



The Role of FDA-Approved Labeling in Medical Malpractice Litigation

by Bill Vaslas and Neil Schreffler

This article reviews the extent to which case law recognizes use of the full FDA approved drug labeling (FDA Labeling) to establish the standard of care for physicians and other prescribers in medical malpractice actions. The two broad categories of approaches taken by the nation's courts are discussed and a more detailed examination is provided of the law in the states of Florida, Illinois, New Jersey, New York and Texas.¹ Finally, this article provides practical trial considerations as well as specific recommendations for physicians.

Background – Learned Intermediary Doctrine and the Physician's Legal Duties

The Learned Intermediary Doctrine, first articulated in 1966 by the Eighth Circuit Court of Appeals,² is highly relevant to any discussion of the standard of care to be applied to a physician's administration of prescription drugs. Unlike many other products, prescription drugs may cause undesirable side effects despite the fact that they have been carefully and properly manufactured. Recognizing this, courts have held



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that “unavoidably unsafe products” are not deemed defective or unreasonably dangerous if there are proper directions for use and adequate warnings regarding potential side effects. The Learned Intermediary Doctrine provides that manufacturers discharge their duty by providing warnings to the physician or other prescriber (physician).

Accordingly, this gives rise to a clear duty on the part of the physician to know the details and risks of the drugs that they prescribe. It is the physician who is in the best position to evaluate the patient’s needs, assess the risks and benefits of available drugs, prescribe and supervise their use.³ The physician is responsible for properly prescribing and supervising the use of prescription drugs and providing adequate information to patients.

FDA Labeling as Evidence of the Standard of Care

FDA Labeling to Establish Standard of Care Related to Prescription Drugs

In a medical malpractice action based upon an alleged improper prescribing, administration or monitoring of a prescription drug, the physician’s actions must be measured against the appropriate standard of care. Given that the proper dosage and usage of drugs can be extremely complex, in a medical malpractice lawsuit there is arguably no better source of the standard of care relating to the dosage and usage of prescription drugs than the information provided by its manufacturer through the FDA Labeling. Indeed, in the last three years, there have been over 325 references to *Physicians’ Desk Reference* (PDR) and the FDA Labeling contained therein in reported cases.

The drug information contained in FDA Labeling and provided to physicians via the PDR and package inserts

must comply with the FDA’s regulations governing the proper labeling of prescription drugs. Many of the legal cases in this area refer to the PDR as legal shorthand for FDA Labeling. Accordingly, an awareness of the extent to which the FDA Labeling contained in the PDR or package inserts establishes or impacts the standard of care is often critical to a successful defense in a medical malpractice case.

Examples of FDA Labeling/PDR Citations and Standard of Care Impact

Two broad approaches to the issue of establishing standard of care for prescription drugs have evolved throughout the various states. In the first approach, FDA Labeling is admissible not only to prove the physician’s knowledge of such information but also as evidence, standing alone without expert testimony, of negligence by the physician who fails to adhere to the FDA Labeling information and warnings. In the second approach, the information contained within the FDA Labeling is also admitted to show the standard of care, but there must also be expert testimony presented to explain this standard of care to the jury.

FDA Labeling Establishes Standard of Care, Without Expert Testimony

In the first approach, the FDA Labeling is recognized as prima facie evidence of the standard of care sufficient for submission to a jury. This is often referred to as the “Mulder rule” as it was enunciated by the Minnesota Supreme Court in *Mulder v. Parke Davis & Co.*⁴ The Mulder rule provides:

“Where a drug manufacturer recommends to the medical profession (1) the conditions under which its drug should be prescribed; (2) the disorders it is

designed to relieve; (3) the precautionary measures which should be observed; and (4) warns of the dangers which are inherent in its use, a doctor’s deviation from such recommendations is prima facie evidence of negligence if there is competent medical testimony [on the issue of proximate cause].”⁵

The manufacturer in *Mulder* had warned that serious and even fatal blood dyscrasias are known to occur after the administration of Chloramphenicol. The warning indicated that Chloramphenicol should be used only for serious infections and should not be used when other less potentially dangerous agents would be effective. The performance of adequate blood studies during treatment was described as “essential.”

