

Rx Ipsa Loquitur

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President's Message



Jay Campbell, ASPL President

Fall Conference in Vegas approaches! And though I've said it before, it bears repeating: ASPL members and attendees owe a huge thank you to the members of the Education and Sponsorship committees, headed by Kim Burns and Mary Ellen Kleiman, respectively. Kim's and Mary Ellen's leadership had produced a line up of terrific educational sessions and sponsorships to make sure they happen.

ASPL elections will soon be upon us. The elections committee will convene over the coming weeks to secure candidates for President-Elect and two Board of Director positions. We have a lot of talented ASPL members; please let me know if you're interested in putting those talents to work for ASPL.

The pharmacy law front is as active as ever. Congress has passed the Ryan Haight Online Pharmacy Consumer Protection Act, which brings federal regulatory power to bear on the issue of prescription drug trafficking via the Internet. The Act provides requirements for online pharmacies distributing controlled substance that are in addition to, and not in lieu of, individual state requirements, and it empowers states to bring suit in federal court for violations. The Act's provisions and operation are sure to be hot legal topic in pharmacy field for some time.

San Francisco has, for the time being at least, beaten back Walgreens' efforts to invalidate a city ordinance prohibiting pharmacies from selling tobacco products. From legal and policy standpoints, San Francisco's action raises a number of interesting questions. And with other cities reportedly considering similar action, the time is right for serious discussion of the appropriate role of local, as opposed to state and federal, regulation directly impacting pharmacy practice.

Thanks for your membership in, and support of, ASPL!

A Pharmacist's Duty to Warn: Trying to Make Sense of All the Legal Inconsistencies

Kim Burns, R.Ph., J.D., and Alan Spies, R.Ph., J.D., M.B.A., Ph.D.

In recent decades, the profession of pharmacy has shifted from centering on dispensing products to providing more cognitive services, including patient counseling. One particular area of malpractice litigation that has evolved as the pharmacists' role in health care has expanded is whether a pharmacist owes a "duty to warn" (DTW). Under the duty to warn theory of liability, patients injured by prescription drugs claim that the pharmacist had a duty to warn about the potential adverse effects and other dangers associated with prescription drugs.

The majority of jurisdictions that have addressed the duty to warn issue have held that there is no general duty for pharmacists to warn patients about their prescribed drugs. Courts holding there is no general duty to warn usually base this upon: (1) interference with the physician-patient relationship, (2) violation of the learned intermediary doctrine, and/or (3) such imposition of liability would contradict public policy.¹ The learned intermediary doctrine (LID) is derived from the theory that physicians are in the best position to choose the appropriate medication and advise patients of the inherent risks of treatment. Numerous courts have extended this doctrine to lawsuits against pharmacists to insulate pharmacists from liability for failing to warn, placing upon prescribing physicians the responsibility of warning patients of the potential risks of prescription drugs.^{2,3,4}

A minority, but growing number of courts have demonstrated a willingness to recognize that pharmacists do have a duty to warn, or at least under limited circumstances^{3,4}, including: when there are obvious inadequacies or clear errors on the prescription; when the pharmacist voluntarily assumes the duty; or when the pharmacist has special knowledge regarding a patient. In addition, other courts finding a duty to warn have either relied on the duty of reasonable care standard, the counseling laws under OBRA '90, or by rejection of the learned intermediary doctrine.^{3,4}

The chart on page 2 provides a summary of recent duty to warn cases that help illustrate the legal inconsistencies amongst various states courts that have addressed the issue. Given the legal inconsistencies amongst various state courts regarding a pharmacist's duty to warn, practicing pharmacists should consider the following recommendations:

- Pharmacists should realize that the duty to warn standard varies from jurisdiction to jurisdiction.
- Though the courts have been slow to apply the duty to warn standard to pharmacists, this standard is becoming more widely accepted.
- No longer can a pharmacist rely on simply a "counting, pouring, licking and sticking" standard as a shield from civil liability.
- With the advent of recent federal legislation, such as OBRA '90, pharmacists are expected to check for drug interactions, correct dosing and drug-disease contraindications, to name a few. Failure to do so may result in legal liability.

