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PERSPECTIVES ON TRAINING AND MONITORING A PHARMACEUTICAL AND/OR MEDICAL DEVICE SALES FORCE

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I. INTRODUCTION

A manufacturer's sales force can be one of its most important assets or one of its biggest liabilities. Sales representatives provide the medical community with necessary technical and marketing information. They can also be a source of liability or provide opportunities to reduce such exposure. They do more than "sell" and educate physicians about the use of the company's products: Sales representatives are the company's front line.

Unfortunately, the activities of sales representatives carry risks. Not only can their actions create legal problems for the company, they can also be an important source of information for plaintiffs' attorneys in pending litigation. A sales representative is likely to have information, not just about how the company wants to promote its products, but about the company's organizational structure, marketing plans, regulatory reporting policies, document retention policies, warnings, product launches, and sales literature. Their understanding of these issues sometimes differs from the company's official policies or positions. Most sales representatives work from home or remote offices, making it difficult for the company to carefully supervise their actions.

This liability potential makes proper training and supervision of the pharmaceutical or medical device sales force an important risk management tool. Ideally, the training and supervision of the sales force should balance medical considerations, marketing needs, regulatory requirements and liability risks. Proper training strikes a balance between effective marketing and risk management: maximizing sales while minimizing liability.

This article presents an overview of the potential areas of legal liability involving the sales force, and a framework for training sales representatives on legal issues, both to prevent lawsuits and to aid the company in successfully defending itself and its products in pending litigation.

II. INITIAL TRAINING

The marketing and sale of pharmaceutical and medical products is unique. The ultimate consumer of the product, the patient, is ill-equipped to make decisions about the selection and use of the product, instead relying on the medical knowledge and judgment of his or her physician. In turn, the physician relies on the manufacturer to provide up-to-date, accurate information about safety, efficacy, testing, and potential risks. This information is transmitted, in part, through sales representatives who, by and large, lack both the medical knowledge of the physicians and the scientific knowledge of those who developed and tested the product. A communication breakdown anywhere in this chain can result in injuries, and in litigation.

However, many potential liability problems can be eliminated (or greatly lessened) by proper training of the sales representatives, both upon hiring and through periodic refresher courses. This training should include a generalized

discussion of products liability principles, the risks inherent in the marketing of medical products, and the role of the sales representatives in avoiding and defending litigation.

In addition to the traditional topics - which cover the science, product specifications, and marketing strategies - an effective training program should include a discussion of the role of the sales representative in creating and minimizing legal liability for the company. The goal is both to increase the sales representatives' level of awareness so that they recognize the role they play, and to enable them to identify and respond to situations of potential legal liability.

In order to increase the chance that this training is not disclosed in future litigation, it is recommended that this overview be given by an in-house attorney or by an outside attorney familiar with the issues. This format may allow these communications to be protected from future disclosure via the attorney-client and/or work product privileges.

The overview should cover the following topics:

A. Product Liability

At the outset, a brief overview of the legal theories involved in a product liability action should be given. Again, the goal is to increase general awareness of the sales force, not to make them lawyers. It should be pointed out that although products liability lawsuits take many forms and vary with each state's laws, a lawsuit typically includes allegations of strict liability, negligence, and/or breach of express or implied warranties. Regardless of which of these allegations are included, the essence of products liability is that the product contained a defect which caused injury to the plaintiff.

There are three general types of recognized product defects: design defects, manufacturing defects, and warning defects. A design defect occurs when, although a product was made according to specifications, there is an inherent flaw in the design which makes it dangerous. A design defect will appear in every unit of the product, making design defect claims particularly dangerous because they can result in a flood of litigation from every user of the product.

A manufacturing defect occurs when one unit of the product differs from the manufacturer's intended result. This type of defect is difficult to prove for most pharmaceutical products and it is, therefore, more common in medical device litigation.