The evidence presented in *Mulder* was that the defendant physician prescribed a lower dosage than recommended in the FDA Labeling that resulted in a prolonged course of treatment causing the aplastic anemia from which the patient died. There was also evidence that the physician failed to have blood tests performed as recommended by the manufacturer’s FDA Labeling. The court ruled that the physician had not followed the standard of care for prescribing Chloramphenicol.

The courts of Florida, Illinois and Texas generally follow the Mulder rule. For example, applying the law of Florida, the Federal District Court in *Buck v. United States*⁶ held, in the absence of any expert testimony, that there was a clear failure on the part of the defendant physician to adequately follow the instructions contained within the FDA Labeling when administering antivenom to the plaintiff, Buck. While the FDA Labeling recommended that the drug be administered intravenously, the defendant physicians administered it intramuscularly. The

court ruled that the physician had not followed the standard of care for administering the antivenom.

The Supreme Court of Illinois, while acknowledging that expert testimony is, as a general rule, essential to the proof of the standard of professional care against which a physician's care must be measured, the court established an exception to that rule that amplifies *Mulder*. The court found that where the drug manufacturer in the FDA Labeling provides explicit instructions for the proper administration of the drug and a warning of hazards attendant to its improper administration, those instructions provide the proof of the proper professional standards and eliminate the need for expert medical testimony.⁷

In the Texas case of *Haught v. Mace-luck*,⁸ the issue before the court was the proper medical standard for the administration of Pitocin. The court held that the standard was established, without expert testimony, by evidence from FDA Labeling in the PDR and the rules of the hospital where the treatment occurred, stating that the "Physicians' Desk Reference specifically contradicted the use of Pitocin when fetal distress is suspected - as, for example, when loss of beat to beat variability and meconium staining are present."⁹

FDA Labeling Establishes Standard of Care Provided Explanatory Expert Testimony is also Presented

A second manner in which FDA Labeling may be used to establish the standard of care requires expert testimony to explain that standard of care to the jury. New York and New Jersey follow this approach. In *Spensieri v. Lasky*,¹⁰ the plaintiff's expert characterized the FDA Labeling information contained within the PDR as authoritative regarding the

use and administration of drugs and further that pharmaceutical manufacturers, by law, must provide the information to the Food and Drug Administration for approval. More specifically, he testified that the PDR represented the standard of care for physicians relative to the use and administration of Ortho-Novum, the drug in question. The plaintiff requested the court to instruct the jury that New York requires doctors to have knowledge of the risks and benefits of the drugs they prescribe and that it is expected that doctors will follow all of the drug manufacturer's recommendations. The proposed jury charge also included a statement that doctors should know the contraindications or risks contained in the patient package inserts. The trial court refused to so charge the jury.

On appeal, New York's highest court declined to apply the Mulder rule alone and stated:

"[W]e reject the contention that the PDR constitutes prima facie evidence of a standard of care. ... The testimony of an expert is necessary to interpret whether the drug in question presented an unacceptable risk for the patient in either its administration or the monitoring of its use."

The court went on to say:

"In this case, plaintiff's expert testified that in his opinion, the PDR represented the standard of care for physicians in the use and administration of prescription drugs."¹¹

The court also noted that "[t]he package insert information for most drugs is reprinted in the PDR....Although plaintiff only sought admission of the PDR entries on Ortho-Novum in this case, we see no substantive difference between PDR entries and drug package inserts."¹²

The New Jersey courts have taken a similar approach. In *Morlino v. Medical Center of Ocean County*,¹³ the FDA Labeling for Ciprofloxacin, the drug in ques-

tion, warned that it was not an appropriate drug for pregnant patients or children. Plaintiff's experts made reference to the PDR in their testimony and the FDA Labeling in the PDR was admitted into evidence. The plaintiff requested the judge to instruct the jury that they could find the defendant liable on the sole basis that he had violated the FDA Labeling found in the PDR. The trial court refused that request and the New Jersey Supreme Court affirmed rejecting the premise that a violation of the PDR without production of expert testimony is prima facie evidence of negligence. The court stated "the jury may consider package inserts and parallel PDR references, when they are supported by expert testimony, to determine the appropriate standard of care in a medical malpractice case."¹⁴