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Duty to Warn

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- Where a potential contraindication or adverse reaction is foreseeable on the part of the pharmacist, the pharmacist may be found negligent if he/she fails to take proper action.
- If a pharmacist advertises or voluntarily undertakes a duty to check for drug interactions, the pharmacist may be found liable if he/she fails to perform this service.
- Pharmacists should always counsel patients and answer any questions they may have.
- Pharmacists should always provide patients with available or regulated written drug information. However, simply providing patient information sheets does not shield the pharmacist from potential liability.
- When a question arises, the pharmacist should always consult the patient's physician. Though some courts have held that this potentially interferes with the physician-patient relationship, failure to do so could result in pharmacist liability for patient harm.

Although the majority of courts have yet to hold that pharmacists owe a duty to warn their patients, practice standards are changing. Pharmacists, due to increased knowledge and responsibility in practice, will be held to a higher legal standard, a standard that will eventually include a duty to warn. Pharmacists should not rely on the law to determine their level of professional practice, but rather, should provide these services to all patients.

Adapted from a poster presented at the American Society for Pharmacy Law 33rd Annual Meeting/ American Pharmacists Association 155th Annual Meeting, San Diego, California, March 14-17, 2008. Kim Burns is Associate Professor, LECOM School of Pharmacy, and Allen Spies is Assistant Professor, Southwest Oklahoma State University College of Pharmacy.

1. Brain L. Porto, Annotation, *Civil Liability of Pharmacists or Druggists for Failure to Warn of Potential Drug Interactions in Use of Prescription Drug*, 79 A.R.L. 5th 409 (2006).
2. R. Paul Asbury, *Pharmacist Liability: The Doors of Litigation are Opening*, 40 Santa Clara L. Rev. 907 (2000).
3. James Barney, *Dancing Towards Disaster or the Race to Rationality: The Demise of the Learned Intermediary Standard and the Pharmacists' Duty to Warn*, 39 Gonz. L. Rev. 399 (2004).
4. Jaclyn Casey, *Prescription for Compromise: Maintaining Adequate Pharmacist Care Contraindicates Imposition of a General Duty to Warn*, 17 Wash. U. J.L. & Pol'y 287 (2005).
5. 887 So. 2d 881 (Ala. 2004).
6. 2004 WL 2943271 (Conn. Super. Ct.).
7. 612 S.E.2d 25 (Ga. Ct. App. 2005).
8. 2006 WL 2588147 (E. D. La.).
9. 2003 WL 23018810 (Mass. Super.).
10. 2005 WL 1846289 (Mich. App.).
11. 825 So. 2d 658 (Miss. 2002).
12. 30 S.W.3d 455 (Tex. App. 2000).

The following chart provides a summary of recent duty to warn cases that help illustrate the legal inconsistencies amongst various states courts that have addressed the issue.

