To The Point
Sales Force Product Liability: Life Sciences

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A sales force is at the front line of an organization and is one of the most important assets to a life science company. However, there are risks associated with their actions that could potentially expose a company to liability and require legal defense in a product liability lawsuit. Therefore, developing appropriate company policies regarding sales force liability exposures could reduce the sales force-related product liability loss risk.

Sales Force Training Need

Liability prevention for internal and external representatives should begin when a company develops marketing plans. Understanding legal theory, regulation, and patient injury allegations can be just as important as teaching the science, product specifications, and marketing strategies for a product.

The goal is to increase sales representatives' (sales reps') awareness so that individuals recognize their role. Each company should provide proper training and supervision of the sales force, both upon hiring and through periodic refresher courses. Training should include the following:

- A generalized discussion of product liability principles
- The risk paradigm inherent in the marketing of medical products
- The sales reps' role in avoiding and defending litigation

Note: The training program should be developed by or with legal counsel.

Product Liability

Product liability arises when a product is alleged to contain a defect that causes injury to a plaintiff. A brief overview of product liability legal theories prepared by legal counsel will help sales reps understand the concepts and how they can affect liability. The three general types of recognized product defects include:

- **Design defect** – when an inherent flaw in a product or service's design makes it dangerous.

- **Manufacturing defect** – when the product differs from the manufacturer's specifications.
- **Warning defect ("failure to warn")** – when the plaintiff alleges they were not adequately informed of the dangers associated with the product and that had they known, they would have refused to use the product. Failure to warn litigation tends to be the most common allegation against life sciences companies, and a sales representative's actions or comments may directly affect a "warning defect" legal action.

Note: For a more in-depth discussion of the different types of products defects, contact legal counsel.

Off-Label Promotion and Off-Label Use

"Off-label" refers to a drug or medical device used for a purpose other than what regulators approved.

Physicians are permitted to use a drug or device for any purpose they believe is medically useful. However, drug and device companies are prohibited from promoting their products for such "off-label" uses, even if that off-label use has become the standard of care in the medical community. Therefore, sales representatives should be aware of potential unapproved uses of a product, recognize new ways that products are being used off-label, and not promote drugs or devices for those uses.[1]

Life Science companies should work with legal counsel to develop an established set of responses to off-label inquiries and regularly communicate them to the sales force. For example, how to respond when:

- A specialist requests samples or information regarding a product not approved in that specialty.
- A hospital department orders a medical device not approved in that department's specialty.
- A physician intends to use a drug for an off-label purpose or to self-prescribe.

When responding to a physician's questions about an off-label use, sales representatives should exercise caution to avoid being perceived as promoting that use.[2] A good way to ensure sales reps are comfortable when confronted with these situations is to perform role-playing exercises during training sessions so they know how to act and what to say. Chubb also recommends involving legal counsel in training about off-label use.

Distributing Published Literature

Physicians who use drugs or devices off-label may publish their scientific findings in journal articles or reference publications. Although drug and device manufacturers may not market their products off-label, they can disseminate these publications to healthcare professionals. Such dissemination of information should meet FDA's "Good Reprint Practices.[3]" Discuss such dissemination with legal counsel.

Before an article is considered for dissemination, a review by staff knowledgeable about on-label promotion should confirm that it:

- Is published by an organization whose editorial board has independent experts with expertise relevant to the article.
- Has been peer-reviewed.
- Is not in the form of a company sponsored publication.
- Is not primarily written, edited, or distributed by, for, or at the request of a drug or device company.

Before distributing an article related to off-label uses of a drug or device, confirm that:

- The article is unabridged.
- The article is clean of any highlights, summaries, or other conclusory statements made by the company.
- The article prominently states that the uses described have not been approved or cleared by the FDA.
- Any financial interest the author has in the product or company is prominently stated and fully disclosed.
- Any known significant risk or safety concern related to the off-label use is disclosed.
- The approved label or product insert must accompany the article.
- The article must be accompanied by a full bibliography of publications related to prior publications of the device, studies, and findings.
- The article must be accompanied by a representative opposing article that reaches a different conclusion if one exists.
- The article may not be included with promotional materials.

Overpromoting

Excessive product marketing is a common pitfall of ambitious sales representatives or paid influencers and represents a critical liability risk to life science companies. Examples of overpromoting include:

- Overstating a product's benefits or minimizing its risks—even where the written warnings are otherwise adequate. Such misleading statements may cause a physician to prescribe a drug or device to a patient that might not have done otherwise.
- Misrepresenting the safety of the drug or device—for example, using terms like "absolutely safe."
- Misrepresenting ongoing research concerning the product's safety or minimizing reports of adverse events.

Less obvious forms of overpromoting include "watering down" the written warnings in conversations with the physicians. For example:

- Failing to draw physicians' attention to revised package inserts, "Instructions for Use (IFU)," etc.

Proper employee training and document handling are critical to a company's effective defense.

- Touting the safety and indications of the drug in sales calls without discussing the dangers.
- Not drawing physicians' attention to reports in the literature of dangers associated with use.
- Failing to address questions about reports in the literature honestly.
- Inaccurately countering physicians' concerns regarding the product's dangers.