Effect of FDA Labeling on the Issue of Informed Consent

The FDA Labeling is also relevant to a claim against a physician based on lack of informed consent obtained from the patient. Such an action typically requires proof that the prescribing Physician failed to disclose to the patient the reasonably foreseeable risks and benefits involved so as to permit the patient to make a knowledgeable decision regarding undergoing the recommended treatment.¹⁵ Courts have permitted the admission of the FDA Labeling to establish the prescribing physician's responsibility to inform the patient of possible dangers in the use of a given drug.¹⁶

As stated by the court in *Sanzari v. Rosenfeld*, "the [package insert] is evidence of the fact that Dr. Rosenfeld was on notice Epinephrine might be harmful to hypertensive patients."¹⁷ In that case, the defendant stated that he had read the package insert at some earlier time. In telling terms, the court went on to say "even if he had not read it, the jury could

reasonably conclude that under the circumstances, he should have read it.”¹⁸

Practical Trial Considerations

A Physician’s first reading of the full FDA-approved drug label should not occur during trial prep. With FDA Labeling either establishing the standard of care or supplementing expert opinion regarding the standard of care, this should ideally occur well ahead of the advent of litigation.

One of the first sources of information consulted by an attorney for either the plaintiff or the defendant in a medical malpractice case involving a drug is the FDA Labeling in the PDR. It will be used by plaintiff’s attorney to attempt to establish a departure from good and accepted practice and, where permitted, by plaintiff’s experts to bolster their testimony. It will be used to cross-examine the defendant physicians and defense experts.

Although the exact use of literature varies among jurisdictions and courts, it remains a potentially powerful tool that can be utilized to establish or support opinions about the standard of care. In New York, for example, a physician can be questioned about a medical text if the physician admits that the work is authoritative.¹⁹ A physician can attempt to avoid such a cross-examination by insisting that the text in question is not authoritative. That position is less tenable in the case of a reference source bearing the title *Physicians’ Desk Reference*. The credibility of a physician who denies that the PDR is authoritative is likely to be called into question by the jury and the court.

Many jurors are familiar with the PDR and have seen this book in their physicians’ offices. Jurors therefore may find it odd if a physician opines that the PDR or the information contained therein is not authoritative. Jurors also may find persuasive the fact that information in

the PDR has been reviewed and approved by the FDA. As well, the information is based on clinical information provided by drug manufacturers who have a vested interest in the accuracy and reliability of the information they provide, as they are required by law to perform clinical drug studies and put their drugs on the market only after the drugs have been approved by the FDA. Accordingly, it is difficult for physicians to distance themselves in a court of law from the FDA Labeling found in the PDR.

FDA Labeling is also relevant to off-label use of a drug. Off-label use of prescription drugs, in and of itself, does not constitute malpractice, but the courts may view the FDA Labeling as the gold standard relating to the prescribing, administration and monitoring of prescription drugs. At a minimum, physicians are well advised to know before prescribing, and well before trial prep, whether a particular use of a drug is within indications called for in the FDA Labeling, or is in fact an off-label use.

It is also important to note that FDA Labeling is not static and often changes based upon new information available regarding prescription drugs. Labeling changes may occur, for example, as a result of evidence from recent clinical trials, adverse drug events reports or new FDA-approved indications. According to the PDR records, over 25 percent of prescription drugs have had material changes in their FDA Labeling in a typical year.

FDA Labeling also can be modified as a result of changes at the FDA itself. For example, according to the FDA’s web site, “On September 27, 2007, President George W. Bush signed into law H.R. 3580, the Food and Drug Administration Amendments Act of 2007 (FDAAA). This new law represents a very significant addition to FDA authority and provided

the resources needed to conduct the complex and comprehensive reviews necessary to new drugs and devices.” As a result, the FDA has expanded the requirements for FDA-approved labeling of many new and existing prescription drugs, thereby altering both the regulatory landscape and the FDA Labeling for many drugs. This also altered the standards to which physicians may be held in properly prescribing these drugs. For example, new Risk Evaluation and Mitigation Programs (REMS) have been created for over 100 drugs that often entail new Medication Guides for patients and new prescribing information for Physicians, all of which have become part of the full FDA-approved Labeling. Physicians are therefore well advised to read, understand and periodically review the full FDA Labeling for the drugs that they commonly prescribe.

