare provider clients. Sales personnel should be trained to automatically default to the written company protocols for referring off-label questions to the company’s medical relations/professional relations departments. Off-label discussions should never originate from the sales representative. **Establish a Written Protocol for Use of Call Notes**

If your sales force uses call notes, the call notes should accurately reflect any detailing sessions where an off-label question comes up. The note should explain the nature of the question, actions taken by the representative, and the manner in which follow-up took place. Call notes should never merely reference an off-label question, inquiry, or discussion without making it clear that: 1) the discussion was initiated by the physician, not the sales representative; and 2) that the question was referred to the medical representatives per company protocol. **Train Sales Representatives on Proper Distribution of Medical Journal Articles on Unapproved Uses**

In its recent January 2009 industry guidance document, the FDA addressed its position on the distribution of medical journal articles or publications regarding unapproved uses. While the guidance document should be referenced for the complete details, in sum, scientific or medical journal articles that are distributed should be: a) reputable; b) peer-reviewed; c) neither published nor influenced by drug or device manufacturers; d) supported by sound clinical investigations or trials; e) distributed in unabridged form without marks, notes, or highlights; f) accompanied by the label; g) distributed separately from promotional materials; h) accompanied by a statement describing the information therein as an unapproved use; i) accompanied by conflict of interest
statements; and j) accompanied by a listing of significant risks associated with unapproved uses not referenced in the journal. **No Homemade Sales Pieces**

All sales and detail pieces should be approved and distributed by the company. Any homemade sales pieces — to include modification of existing approved sales pieces — should be viewed as a violation of company protocol resulting in counseling or termination. **Make It Clear Violations Will Not Be Tolerated**

Sales personnel should be informed in writing that violations involving off-label promotion are serious and could result in not only a negative review and/or termination, but could also result in civil and/or criminal liability. **Reiterate and Review Exactly What Comprises Off-Label Usage**

The current indications and labeling should be well understood by the sales team. If it is not in the label, it cannot be promoted.

**2. Regulations Regarding Sampling**

Product sampling is an effective way to provide physicians with a means to distribute samples of your product to patients. A drug sample is defined as a unit of the drug “that is not intended to be sold […] and is intended to promote the sale of the drug.” Furthermore, “No person may sell, purchase, or trade to offer to sell, purchase, or trade any drug sample.” Pharmaceutical companies may provide samples to practitioners upon request so long as the samples provided to physicians are documented by the physician’s name, date, quantity of drug, and type of drug. The sample form should be signed by the healthcare provider receiving the samples. Liability associated with improper sampling methods can be limited by the following:

- ensuring that all sampled products are accompanied by the appropriate package inserts and, if required, the appropriate patient information sheet;
- training the sales representatives to inform the sample recipients that the samples provided may not be sold or billed (this can be incorporated in the sample receipt form signed by the healthcare provider);
- labeling individual samples as sample units that cannot be sold;
- ensuring that all sample recipients verify samples and sign for samples;
- training sales representatives to keep accurate sampling records; and
- conducting periodic, random sampling audits to ensure that sample inventories maintained by sales representatives match the sample distribution paper trail.

**Developing a program to minimize the possibility of off-label promotion will help develop a sales force with the tools and the training to promote in accordance with the regulations and policies. Moreover, a thoroughly developed and properly applied training program can help you demonstrate at trial that your company has a commitment to full compliance with the federal mandates.**

**3. Regulations Regarding Fair Balance**

Promotional and advertising materials must present a fair balance between effectiveness and risk information. The fair balance requirement is set forth in greatest detail with regard to advertising; essentially the same requirements apply with respect to promotional labeling through the FDCA provisions that prohibit false or misleading statements. Related to the fair balance requirement is the mandate that prescribing information accompany most pieces of advertising and promotional materials. Prescribing information in and of itself though is not adequate to meet the fair balance requirements; the promotional materials must still present the information in a manner not only consistent with the labeling, but also in a balanced, equitable fashion.