State / Case Pharmacist DTW	Facts / DTW Allegations	Court Holding
Alabama Walls v. Alpharma ⁵ DTW under specific circumstances	Pregnant wife used husband's Lindane prescription and gave birth to child with medical conditions. Plaintiff alleged pharmacy failed to provide adequate warning of the risks associated with Lindane.	LID forecloses any duty upon a pharmacist filling a physician's prescription, valid and regular on its face, to warn the patient or other ultimate consumer, except insofar as the prescription orders, or an applicable statute or regulation expressly requires.
Connecticut Deed v. Walgreens ⁶ DTW under specific circumstances	Plaintiff alleged that Walgreens violated OBRA '90 and failed to warn decedent and inform prescribers that the use of the combined medications would cause harm and were unsafe.	LID provides for no general DTW under given circumstances; however, exceptions apply when there is specific knowledge; pharmacy makes representation they engage in process of evaluation of medications; or there is something patently and unambiguously wrong with the prescription. In addition, OBRA '90 did not create private cause of action.
Georgia K-Mart v. Chamblin ⁷ No DTW	Plaintiff alleged pharmacy had a DTW, based on OBRA '90, of any potential side effect, including rare Stevens Johnson Syndrome.	No general DTW based on LID and interference with physician-patient relationship. OBRA '90 does not establish a generalized DTW on every possible side effect. OBRA '90 requires an offer to counsel which plaintiff did not show pharmacy failed to offer counseling.
Louisiana Stanley v. Wyeth ⁸ DTW under specific circumstances	Patient died after taking generic Cordarone. Plaintiff alleged the pharmacist failed to include the FDA required Medication Guide and that this was a proximate cause of illness and death.	DTW can exist where there are excessive doses or obvious inadequacies on a prescription. Failing to provide a Medication Guide may also constitute a failure to warn by the pharmacist.
Massachusetts Brienze v. CVS ⁹ DTW under specific circumstances	Injured patient alleged that the pharmacy had a DTW of potentially adverse interaction between two drugs taken together and which were both dispensed from the same pharmacy.	Massachusetts law does impose a duty on pharmacists to warn the customer when filling two prescriptions that adversely interact with one another. LID does not apply to this case. Duty still possible despite the provided pharmacy leaflet which warned of the interaction and the pharmacy offering counseling.
Michigan Saukas v. Walker Street Pharmacy ¹⁰ DTW under specific circumstances	Injured patient alleged pharmacy had DTW under OBRA '90 of drug which interacted with another drug received from pharmacy six months prior and still taken by patient through mail order pharmacy.	No DTW under given circumstances; however, duty may arise under other circumstances. In addition, OBRA '90 does not alter Michigan common law.
Mississippi Moore v. Memorial Hospital & Winn-Dixie ¹¹ DTW under specific circumstances	Plaintiff alleged pharmacy had DTW and was negligent in selling a drug contraindicated for a pregnant woman that harmed infant.	No DTW under LID. Exceptions to LID do apply, but not for this case. In addition, OBRA '90 does not give rise to independent cause of action.
Texas Morgan v. Wal-Mart ¹² DTW under specific circumstances or if reasonable pharmacist would warn	Parents of deceased child alleged pharmacy had DTW of adverse reactions and that OBRA '90 requires a duty to counsel.	Pharmacists do not have general DTW patients of potential adverse reactions absent evidence of any special circumstances or neglect in face of information in which a reasonable pharmacist would have acted. OBRA '90 also can't be read as a general DTW. Special circumstances could create duty for pharmacists, as their role has changed a lot over the years.



Downing v. Hyland Pharmacy, No. 20060771 (Utah Supr. Ct., September 16, 2008)

By Kerry Moskol, JD and Roger Morris, JD

Supreme Court of Utah Concludes that Pharmacists Owe a Duty of Care with Respect to Dispensing Drugs Not Authorized for Sale by the FDA or Manufacturer

On September 16, 2008, the Supreme Court of Utah reversed a state trial court's decision granting summary judgment to a pharmacy who was accused of negligently filling prescriptions for fenfluramine ("fen-phen") after fen-phen had been withdrawn from the market by the Food and Drug Administration (FDA) and the manufacturer. In its decision, the Court concluded that the learned intermediary rule would not preclude a negligence claim against a pharmacy for dispensing a prescribed drug that had been withdrawn from the market, and that pharmacists under such circumstances owe their customers a duty of care.

In *Downing v. Hyland Pharmacy*,¹ the defendant pharmacy, Hyland Pharmacy ("Pharmacy") filled Steven Downing's prescription for fen-phen between 1996 and 2000. In August 2004, Downing brought negligence claims against Hyland Pharmacy for continuing to fill prescriptions after fen-phen had been removed from the market by the FDA and the manufacturer. The Pharmacy subsequently filed for summary judgment arguing that the pharmacy acted as a reasonably prudent pharmacy in filling the prescriptions and thus, did not breach any duty.

The trial court granted the Pharmacy's motion for summary judgment holding that the "learned intermediary" rule, as previously adopted by the Utah Supreme Court, precluded the plaintiff's claims. Specifically, the trial court relied on *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*,² where the Court held that the learned intermediary rule exempts pharmacist from liability if they fill a prescription as directed by the manufacturer or physician. In coming to this decision, the trial court also considered cases from other states that applied the learned intermediary rule to negligence cases.