Recommendations for Physicians

In view of the relevance of FDA Labeling in establishing or affecting the standard of care to which Physicians are held in medical malpractice litigation, the following recommendations are prudent:

1. Read and understand the full FDA Labeling for all drugs prescribed,
2. Periodically review the full FDA Labeling with an eye toward changes,
3. Know which uses of a drug are compliant with FDA Labeling and which are off-label uses,
4. Whether the source of drug reference is print, web-based, electronic, mobile device, dosing guide or an electronic health record (EHR) system, access to and knowledge of the full FDA labeling is essential as it may be critical to a successful defense in a court of law, and
5. Given the potential significance of the full FDA Labeling, both clinical-

ly and legally, avoid reading it for the first time during litigation. In other words, “a physician’s first reading of the full FDA-approved drug label should not occur during trial prep.”

Conclusion

The FDA Labeling of prescription drugs is highly important information for physicians to know because it can establish or impact the standard of care to which physicians are held in professional liability litigation. In some states the FDA Labeling, standing alone, establishes the standard of care and is referred to as the *Mulder* rule. A second approach uses the FDA Labeling as the standard of care but also requires that expert testimony be presented.

Irrespective of the law in any given state, acquiring and maintaining familiarity with the FDA Labeling before prescribing a drug may help avoid a lawsuit, and may be extremely helpful in defending a lawsuit. In the event of a law-

suit, a prospective familiarity with FDA Labeling may facilitate an explanation for a reasoned variance from recommended use in a given patient.

If a Physician has not complied with FDA Labeling or was unfamiliar with the pertinent details within FDA Labeling at the time of prescribing, that fact will not be kept a secret at trial. The only time a plaintiff’s lawyer will not use the FDA Labeling in a drug-related case is if the defendant physician has complied with it, in which case the physician’s lawyer will likely use it in defense of the physician. Reading and periodically reviewing FDA Labeling for drugs prescribed by a physician is prudent in order to avoid the potential vulnerability of reading it for the first time in preparation for trial. Inevitably, the FDA Labeling will either help or haunt a physician at trial. ▲

the five states mentioned, there are exceptions to the general rules referenced herein. In addition, there may be particular facts with respect to a specific drug or patient population that require special consideration. For this reason, this article is intended only to provide general background information and not to provide legal advice about how prescribing health care providers or manufacturers and distributors of drugs should discharge their legal obligations in any particular state or in any given situation.

- 2 *Sterling Drug v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966).
- 3 *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87 (2d Cir. 1980).
- 4 *Mulder*, 288 Minn. 332 [1970].
- 5 *Mulder*, 288 Minn. at 339-340.
- 6 433 F.Supp. 896 (N.D. Fla 1977).
- 7 *Ohligschlagler v. Proctor Community Hosp.*, 55 Ill. 2d 411 (1973).
- 8 681 F.2d 291 (5th Cir. 1982) (applying Texas law).
- 9 *Haught*, 681 F. 2d at 304.
- 10 94 NY2d 241 (1999).
- 11 *Spensieri*, 94 NY2d at 240.
- 12 *Spensieri*, 94 NY2d at 237.
- 13 152 NJ 563 (1998).
- 14 *Morlino*, 152 NJ at 578.
- 15 See, e.g., New York Public Health Law Section 2805-d.
- 16 *Sanzari v. Rosenfeld*, 34 NJ 128 (1961).
- 17 *Sanzari*, 34 NJ 128 at 140.
- 18 *Sanzari*, 34 NJ 128 at 140.
- 19 See, e.g., *Mark v. Colgate Univ.*, 53 A.D.2d 884 (NY App. Div. 2nd Dept. 1976).

1 Although this article summarizes general legal principles applicable in many states and focuses on