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Legal Issues in Active Medical Product Surveillance March 2010

PANEL 4
Addressing Legal Liability in Medical Product Safety Surveillance

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INTRODUCTION

Pharmacovigilance is a developing science and the results of drug safety analysis are rarely precise. Drug safety "signals" may be observed in an analysis, often requiring follow-up to obtain more information to confirm causation to compare the findings across multiple information sources to confirm the validity of the conclusions. During the "gray zone" that exists between the first drug safety signal and confirmation (or refutation) of the signal's validity, pharmacovigilance experts are wary about communicating their findings to others. False positives run the risk of alarming patients, potentially causing them to stop medication therapy that may have real benefit to them. Alarming the public may also have an unwarranted negative effect on a drug manufacturer's product and reputation. The proverbial "wild card" in pharmacovigilance activities is whether these activities will generate any risk of tort liability under state law for failing to act on drug safety findings or for acting too soon on those findings and harming a drug manufacturer's product.

NEGLIGENCE FOR FAILURE TO WARN PATIENTS

Duty to Warn

The law of negligence potentially imposes a duty to warn of known drug dangers. Generally, the tort of negligence is comprised of three elements: (1) a duty that the defendant owes to the plaintiff; (2) the defendant's failure to conform its conduct to the requisite standard of care required by the defendant's relationship with the plaintiff; and (3) an injury to the plaintiff resulting from that failure.[1] To determine whether a duty exists, courts look to a state's statutes and controlling law,[2] so this analysis necessarily will vary from state to state.

In the drug safety arena, courts have tended to impose a duty to warn of potential drug risks on the individuals or entities in the best position to evaluate the risk and take action to protect users of prescription drugs—drug manufacturers and physicians.[3] Drug manufacturers have a common law duty to warn doctors, and sometimes patients, of prescription drug risks.[4] In turn, doctors have a duty to warn their patients of potential drug risks.[5] In this way, the law has developed a system for warning patients about prescription drug risks in the most efficient and effective manner.

Where drug safety surveillance generates information regarding drug risks that is not available to the drug manufacturer or physicians, however, the situation falls outside of the established mechanism for protecting prescription drug users. Not surprisingly, because this is such a new field, courts have not

addressed whether non- manufacturers would have a duty to warn patients of potential risks learned about prescription drugs. Consequently, the participants in drug safety surveillance should look to their state laws regarding when courts in their states have imposed a duty to warn patients in other circumstances, in an attempt to forecast whether courts are likely to impose a duty based on pharmacovigilance information.

Ordinarily, a person does not owe a duty to others to protect them for conditions not created by that person.[6] However, there are circumstances where courts have imposed a duty to act where the risk of harm is created by others. First, some state courts have imposed a general duty on hospitals to warn about outcomes of care provided to patients. Courts across the country are starting to utilize negligence principles to expand the potential liability of a hospital for care received by patients in the hospital. Historically, a hospital's liability for negligence related to patient treatment was limited to theories of *respondeat superior* or negligence in staffing incompetent medical personnel.[7] In recent years, however, hospitals are becoming less insulated from tort liability to patients for treatment provided in the hospital and a number of courts ''have enunciated what has been called the doctrine of corporate responsibility, which recognizes the existence of a duty owed directly by a hospital to a patient in connection with the care and treatment given to him.''[8] One court, for example, identified a broad duty of a hospital to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.[9] If a hospital patient is taking a drug that the hospital's pharmacovigilance research has found potentially unsafe, a court might find a duty under the corporate responsibility doctrine to inform the patient of that risk.

Second, some courts have imposed a duty to warn when one party is aware that another could be harmed by a third party.[10] While states vary widely on how this is applied and the level of foreseeability necessary, this line of cases could result in the imposition of a duty to warn.