Finally, the most common products liability claim is a warning defect, also called a "failure to warn." Warning defects occur when the plaintiff alleges he or she was not adequately informed of the dangers associated with the use of the product and that, had the dangers been disclosed, plaintiff would have refused to use the product. Failure to warn claims are common because they are usually the easiest to prove: rather than hiring a specialized expert engineer or pharmacologist to testify about the design or manufacture, the plaintiff need only hire a local physician to testify that the warnings were inadequate, or that additional or different warnings would have affected the doctor's decision to prescribe the product. Such testimony is much easier to obtain and more subjective in nature.

B. Overpromotion

Overpromotion - the overly aggressive marketing of a product - is the most common pitfall of zealous sales representatives and the most critical liability risk. It can be in the form of overstating a product's benefits or minimizing its risks. Such activities result in a failure to adequately warn physicians of the product's dangers, even where the written warnings are otherwise adequate. The fact that the package inserts and other written labeling fully comply with applicable FDA requirements will not preclude liability where: (1) the company overpromotes the drug; and, (2) those promotional efforts cause the physician to prescribe the drug to plaintiff.¹

The most obvious form of overpromotion is when the sales representative affirmatively misrepresents the safety of the drug or device. For example, manufacturers can be subject to liability where the sales representative misstates the safety of the drug,² or overstates the case by using terms like "absolutely safe."³ Overpromotion can also occur when, to allay a physician's concerns, the sales representative makes misrepresentations regarding ongoing research concerning the product's safety or minimizes reports of adverse events.

In addition to such obvious examples of overpromotion, there are many more subtle forms. For example, it occurs when, although there are no outright misrepresentations, the sales representative "waters down" the written warnings in his or her conversations with the physicians.⁴ Courts have found that written warnings were diluted by sales representatives who (1) failed to draw the physicians' attention to revised package inserts identifying new risks or indicating higher risks than previously described;⁵ (2) touted the safety and indications of the drug in sales calls without discussing the dangers;⁶ (3) did not draw physicians' attention to reports in literature of dangers associated with use,⁷ or failed to honestly address questions about reports in the literature; or, (4) were encouraged by management to inaccurately counter physicians' concerns regarding the drug's dangers.⁸

Finally, promotional give-aways such as notepads, calendars, and the like, may be evidence of overpromotion, and the number and types of give-aways provided to physicians have been admitted into evidence by some courts.⁹

The provision of adequate, balanced warnings to physicians is perhaps a manufacturer's best defense against liability. Too much time and energy is invested in the creation, approval, and distribution of proper labeling to permit the dilution of warnings. Although aggressive marketing may be necessary in today's competitive pharmaceutical marketplace, marketing zeal should be tempered with careful training to avoid overpromotion and reduce liability.

C. Off-Label Use

Somewhat related to overpromotion is the concept of an "off-label use"; it is the promotion of a product for uses other than those approved by the FDA. Physicians are, of course, permitted to use a drug or device for any purpose which they, in their medical judgment, believe will assist the patient. Great strides in medical treatment have been made because physicians discovered previously unrecognized uses for a drug or device.

In contrast, however, manufacturers can only sell and promote products for those uses which are approved by the FDA. Promotion for unapproved “off-label” uses is prohibited, even if it has become the standard in the medical community to use a drug or device for a certain unapproved use.

Sales representatives should therefore be aware of potential unapproved uses and be careful not to promote drugs or devices for those uses. For example, sales representatives should use caution when a specialist requests samples or information regarding a product not approved for use in that specialty, when a hospital department orders a device not approved for use in that department’s specialty, or when a physician expresses an intention to use the product for an off-label purpose. Sales representatives should also use caution when responding to a physician’s questions about an off-label use, lest they be deemed to have promoted that use.

D. Distributing Published Literature Regarding Off-Label Uses

Even though manufacturing companies may not promote off-label uses for an approved drug or medical device, scientific advancements regarding off-label uses are often published in journal articles or reference publications which then may be disseminated by manufacturers to health care professionals.