Providing adequate, balanced warnings to healthcare professionals is one of a company's best defenses against liability. Marketing zeal should be tempered with careful training to avoid over-promotion and reduce liability.

An important step to help verify that these actions are being appropriately addressed is for management to perform joint travel with their sales reps. When and where warranted, coaching opportunities should be applied when improper sales and marketing practices are being exhibited. A formal compliance program with disciplinary procedures helps enforce on-label promotional conduct.

Spoliation Mitigation Practices

Spoliation is a legal theory that addresses tampering with, deleting, altering, or otherwise modifying evidence as part of a legal proceeding. Company documents, including emails or, potentially, digitized voicemails and SMS texts, are discoverable in legal actions. Proper employee training and document handling are critical to a company's effective defense. Improper document handling and poorly worded/selected statements can implicate a company in wrongdoing and impede its defense. Therefore, it is vital that sales representatives, who often work from home, follow the company document retention policy and receive ongoing training on how to communicate defensively.

The sales force should be trained on the company's policies regarding document retention, destruction, or return, including diaries, appointment books, and follow-up training materials. Audit or follow-up procedures should be created by management to ensure compliance with these policies.

Company-Sponsored Meetings and Conferences

Meetings a company hosts or sponsors for health care professionals provide an important forum for exchanging information about products. Whether these meetings are simple in-office presentations for physicians and their staff or product launches at conventions or tradeshows, they can be a source of liability. All presentations and written materials distributed to physicians must comply with the FDA's labeling guidelines, and any statements employees make at such meetings must be consistent with these guidelines. Sales representatives must be careful their statements do not overpromote the product, promote off-label use, or diminish warnings.

Homemade Promotional Materials

Approval from regulators, such as the FDA, is required for all promotional literature and materials provided to physicians by life science companies. Distributing “homemade” materials can expose a company to liability, fines, and other regulatory actions.

Comparisons to Existing Products

Sales representatives should avoid criticizing the company's older products in their efforts to sell new or improved products. Such criticism could suggest that the older models are in some way defective.

Responding to Adverse Events

Because of their frequent contact with prescribing physicians, sales representatives can be the first in the company to learn of a serious adverse event concerning a product.

Sales representatives should be trained to respond properly to such incidents from a regulatory and litigation standpoint. Sales force training should include when and how to report an adverse event and specifically whom to contact at the company to document the adverse incident within specified timelines put forth by regulatory agencies.[4]

The plaintiff can use the sales representative's failure to report adverse events to indicate a corporate pattern of under-reporting adverse events. This situation undermines the company's data concerning the prevalence of a particular adverse event or a potential argument that there was no knowledge of risk.

Post-Incident Retention / Retrieval of Products

The product and packaging should be retrieved for analysis, if possible, following an adverse event report. An analysis can help form a solid defense or allow for understanding previously unforeseen issues. Each company should develop a detailed protocol for processing and handling retrieved products, covering areas such as obtaining, labeling, storing the product, and how to proceed when the product cannot be retrieved.

Failure to establish or enforce procedures regarding product retrieval can result in liability under the "spoliation of evidence" theory mentioned earlier. Sales representatives should be instructed that their incorrect actions regarding such evidence, whether the product itself or the sales representative's documents, can create this liability and impact the outcome of litigation.

Direct Contact with Patients

Sales representatives can have direct contact with the patient in several ways, such as in the operating room, observing the procedure, or visiting the patient post-procedure to observe how the device functions. Direct contact can expose a company to liability. For example, a company could be sued for medical malpractice if the physician used the device incorrectly. Sales reps should be trained to interact with patients within the boundaries of the approved product labeling because every situation is different. A prosthetic fitter will have different direct patient contact expectations than an operating room sales rep. Sales reps should never be involved in surgery, nursing, or medical decision-making.

Role in Claims and Lawsuits

Unfortunately, even a robust training program may not avoid litigation. Once a claim or lawsuit is filed, the sales representative may be a key player in a company's defense. Preparing the sales force before and during litigation can ensure that the sales representative helps rather than hinders a company's case. The sales representative should be interviewed by appropriate management personnel with legal counsel as soon as possible to protect the conversation from discovery. Sales representatives must provide all documents regarding the incident upon request. Legal counsel can brief the sales rep on the appropriate conduct concerning communications and actions associated with the case.

A well-trained sales force that is savvy about the potential product liability risks they may face or create and has the knowledge and tools to avoid those liability pitfalls can help a company prevent or reduce product liability lawsuits. This will help ensure the company's overall success.

References

1. **Pharmaceutical Research and Manufacturers of America (PhRMA) Code of Interactions,** https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Code---Final.pdf
2. **Medical Device Manufacturers Association (MDMA) Code of Interactions,** https://www.nuvasive.com/wp-content/uploads/2021/03/11.05.19_MDMA_Revised_Code.pdf
3. **Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices,** https://www.fda.gov/media/88031/download
4. **Medical Device Adverse Event Reporting Regulations,** http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803

Resources

PhRMA Code of Interactions Topic Page, https://phrma.org/resource-center/Topics/STEM/Code-on-Interactions-with-Health-Care-Professionals

Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf

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