Third, courts in some jurisdictions have recognized negligence-based duty claims where a defendant assumed an undertaking on which a plaintiff reasonably relied, resulting in physical harm to the plaintiff.[11] Under this legal theory, it is possible that a patient could argue that, by implementing a drug safety project, the entity undertook a service for the benefit of its patients to learn of adverse drug effects and, therefore voluntarily assumed a duty to notify the patients of any adverse findings discovered. However, because liability does not attach under this theory unless there is a reasonable expectation by the patient that the entity would notify the patient of any discovered drug dangers, the risk of such a claim would be minimal if the patient is unaware of the project and if the entity does not publicize a plan to inform patients of adverse drug effects discovered.[12]

Discharging the Duty to Warn

The scope of a duty to act on information learned through pharmacovigilance is likely to vary from situation to situation and from state to state, making a bright-line rule unworkable. If a court finds a duty to warn, a court likely would consider a number of factors in evaluating the appropriate way to discharge that duty, particularly the validity of the findings and the magnitude of the risk identified.

If pharmacovigilance does not reveal information different from that already available to the FDA and drug manufacturers, a court is unlikely to require the participant to directly inform patients—even if the patient was not warned of the drug risks by the patient's physician—because steps have already been taken to protect the consumers of the drug from the particular risk at issue.

However, where the participant identifies a new or greater risk that is not yet known to the FDA or the drug manufacturer, a court likely would require the participant to act in some manner. The participants will have a range of potential actions to take, including informing the FDA, the drug manufacturer,

physicians and patients. Public policy considerations influence what type of action a court would require to discharge a duty to warn, including such factors as the following:[13]

1. The degree of certainty of injury to the individual: For example, if the validity of the study is low and results need confirmation through other data sources to draw firm conclusions, we believe that a court would not likely impose reporting obligations on a Sentinel Initiative participant. One court noted serious concerns that requiring warnings would lead defendants to warn ''of all known side effects, no matter how minute or unproven.''[14] On the other hand, if the findings are valid and the harm to the individuals taking the drug is foreseeable, a court likely would require some action.

2. The magnitude of potential harm to the individual: If drug safety findings indicate a life-threatening condition, courts would be more likely to require action than if the findings indicate risk of a minor health issue.

3. The feasibility of a reporting mechanism and the reasonableness of the burden imposed by reporting: For example, the requirement to identify and notify all patients taking a drug throughout a large health system would impose substantial expense on the system.

   Reporting to patients and physicians before confirmation of the validity of the findings could also expose the system to business tort liability for corporate defamation, commercial or product disparagement (also known as trade libel or injurious falsehood), and intentional interference with an advantageous or existing business relationship. As a recent example, Biopure Corp., a manufacturer of an oxygen therapeutic product, recently instituted a lawsuit against an NIH investigator for co-authoring an article and several letters publishing negative comments about the product.[15] The author had concluded that various studies found increased risks associated with the use of Biopure's product, even though numerous clinical trials were still underway at the time the article was published. While the defendant in the Biopure case is alleged to have acted with malice to harm Biopure's business because the author is a co-inventor on a pending patent for competing technology, the resolution of this case will be relevant to analyzing the risk of potential claims against researchers for publishing negative information about drugs.

   On the other hand, the burden of reporting findings to the FDA and the drug manufacturer—who then can appropriately analyze the risk to individuals taking the drug and notify physicians through appropriate channels—would not be substantial. Moreover, by notifying the FDA and the drug manufacturers, the participant would take reasonable steps to communicate its findings to the entities most able to get the word out to doctors who could then, in turn, warn their patients.

4. The potential harm to the public by reporting: ''Over-reporting'' drug safety findings without confirmation of findings could have a negative impact on individuals taking drugs with potential therapeutic value.

5. The possibility that finding a duty to report would negatively impact the Sentinel Initiative as a whole: If courts impose a duty for individual participants in the system to report adverse findings to physicians and patients, it will have a negative impact on the willingness of hospitals, health systems, HIEs, health plans and other data sources to participate.