Recognizing that the public’s health may be advanced by a health care professional’s receipt of such literature, the FDA, on February 15, 2008 released a draft guidance providing its recommendations concerning “Good Reprinting Practice” which contained specific requirements for manufacturers to follow when disseminating articles regarding off-label uses of its drug or medical device.

1. Requirements An Article Must Meet Before Considering Its Dissemination

Before a company disseminates an article to a health care professional regarding off-label use of its product, the company should confirm that the article: (i) is published by an organization who maintains on its editorial board independent expert(s) with relevant expertise related to the proposed article; (ii) has been peer-reviewed; (iii) is not in the form of a supplement or company sponsored publication; and (iv) is not primarily distributed by, or written at the request of or edited by, a drug or device company.

Examples of publications that do not follow the above listed guidelines include letters to editors, abstracts of a publication; reports of Phase 1 trials in healthy subjects, or references to publications that contain little or no substantive discussion of the relevant investigation or data.

2. Requirements A Manufacturer Should Follow When Distributing The Article

Before a manufacturer distributes an article related to off-label uses of its drug or device, the manufacturer should confirm that the article meets the following standards: (i) the article should be unabridged; (ii) the article should be clean of any highlights, summaries or other conclusory statements made by the manufacturing company; (iii) the article must prominently state that the uses described have not been approved or cleared by the FDA; (iv) a full disclosure of any financial interest by the author of the article must be prominently stated; (v) significant risk or safety concerns known to the

manufacturer related to the off-label use must be disclosed; (vi) the article must be accompanied by the approved label or product insert; (vii) the article must also be accompanied by a full biography of publications related in any way to prior publications of the device, studies and findings; (viii) the article shall be accompanied by a representative opposing article that reaches a different conclusion, if one exists; and (ix) the article may not be included with promotional materials.

The FDA's new draft guidelines have not yet been formally adopted, however, they do provide direction to companies when considering the dissemination of articles or publications related to off-label uses of its product.

E. Document Handling and Retention

Company documents, including those of sales representatives, are critical evidence in most cases. Unfortunately, most sales representatives work from home or from a remote office, making it difficult for management to keep track of their documents. Some sales representatives retain everything; such a practice can cause problems if that sales representative is ever subpoenaed for deposition and asked to produce records in his or her possession, or if the sales representative has kept copies of documents which the company has destroyed pursuant to a valid document retention policy. Other sales representatives will save nothing, perhaps making it difficult to track information needed for a lawsuit or creating liability issues (including, potentially, a spoliation of evidence claim) by violating the company's document retention policy.

Although most manufacturers have specific policies regarding transmission of certain documents, including call sheets and sample records, to company headquarters, many have no provisions for other types of documents. Manufacturers should consider providing instructions to sales representatives regarding document retention for all documents, including diaries, appointment books, and the like. Companies that periodically provide follow-up training materials to sales representatives should also consider creating policies regarding the retention, destruction, or return of those documents. Ideally, even though sales representatives work away from the company's offices, they should operate under the company's overall document retention policy, and safeguards should be created by management to ensure compliance with these policies.

F. Company-Sponsored Meetings and Conferences

Manufacturers often host or sponsor meetings for physicians about their products, and these meetings provide an important forum for exchange of information about the products. Such meetings can take many forms, ranging from a simple in-office presentation for a physician and his or her staff, to attendance at hospital grand rounds, to more formal meetings with medical experts or panels to discuss the risks and benefits of the products and reported adverse reactions. Similarly, sales representatives may participate in physician conventions, trade shows, or product launches where they communicate with physicians about the company's products.

These meetings, while undoubtedly an important sales tool, can also be a source of liability. All presentation materials and written materials distributed to physicians at any meeting must comply with the FDA's labeling guidelines. In addition, statements made by company employees at such meetings must be consistent with the

approved labeling and can be admissible evidence of the company's knowledge regarding a particular risk or of overpromotion.¹⁰ Sales representatives should be cautious about their statements at such meetings.