The only promotional materials sales representatives should use are the ones distributed to the sales force by the company. Accordingly, issues regarding fair balance in promotional materials should be addressed at the outset by representatives from marketing, legal and regulatory prior to distribution to the sales force. Regardless of what promotional item individuals use when detailing, sales representatives should always provide and/or present a package insert with every promotional material given to or reviewed by a physician. Sales representatives should also be timely notified to stop using any and all distributed promotional materials which the FDA may later deem misleading or lacking fair balance.

**II. Industry Guidance**

In addition to the guidance provided by the federal regulations and statutes, companies may also look to industry standards for ethical behavior between healthcare professionals and pharmaceutical and medical device companies. These standards provide a supplement to the regulatory guidelines and provide further proof in the courtroom that your company is taking steps — over and above the federally mandated requirements — to ensure that the sales and marketing message is delivered consistently and equitably in an ethical, responsible manner.

For pharmaceuticals, the Pharmaceutical Research and Manufacturers of America (PhRMA) has promulgated guidelines via its *Code on Interactions with Healthcare Professionals*. For devices, the Advanced Medical Technology Association (AdvaMed) likewise recently revised its *Code of Ethics on Interactions with Health Care Professionals*. For training purposes, the principles
in both Codes provide an ethical compass that sales representatives may use as a reference point — alongside the federal regulations — when detailing their products. Topics covered in the respective Codes include the following:

• cash payments, gratuities, and gifts to healthcare providers;
• educational and practice-related items to healthcare providers;
• entertainment and recreational activities for healthcare providers;
• product sampling;
• conference and meeting guidelines;
• continuing medical education (CME) guidelines and subsidies;
• third-party conferences;
• grants and donations;
• financial assistance, scholarships, or educational funding for medical students;
• sales and promotional meetings;
• consultants;
• reimbursement, billing, coding, and other technical information to healthcare professionals;
• research funding;
• formulary issues; and
• sales force training guidance.

In addition, the PhRMA Code provides a good summary of what companies should consider when training their sales force which touches on many of the subjects raised here:

Companies should ensure that all representatives who are employed by or acting on behalf of the companies and who visit healthcare professionals receive training about the applicable laws, regulations, and industry codes of practice, including this Code, that govern the representatives’ interactions with healthcare professionals. In addition, companies should train their representatives to ensure that they have sufficient knowledge of general science and product-specific information to provide accurate, up-to-date information, consistent with FDA requirements.

Companies should provide updated or additional training in all of these areas as needed for their representatives who visit healthcare professionals.

Companies should also assess their representatives periodically to ensure they comply with relevant company policies and standards of conduct. Companies should take appropriate action when representatives fail to comply.27

III. Conclusion

As plaintiffs’ trial strategies continue to evolve more and more towards alleged marketing and promotional violations, it is imperative that sales representatives have a thorough understanding and appreciation of the compliance obligations inherent in their job. A comprehensive training program provides a foundation for these individuals to effectively challenge any such allegations while also providing the company with an effective way to demonstrate that, at all times, regulatory and industry compliance was at the forefront of its marketing plan.

1 Part II of this series, which will appear in the next Pro Te Solutio, will focus on preparing your sales representatives if and when they are called to testify at deposition or trial.
4 21 C.F.R. §202.10(l)(2).
7 Id.
10 21 C.F.R. 202.1(e)(6). This list is illustrative and not exhaustive.
15 Available at <http://www.fda.gov/oc/op/goodreprint.html>.
17 Id.
19 Id.
22 Id. at 38; see also, 21 C.F.R. §§201.100(d), 202.1(e).
24 “Companies are required to submit promotional materials ‘at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product.’” 21 C.F.R. §314.81(b)(3)(i).
FDA may subsequently require withdrawal or revision of sales pieces if deemed misleading or lacking fair balance.
26 Available at <www.advamed.com>.
27 PhRMA Code on Interactions with Healthcare Professionals at 7.

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