In sum, the potential liability for failing to report findings directly to physicians or patients is uncertain. It depends on a variety of public policy factors, which could be weighed differently by courts in different states, and depends on the particular circumstances presented by the plaintiff.

RECOMMENDATIONS

In order to operate successfully, the Sentinel Initiative and its participants will need certainty about how they are to conduct drug safety analysis and their appropriate response to drug safety findings. The panel should consider what steps may be helpful to provide more certainty to avoid potential liability. These steps might include:

- Will it be helpful for the FDA to develop model policies about when, how and to whom to report findings so that system can produce reliable and confirmed data to guide drug decisions, in order to create a standard of care for pharmacovigilance that would be applied by courts?
- Will it be helpful to have limited statutory immunity from negligence actions for Sentinel Initiative participants?

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[1] *See, e.g. Ingram v. Hook's Drugs, Inc.,* 476 N.E.2d 881 (Ind. 1985).
[2] *See, e.g., Stanley v. McCarver,* 208 Ariz. 219, 92 P.3d 849 (2004).
[3] *See Reyes v. Wyeth Labs*., 498 F.2d 1264, 1276 (5th Cir. 1974); *McKee v. American Home Products Corp*., 113 Wash.2d 701, 711-20, 782 P.2d 1045 (1989) (holding that a pharmacist does not have ''a duty to question a judgment made by the physician as to the propriety of a prescription or to warn customers of the hazardous side effects associated with a drug'') (*citing* W. Keeton, R. Keeton & D. Owen, Prosser and Keeton on Torts § 96, at 688 (5th ed. 1984) (''It is the physician who is in the best position to decide when to use and how and when to inform his patient regarding risks and benefits pertaining to drug therapy.'')).
[4]*See, e.g. Schaerrer v. Stewart's Plaza Pharmacy, Inc.,* 79 P.3d 922 (Utah 2003) (manufacturer is obligated to warn of any dangerous side effects of which it knows or has reason to know); *Motus v. Pfizer Inc.,* 196 F. Supp. 2d 984 (C.D. Cal. 2001 (manufacturer duty to warn about any known or reasonably knowable danger); *Martin v. Hacker,* 83 N.Y.2d 1, 628 N.E.2d 1308, 607 N.Y.S.2d 598 (1993) (manufacturer duty to warn of all potential dangers in its prescription drugs that it knew, or in the exercise of reasonable care, should have known to exist); *Wagner v. Roche Laboratories,* 77 Ohio St. 3d 116, 671 N.E.2d 252 (1996) (manufacturer has duty to warn of all potential adverse reactions inherent in use of the drug which manufacturer, being held to standard of expert in the field, knew or should have known at the time of marketing); *Edwards v. Basel Pharmaceuticals,* 933 P.2d 298 (Okla. 1997) (manufacturer required to warn of dangers which are foreseeable and known to the manufacturer); *Ziliak v. AstrazenecaLP,* 324 F.3d 518 (7th Cir. 2003) (under Indiana law, duty to provide adequate warnings arises when the manufacturer knows or should know of a risk posed by the product); *Ortho Pharmaceutical Corp. v. Chapman,* 180 Ind. App. 33, 388 N.E.2d 541 (1979) (manufacturer's duty to warn of risks attendant in use of its product does not arise until manufacturer knows or should know of a risk involving the drug's use; a manufacturer cannot be required to warn of a risk unknown to science).
[5]*See, e.g., Moore ex rel. Moore v. Memorial Hosp. of Gulfport,* 825 So.2d 658 (Miss. 2002); *Coyle v. Richardson-Merrell, Inc.,* 526 Pa. 208, 584 A.2d 13183 (1991); *Morgan v. Wal-Mart Stores, Inc.,* 30 S.W.3d 455 (Tex. App. 2000); *Silves v. King,* 93 Wash. App. 873, 970 P.2d 790 (1999); *McKee*, 113 Wash.2d 701, 709.
[6] *See, e.g., DeJesus v. U.S. Dept. of Veterans Affairs*, 479 F.3d 271, 281 (3rd Cir. 2007); *F.D.P. v. Ferrara*, 804 A.2d 1221 (Pa.Super.Ct. 2002) (holding that, generally, there is no common-law duty to protect third parties from harm); *Luoni v. Berube*, 431 Mass. 729, 733-34, 729 N.E.2d 1108 (2000); *Cremins v. Clancy*, 415 Mass. 289, 296, 612 N.E.2d 1183 (1993); *Harris v. Pizza Hut of Louisiana, Inc*., 455 So.2d 1364, 1371 (La. 1984).
[7] *See Strubhart v. Perry Memorial Hospital Trust Authority*, 903 P.2d 263, 275-76 (Okla. 1995); *Fridena v. Evans*, 127 Ariz. 516, 622 P.2d 463 (1981); *Tucson Medical Center v. Misevch*, 113 Ariz. 34, 545 P.2d 958 (1976).
[8] 12 A.L.R.4th 57 (2008); *see, e.g., Darling v. Charleston Community Memorial Hospital*, 211 N.E.2d 253 (Ill. 1965); *Rodrigues v. Miriam Hospital*, 623 A.2d 456, 462-63 (R.I. 1993) (applying doctrine of corporate negligence where hospital failed to exercise reasonable care in selecting staff); *Thompson v. Nason Hospital*, 591 A.2d 703, 707-08 (Pa. 1991) (holding that corporate negligence doctrine may apply to impose liability if hospital ''fails to uphold the proper standard of care owed its patient''); *Insinga v. LaBella*, 543 So.2d 209, 213-14 (Fla. 1989) (adopting corporate negligence doctrine where hospital breached duty to ''select and retain'' competent staff).
[9] *Thompson*, 591 A.2d at 707-08.