G. Homemade Promotional Materials

All promotional literature and materials provided to physicians by sales representatives must be reviewed and approved by the FDA, and the distribution of unapproved materials can result in substantial fines.¹¹ Sales representatives must take care not to distribute any "homemade" materials to doctors, no matter how innocuous or similar they may be to the company's approved materials.

H. Comparisons to Existing Products

Manufacturers are constantly improving their products, and sales representatives are understandably anxious to have customers replace old items with new and improved products. However, in their efforts to sell new products, sales representatives should be careful to avoid criticizing the older products. For example, if a company has introduced a new type of cardiac monitor, a sales representative should be instructed to avoid the temptation to promote it by suggesting that the older model is less reliable or in some way defective.

I. Gifts to Physicians

The American Medical Association (AMA) has promulgated detailed ethical guidelines for physicians, and sales representatives should be aware of the portions of the Code of Medical Ethics that pertain to the pharmaceutical industry.¹² Physicians are permitted to accept promotional materials from sales representatives, as well as modest gifts which "primarily entail a benefit to patients and should not be of substantial value" such as textbooks.¹³ Physicians cannot accept honoraria or reimbursement of travel expenses for attendance at out-of-town meetings unless the physician is on the faculty of the conference or is a true "consultant" to the company.¹⁴ However, manufacturers are permitted to provide funding directly to conference sponsors to underwrite registration fees.¹⁵

The Advanced Medical Technology Association (AdvaMed) also has a Code of Ethics, which addresses gifts and subsidies to physicians. The AdvaMed's Code provisions are essentially identical to the AMA Code. Sales representatives should be familiar with the applicable Code of Ethics, and should not provide gifts or subsidies to physicians that violate those provisions.

J. Using Confidential or Insider Information to Promote Products

Sales representatives understandably want to know which physicians are writing prescriptions for the company's products and with what frequency; such knowledge may well affect their sales strategies. One source that some sales representatives may use to obtain this information is local pharmacists, i.e., by reviewing prescription scripts or the pharmacy's computer records.

Sales representatives need to be aware that this practice raises serious invasion of privacy concerns. The patients undoubtedly have a right to keep information about their medical treatment private, and this would include

information about the drugs and products prescribed to them. Disclosure of such practices in subsequent litigation may not only expose the company to added liability for the invasion of privacy, it will also aid a plaintiff's argument that the company is willing to engage in questionable acts to sell its product and may well alienate a jury.

Another problem situation can arise in the managed care field. With the increased prevalence of managed care, more and more health insurers are creating "formularies" of accepted pharmaceuticals, allowing only a limited number of drugs indicated for a specific purpose to be included in the formulary. Some HMOs go so far as to prohibit the detailing of non-formulary drugs to the plan's physicians. Clearly, inclusion in the formulary can be critical to a drug's success, and it may be tempting for a sales representative to make contacts with "insiders" in the hope of getting a drug onto the formulary. Again, as with the use of prescription information, these types of practices may not only cost the company a customer, but, if disclosed in subsequent litigation, could damage the image and credibility of the company.

K. Providing Samples to "Self-Prescribing Doctors"

The supply of samples to physicians is a critical element of effective marketing. Unfortunately, some physicians request samples for their personal use. Self-prescribing is a practice prohibited under the AMA Code of Medical Ethics.¹⁶ A difficult situation arises when a sales representative becomes aware that a physician is using samples for self-medication. Depending upon the circumstances, a sales representative may want to consider refraining from providing samples to physicians whom they know to be engaging in this practice.

III. RESPONDING TO ADVERSE INCIDENTS

When a patient using the company's product suffers an injury, the physician is likely to contact the sales representative to discuss the matter, or at the very least may mention it during the next sales call. Sales representatives should be properly trained to address such incidents, both from a regulatory and a litigation perspective, as the representative's response to the adverse incident may well set the tone for future litigation, or may help avoid litigation altogether.

