

PHARMACY LAW PRESENTATION

*Presented at the annual meeting of the American Pharmaceutical Association in
New Orleans, Louisiana on March 29, 2003*

Title: **Erosion of the “Learned-Intermediary Doctrine:” What Every
Pharmacist (and His Malpractice Insurer) Needs to Know
About Expanding Pharmacist Liability**

Issues: To address the Impact of FDA and state regulations governing practice of pharmacy and professional standards on scope of legal duty to customer; pitfalls of voluntary assumptions of duty; advertising liability; finding an appropriate balance between doing too much and doing too little.

Summary: In implicit recognition of the transformation of the practice of medicine from a physician-based system to a network-based system of patient care and of technological advances that permit maintenance of databases of patient and pharmaceutical information, a growing number of courts as well as regulatory authorities have assigned the professional pharmacist a more active role as a final gatekeeper in protecting the consumer from potential injury. Plaintiffs, by citation to government regulations or through expert testimony about professional standards of conduct applicable to the practice of pharmacy, have succeeded in extending the pharmacist’s legal duty to his customer in certain circumstances to include inquiry about patient conditions, maintenance of patient profiles, diseases and prescription histories; review of such records prior to dispensing a prescription order; calling the physician and/or warning the customer of potential problems with a given prescription; counseling the customer; and choosing appropriate medications under drug formulary restrictions. In satisfying these new duties or in promoting his services to the customer, however, the practitioner may inadvertently be opening himself up to greater liability through voluntarily assuming additional duties or making representations on which the customer relies. The most significant areas of expansion of liability are patient warnings and advertising. The presentation will touch upon significant recent cases that exemplify these trends.

Conclusion: The law in the area of pharmacist liability is unsettled and undergoing rapid, uneven development in the direction of increased liability. The pharmacist should maintain and update patient histories at minimum intervals, which, ideally, the customer would verify through signing. In this uncertain environment, the pharmacist must be especially alert to potential liability in communicating to the customer within the area of his expertise. The pharmacy is well-advised to work closely with counsel to develop and review dispensing protocol on a periodic basis, implement computer programming to support adherence to the protocol, and to approve any proposed patient notifications and public advertising or promotional materials prior to dissemination.