[10] *See, e.g., Doe v. XYZ Services, Inc.,* 1995 WL 809493 (Mass. Super. 1995) (finding hospital duty to warn an adoption agency or the danger of placement of siblings together); *see also Larson v. Wasemiller,* 738 N.W.2d 300, 307 (Minn. 2007)*; Pedroza v. Bryant*, 101 Wash.2d 226, 677 P.2d 166 (Wash. 1984).

[11] *See Mullins*, 389 Mass. 47 (university assumed duty to enhance security on campus thereby owing students duty of care as to their safety); *Thorson v. Mandell*, 402 Mass. 744, 745 (1988); *see also Woods v. O'Neil*, 54 Mass. App. Ct. 768, 769 (2002); *Fieldwork Boston, Inc. v. United States*, 344 F. Supp. 2d 257,264 (D. Mass. 2004). See also Restatement (Second) of Tort, Section 323-324A..

[12] *See, e.g., Cottam v. CVS Pharmacy*, 436 Mass. 316, 322, 764 N.E.2d 814, 820 (2002) (scope of duty depends on patient's reasonable understanding of what the pharmacy has undertaken to provide); *Baker v. Arbor Drugs, Inc*., 215 Mich. App. 198, 205-06, 544 N.W.2d 727, 731 (1996); *Ferguson v. Williams*, 101 N.C. App. 265, 399 S.E.2d 389 (1991).

[13] *See Cottam*, 436 Mass. at 320, 764 N.E.2d at 819 (evaluating whether a duty exists based on ''existing social values and customs, as well as … appropriate social policy.''); *Brown v. Brown*, 739 N.W.2d 313 (Mich. 2007); see also *Marshall v. Burger King Corp*., 856 N.E.2d 1048 (Ill. 2006).

[14] *See Morgan v. Wal-Mart Stores, Inc.,* 30 S.W.3d 455 (Tex. App. 2000).

[15] *Biopure Corp. v. Natanson*, 08-CV-01732 (D.D.C. Oct. 10, 2008).