A. Regulatory Reporting

The FDA has established detailed requirements for the reporting of adverse incidents involving prescription drugs and medical devices.¹⁷ For medical devices, a Form 3500A must be filed with the FDA whenever the company learns that the device may have caused or contributed to a death or serious injury, or where the device has malfunctioned and a recurrence of the malfunction would likely cause or contribute to a death or serious injury.¹⁸ The filing of this report does not constitute an admission of liability or wrongdoing, and the company can note on the report that it denies that the device caused or contributed to the injury.¹⁹

As for prescription drugs, the FDA requires that a Form 3500A be submitted to the FDA within 15 days of learning of an adverse drug reaction that is "serious" (fatal or life-threatening, permanently disabling, requiring hospitalization, prolonging of an existing hospitalization or a congenital anomaly/birth defect, cancer, or

overdose) and “unexpected” (not listed in the current labeling or is greater in severity than that listed in the labeling).²⁰

Because of their frequent contact with prescribing physicians, sales representatives may well be the first company employee to learn of an adverse reaction to a product. Sales representatives should be instructed as to the requirements for filing reports, and should be told who at the company to contact if an adverse incident involving the company’s products is revealed during a sales call.

The failure of a sales representative to comply with the regulatory reporting requirements can result in more than a regulatory violation. In subsequent litigation it may be used to show a corporate pattern of under-reporting adverse events, thus undermining both the company’s data concerning the prevalence of particular adverse events and a potential argument that a risk was not known or knowable.

B. Post-Incident Retention/Retrieval of Products

When an adverse incident involving a medical device occurs, the device or packaging may be key pieces of evidence, particularly where there is an allegation of a manufacturing defect or an issue of product identification. Analysis of the device can help to form a solid defense (or, in some cases, help identify cases appropriate for early dismissal or settlement). Sales representatives can help ensure that the product in question is properly preserved by physicians or others, and that the device is properly labeled so that it is not confused with devices from other patients.

Normally, however, a sales representative should attempt to obtain possession of the involved product and all of its components.²¹ A detailed protocol should be developed for processing and handling such products, including how and when a sales representative should attempt to obtain a product, how a product should be labeled and how and where it should be stored. The protocol should also outline the procedures to follow when the sales representative is unable to take possession of the product. The protocol should provide for some method of product identification and for procedures to minimize the risk that the product will later be lost or destroyed.

Failure to establish or enforce such procedures with respect to a product or company documents can result in potential liability under a spoliation of evidence theory. Spoliation of evidence results when a person or company negligently or intentionally takes action which destroys or damages evidence important to the lawsuit, and that action hinders the plaintiff’s ability to prove his or her case. Sales representatives should be made aware that their actions regarding such “evidence” - whether it be the product itself or the sales representative’s documents - can create this liability and can impact the outcome of litigation.

C. Direct Contact with Patients or Presence During Procedures

A growing area of litigation in the medical device field involves direct contact by the sales representative with the patient. This can come in many forms: the sales representative may be in the operating room, observing the procedure or perhaps providing technical input to the surgeon concerning the device; or the sales representative may visit the patient after the procedure to observe or test the functioning of the device. Either

way, if litigation ensues, the plaintiff's attorney is sure to discover the sales representative's involvement.

This can result in two potential areas of liability. First, presence in the operating room can involve the manufacturer in what would otherwise simply be a medical malpractice action. Second, under the learned intermediary doctrine, a manufacturer's duty (with few exceptions) is to warn the physician, not the patient. However, if a sales representative has direct contact with the patient, it is possible that a court could disregard the learned intermediary defense. Sales representatives should therefore exercise caution when observing procedures or communicating directly with patients.

D. Role in Lawsuits

Of course, no amount of training will prevent all litigation. Once a lawsuit is filed, the sales representative may be a key player in the company's defense. The key is to prepare the sales force before and during litigation to ensure that they help rather than hinder the company's case.