The Court disagreed with the lower court's analysis. While the Court agreed that the learned intermediary rule has been applied to negligence claims in addition to products liability cases, the Court explained that there are recognized limits to the learned intermediary rule's application. The Court said that in the negligence context, the rule is generally applied to warnings about general side effects of the drugs at issue and not to "specific problems known to the pharmacist such as prescriptions for excessively dangerous amounts of the drugs

or for drugs contraindicated by information about a patient."

With these limitations in mind, the Court concluded that the learned intermediary rule would not preclude Downings' negligence claims against the pharmacy for dispensing a prescribed drug that was withdrawn from the market. The Court further held that pharmacists owe consumers a duty of care with respect to dispensing drugs not authorized for sale by the FDA or the manufacturer. In so holding, the Court did not determine whether the pharmacy was negligent in dispensing the drug to the patient. Rather, the Court remanded the case to the lower court to examine the standard of care for a reasonable pharmacist under these circumstances and determine whether the standard was breached.

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¹*Downing v. Hyland Pharmacy*, 2008 UT 65, ___P.3d__.

²*Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 2003 UT 43, 79 P.3d 922.

Inside DEA: *When DEA Visits the Hospital Pharmacy, Will your Client be Ready?*

By Delbert D. Konnor, PharmMS, President DEA Solutions Group, LLC

If your law firm represents hospitals, nursing homes, or other healthcare institutions, it's good practice to recommend at least once each year that they review their procedures to prevent theft or diversion of controlled substances and to ensure ongoing adherence to DEA policies and recordkeeping requirements.

Make no mistake – I'm not suggesting that hospital pharmacy personnel are untrustworthy. No one has more respect for institutional pharmacy practitioners than I do. I can't think of a single member of the American

healthcare team more intimately involved with the patient's medication therapy and welfare.

Too often, though, highly-trained, clinically-oriented, patient-focused hospital pharmacy practitioners are so dedicated to their patient care and professional care activities that they may inadvertently set aside one or more of the myriad of administrative responsibilities associated with institutional practice. "Routine" recordkeeping and paperwork chores may likely rank far down on the typical administrative priority list. Some may actually find spending

time on these "clerical" activities interfere with the time needed for patient care.

That mindset may be understandable, but it can result in an unexpected visit from the Drug Enforcement Administration, embarrassing negative publicity for the hospital, stiff monetary penalties for the institution, and perhaps even a prison sentence for pharmacy personnel.

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DEA Visit

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Consultants who conduct DEA compliance assessments of institutional pharmacies know how important it is to use a checklist to make sure all necessary safeguards are in place to prevent theft and diversion of controlled substances and avoid DEA recordkeeping violations. Law firms representing healthcare facilities where narcotics and other controlled drugs are stored would be wise to recommend that their clients protect themselves by using checklists specific to their practices.

Here's what you should be looking for:

1 – An up-to-date Standard Operating Procedures manual that outlines the security precautions in place for controlled substances, and provides a detailed description of the recordkeeping and reporting responsibilities expected of the institutional pharmacists.

2 – Formal policies establishing which personnel will have access to controlled substances, along with a set of “chain of custody” rules for ordering, handling, storing, dispensing, and administration of controlled substances.

3 – The existence of effective procedures governing the return, destruction, or disposal of outdated controlled substances, and of controlled drugs that may be present in medical waste.

4 – Special procedures in place for the screening and hiring of pharmacists, pharmacy technicians, and all other personnel who may have access to controlled substances.

5 – The active support of hospital administrators and other officials at the facility to foster an appreciation by all members of the pharmacy team that they have obligations and responsibilities beyond those directly associated with patient care.

It is important that institutional pharmacists be reminded that they are guardians of the drug supply and serve as the last and most important gatekeepers responsible for preventing theft and diversion of narcotics and other controlled substances in institutional settings.

Physical and personnel security are paramount to any risk management program that addresses DEA regulations. There's no need for your hospital clients to run afoul of the DEA. Make sure they don't.

Delbert D. Konnor, PharmMS is the former head of Voluntary Compliance for the U.S. Drug Enforcement Administration. He is currently President of the DEA Solutions Group, LLC—a consulting firm formed to help DEA registrants remain in compliance with the nation's drug laws - DelKonnor@DEASolutionsGroup.com.