As soon as the company learns of a new lawsuit, the sales representative for the prescribing physician should be identified and notified of the pending suit. The company should also gather all information it has received from the prescribing doctor or the sales representative concerning the lawsuit. As early as possible, the sales representative should be interviewed by appropriate management personnel and the in-house or outside counsel assigned to the matter - the presence of the attorney aids in ensuring that the conversations will be deemed privileged and protected from disclosure. Make sure the sales representative brings all documents in his or her possession regarding the incident and the physician to the initial interview.

This initial interview serves several purposes:

- It gives the company insight into the incident that is probably not revealed in the complaint;
- Permits a preliminary evaluation of the legal issues presented by the suit and a preliminary strategy;
- Educates the sales representative about the litigation process and the representative's role; and,
- Permits evaluation of the sales representative as a potential witness.

The first order of business at the initial interview is to admonish the sales representative not to discuss the case with anyone - not other sales representatives, not the plaintiff's counsel, not even the doctors. If doctors or hospitals are named as defendants in the suit, it may well be a topic of conversation among hospital and medical office personnel - all of whom might someday be asked to testify about their conversations with the sales representative. The company's law and public relations departments can help formulate an approach to the doctor that recognizes the customer relationship without harming the company's litigation strategy.

At the same time, clear channels of communication must be established between the sales representative and the company. Make sure that the sales representative knows who to contact if he or she has questions, if there are media inquiries, or if he or she receives service of a complaint or a subpoena.

At the interview the following issues should be covered:

- Review in detail the sales representative's recollection of visits to this doctor or hospital;

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- When sales calls were made in relation to the incident;
 - Whether the physician is experienced with the particular drug or device;
 - Whether this drug or device is indicated for uses within this physician's specialty and, if not, why this drug or device was detailed to this physician;
 - Whether the physician had particular questions about the indications for use and the risks and, if so, how the sales representative responded;
 - Whether revised labels or package inserts were provided shortly before the incident and, if so, whether the sales representative called the physician's attention to the new or revised warnings;
 - Whether promotional items were given to the physician;
 - What the sales representative has heard in the field regarding the details of the incident;
 - Whether regulatory requirements and company policies regarding samples and call records were met;
 - Review of the representative's records regarding sales calls, samples provided to the attending physician, and direct contacts with the patient; and
 - Whether regulatory guidelines required that an adverse event report be made to the FDA regarding the incident and, if so, whether such a report was made.

This initial interview also permits preliminary evaluation of the sales representative's value as a potential witness in the lawsuit. For better or worse, the sales representative will be a likely candidate for deposition; he or she is both easy for the plaintiff's attorney to identify and located in the area where the incident occurred, making a deposition easy to schedule and relatively inexpensive. In addition, the plaintiff's attorney may well presume that the sales representative is less sophisticated than management, and thus a better target. The initial interview goes a long way toward deciding whether, if the company has a choice, this sales representative is one the company would like to have deposed, and the discussions in the initial interview can lay the groundwork for preparing the sales representative to testify.

Of course, the plaintiff's attorney is not the only person the sales representative will have to deal with. Many medical cases generate significant media attention, and the involved sales representative may be contacted by reporters. The sales representative should be instructed on how to respond to the media, if at all.

Finally, the initial interview provides valuable insight into the effectiveness of the company's training program: whether the sales representative has a clear understanding of the company's policies and general legal liabilities, and whether additional or more frequent follow-up training is needed.

If the deposition of the sales representative is requested, make sure he or she is well-prepared. The plaintiff's attorney is likely to use the sales representative's deposition as a stepping-stone to additional depositions and written discovery. Moreover, the sales representative's testimony may be used in other pending or future litigation against the company.

The company should bear in mind that the sales representatives can be a wealth of information about the company. In addition to questions about the specific incident, expect a deposition to include questioning on the following topics:

- The organizational structure of the company and the sales department;

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- Marketing strategies;
 - Sales meetings, launch meetings, and promotional meetings;
 - How sales calls are made, and what the company instructs the sales representatives to do during such calls;
 - Whether the company sponsors events involving physicians, and the extent to which physicians are reimbursed for attending such events;
 - The company's policies for responding to physician questions about adverse reactions and reported incidents of reactions;
 - The use of promotional service items and giveaways;
 - The company's policies regarding documents, including what documents are sent from the field to headquarters, and what documents the sales representatives should retain;
 - Hiring of new sales representatives, including minimum job requirements and other pre-hire screening;
 - Initial training of sales representatives, including testing;
 - Follow-up training, refresher courses, and mentoring in the field;
 - Compensation of sales representatives, including bonus and incentive programs;
 - The basis for performance reviews, including quotas; and,
 - The sales representative's compliance with company policies for reporting adverse events.

IV. CONCLUSION

Sales representatives are a critical group in any pharmaceutical or medical device company, and they play a vital role in the company's success in avoiding or prevailing in litigation. Although the sales representative's job, by its very nature, creates a potential for liability, these risks can be minimized by proper training and supervision. The sales force can be, and is, more than a marketing resource - it is a tool for minimizing corporate liability, and implementation of a comprehensive training program can be a valuable dose of preventive medicine.

ENDNOTES

- 1 Whitley v. Cubberly, 210 S.E.2d 289 (N.C. App. 1974).
- 2 Crocker v. Winthrop Laboratories, 514 S.W.2d 429 (Tex. 1974). The Texas Supreme Court affirmed a judgment in favor of plaintiff who died from an addiction to the painkiller Talwin®; the prescribing physician testified that the company sales representative specifically stated that Talwin® was nonaddictive and “as safe as aspirin.”
- 3 Albertson v. Richardson-Merrell, 441 So. 2d 1146 (Fla. App. 1983). The plaintiff was permitted to proceed with a fraud action based on sales representative’s assertion to the physician that the drug was “absolutely safe.”
- 4 Tinnerholm v. Parke, Davis & Co., 285 F. Supp.432, 440 (S.D.N.Y 1968), aff’d as modified, 411 E2d 48 (2d Cir. 1969) (applying New York law); Love v. Wolf, 226 Cal. App. 2d 378 (Cal. App. 1964); Stevens v. Parke, Davis & Co., 9 Cal. 3d 51 (1983); Incollingo v. Ewing, 282 A.2d 206 (Pa. 1971) abrogated on other grounds by Kazckowski v. Bolubasz, 491 Pa. 561 (Pa. 1980)(holding that action designed to stimulate use of the product should be examined in determining the adequacy of the warnings given).
- 5 Tatum v. Schering Corp, 795 F. 2d 925 (11th Cir. 1986). Summary judgment for manufacturer was reversed; the court stated that a jury could decide that a reasonable manufacturer would use sales representatives to describe new or different warnings.
- 6 Holley v. Burroughs Welcome Co., 348 S.E.2d 772 (N.C. 1986). (An expert physician’s affidavit that defendant failed to give fair balance of risks and benefits of Anectine® sufficient to preclude” summary judgment).
- 7 Sterling Drug, Inc. v. Yarrow, 408 F.2d 978 (8th Cir. 1969) (judgment for plaintiff affirmed).
- 8 Stevens v. Parke, Davis & Co., 9 Cal. 3d 51 (1983).
- 9 Salmon v. Parke, Davis & Co., 520 E2d 1359 (4th Cir. 1975); Stevens v. Parke, Davis & Co., 9 Cal. 3d 51 (1983). Both courts held that a jury could infer that promotional give-aways which did not include warnings associated with Chloromycetin could nullify the written warnings in the package insert.
- 10 Sabel v. Mead, Johnson & Co., 737 F. Supp. 135 (D. Mass. 1990). The court found that statements made by company employees at a meeting with outside medical experts regarding the warnings that should be given to physicians were probative of the state of the company’s knowledge, although the evidence was ultimately excluded because its value was outweighed by the potential for prejudice.
- 11 21 U.S.C. § 352(n); 21 C.F.R. § 202.1.
- 12 For a more complete analysis of the AMA’s guidelines, see Robert B. Conley, *The AMA’s Gift Guidelines*, 10 FOOD, DRUG, COSMETIC AND MEDICAL DEVICE LAW DIGEST 19 (1993).
- 13 AMA Code of Medical Ethics, § 8.061(1) and (2); AdvaMed Code of Ethics.
- 14 *Id.*, at § 8.061(5); AdvaMed Code of Ethics.
- 15 *Id.*, at § 8.061(3); AdvaMed Code of Ethics.
- 16 *Id.*, at § 8.19.
- 17 The FDA has encouraged practitioners, health care institutions and manufacturers to notify the agency of such occurrences on Forms 3500 (voluntary) and 3500A (mandatory). These methods of notifying the FDA were developed under the MedWatch systems, explanations of which can be found at Russell D. Munves, *New Medical Device Reporting Requirements from the Domestic and Foreign Manufacturer’s Perspective*, 13 FOOD, DRUG, COSMETIC AND MEDICAL DEVICE LAW DIGEST DIGEST 113 (1996); and Curtis G. Oltmans and Colleen T. Davies, *New Rule Protects Identities in Adverse Drug Reaction Reports*, 12 FOOD, DRUG, COSMETIC AND MEDICAL DEVICE LAW DIGEST 64 (1995).
- 18 21 C.F.R. § 803.1 (a); 21 C.F.R. § 803.3
- 19 21 C.F.R. § 803.16
- 20 21 C.F.R. § 310.305(b)
- 21 It should be noted that some companies do not want sales representatives to become involved in obtaining medical devices and/or drug products that may be the subject of an adverse incident. In such cases, the company’s standard operating procedure may, for example, direct the sales representative to provide the available information to a particular group (e.g., regulatory affairs) for them to initiate the product return procedure.

AUTHORS



Anthony G. Brazil is a partner with Morris Polich and Purdy. The primary focus of Mr. Brazil's practice is the representation of pharmaceutical, medical device and biotech companies in a broad array of product liability claims as well as other complex and multidistrict litigation matters. He is currently acting as National Coordinating Counsel for the manufacturer of contact lens solutions, a manufacturer of a schedule II controlled substance used in the manufacturer of pain medications, the worldwide leader in the design and development of robotic technology utilized in minimally invasive surgery, and a manufacturer of modular hip prosthesis. He is also national coordinating counsel for the leading manufacturer of excimer lasers for refractive surgery. In addition, he provides risk management and counseling services for pharmaceutical, medical device and biotech companies. Mr. Brazil serves as California counsel for corporations in the Fen-Phen, pedicle screw, VIOXX, Fosamax and Thimerosal vaccine litigation. In addition, he has acted as national, regional and local counsel in nationwide pharmaceutical, medical device, and mass tort litigation. Representation includes compounds for the treatment of arthritis, diabetes, latex, gloves, mental illness, endocrine disorders, pain and infection and devices ranging from surgical robots to infusion pumps, pacemakers, defibrillators, lasers, angioplasty products, patient monitors, blood gas products, prosthetic devices and radiation equipment.



Karen M. Firstenberg is an associate with Morris Polich and Purdy. The primary focus of Ms. Firstenberg's practice is the representation of pharmaceutical, medical device and biotech companies in a broad range of product liability claims as well as other complex litigation matters. Ms. Firstenberg has successfully defended Fortune 300 and 500 companies in both trial and arbitration, including obtaining defense verdicts in multi-million dollar product liability claims at trial. Ms. Firstenberg has served as both national and local counsel, successfully defending numerous lawsuits in the fields of medical product devices, pharmaceutical, aerospace, asbestos, automotive, and vertical transportation.



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