

# Legal issues surrounding therapeutic interchange in institutional settings: An update

David B. Brushwood, RPh, JD

## ABSTRACT

The rise over the past decade of corporate liability, managed care, and pharmaceutical care has had the potential to shift the legal landscape for therapeutic interchange in the institutional setting. However, legal developments over this period reveal that an appropriately designed and managed formulary system continues to be a liability-reducing factor for health care institutions that perform therapeutic interchange consistent with such a formulary system. This article surveys the legal trends and opinions that led to that conclusion, featuring specific discussions of institutional liability, prescriber liability, and managed care liability. It also provides advice on how health care institutions can minimize any liability risks surrounding therapeutic interchange and similar medication management techniques.

(*Formulary* 2001;36:796–804.)

**Mr. Brushwood** is professor of pharmacy health care administration, College of Pharmacy, University of Florida, Gainesville.

Address correspondence to David B. Brushwood, RPh, JD, Professor of Pharmacy Health Care Administration, University of Florida, P.O. Box 100496, Gainesville, FL 32610-0496 (brushwud@cop.health.ufl.edu).

**T**herapeutic interchange has been defined as “a process through which one medication is dispensed and administered in place of another chemically unique medication, under an established policy within an organized health care setting using a formulary system.”<sup>1</sup> Although potentially controversial when done in an ambulatory care setting, therapeutic interchange has been referred to as “straightforward, consistent, and ethical”<sup>2</sup> when done in an institutional setting. The distinction, it has been argued,<sup>2</sup> is that staff in an institutional setting are subject to a single formulary and pharmacists and physicians in such a setting do not stand to gain financially from therapeutic interchange.

Despite the wide prevalence of therapeutic interchange, questions arise about the risk of legal liability for patient harm that might occur as a result of it. The following discussion of these legal questions primarily addresses therapeutic interchange within the institutional setting, although some of the observations and conclusions may be applicable to the ambulatory setting as well. Guidelines on formulary system management adopted by the American Society of Health-System Pharmacists (ASHP) specifically address therapeutic interchange.<sup>3</sup> The discussion that follows is based on the assumption that an institution using therapeutic interchange is compliant with these ASHP guidelines.

## Background and Context

Liang et al addressed the issue of legal liability surrounding therapeutic interchange in a review published in 1988.<sup>4</sup> They concluded that therapeutic interchange did not appear to be a risk management problem. Rather, they argued that “the formulary system actually appears to be a risk-limiting factor if properly operated.”<sup>3</sup> There is a solid legal opinion that has withstood the test of time. In the intervening years there have been no reported legal cases in which liability against a health care provider or institution has been upheld based on harm caused by therapeutic interchange.

However, changing times can change responsibilities—and liabilities. Thus, the rationale of the 1988 review may not necessarily be applicable to today’s health care industry. In particular, the rise of corporate liability, managed care, and pharmaceutical care over the past decade has the potential to change relationships and responsibilities. Under corporate liability, a health care institution is considered a primary health care provider, with a separate responsibility to its patients from that of the attending physicians who treat those patients.<sup>5</sup> Managed care organizations (MCOs) have implemented restrictive payment programs that challenge institutions to develop creative ways of providing quality care while still showing a profit.<sup>6</sup> Pharmaceutical care has been widely recognized as the mission of pharmacy practitioners, and it brings with it a firm commitment to outcomes-oriented practice.<sup>7</sup> Each of these factors presents new practice challenges that justify reassessing the potential for liability in therapeutic interchange.

## Regulatory Issues

Health care providers and pharmaceuticals are highly regulated by government agencies. Violation of a government statute or regulation increases the possi-

bility that the violator will be held liable for malpractice if the violation causes harm to a patient.<sup>8</sup> Both federal and state laws may present the possibility for liability-increasing violations of statutes and regulations. Thus, the potential for liability in therapeutic interchange depends on the extent to which federal and state government agencies regulate this practice.

Federal regulations administered by the FDA primarily address issues of product integrity, while state regulations administered by licensing boards primarily address issues of professional practice. Despite arguments to the contrary, the FDA is generally considered to lack authority to limit physician prescribing.<sup>9,10</sup> The rationale for the lack of restrictions on physician prescribing under the Food, Drug and Cosmetic Act (FDCA) is said to be that such restrictions would ignore patients' therapeutic needs and unnecessarily interfere with the practice of medicine.<sup>11</sup>

**Off-label use.** Usually when one drug is interchanged for another, pursuant to a formulary system, the indications for the two drugs do not exactly match each other. This may lead to concern that the dispensed drug is being used for an off-label indication. However, it has long been recognized that a physician who prescribes a drug for an off-label use does not violate the federal FDCA.<sup>12</sup> This approach is a sound one since package inserts are often not up-to-date and patients have the right to have their physicians make decisions based on all available knowledge.

Until recently, the prevailing view has been that even though physician prescribing for off-label indications cannot be regulated by the FDA, manufacturer promotion for off-label indications can be. Yet recent judicial decisions<sup>13,14</sup> suggest that perhaps the FDA cannot even regulate manufacturer promotion to the degree once thought permissible. The clear trend in the law is toward less regulation of off-label uses.

**Patients versus populations.** The FDA readily acknowledges its own limits. In a May 1999 report titled *Managing the Risks From Medical Product Use*,<sup>15</sup> the agency contrasted its own role of evaluating risks to populations with health care providers' very differ-

ent role of managing risks for individuals. After describing the agency's important function in product approval and labeling review, the report observed: "Once medical products are on the market, however, ensuring safety is principally the responsibility of healthcare providers and patients, who make risk decisions on an individual, rather than a population, basis."<sup>15</sup>

Of course, the FDA has an interest in the activities in which health care professionals engage, such as therapeutic interchange.<sup>16</sup> Yet the agency's interest is in updating information for health care providers, not in controlling their decisions. The FDA report noted: "FDA's risk management role in the

---

The FDA says its role should be expanded to better support—but not supplant—the individualized decisions health care providers make.

---

postmarketing period is primarily to make sure that accurate, up-to-date information is available to those managing risks and benefits."<sup>16</sup> The report concluded that the agency's role should be expanded to better support—but not to supplant—the individualized decisions health care providers make.

**Limits of federal jurisdiction.** Therapeutic interchange cannot violate the FDCA, or FDA regulations, because neither the FDCA nor FDA regulations address therapeutic interchange. The FDA may require drug sponsors to provide practitioners with information about the risks of therapeutic interchange under certain circumstances—either directly, or indirectly through product labeling. However, the practice of therapeutic interchange is not directly controlled by federal law.

Moreover, information from the FDA must be evaluated with care, because FDA language may not mean what one would ordinarily believe it to mean. For example, "therapeutic equivalents" when used by the FDA in its publication *Approved Drug Products with Therapeutic*

*Equivalence Evaluations* (ie, "The Orange Book") refers to products that "contain identical amounts of the same active drug ingredient in the same dosage form and route of administration."<sup>17</sup> This definition describes what practitioners usually believe to be generic equivalents, not therapeutic equivalents. Reliance on this definition in development of therapeutic interchange policies would unnecessarily restrict formulary management and could lead to unintended consequences.

**State licensure.** The definitions and responsibilities most relevant to health care providers are those in the statutes and rules of state licensing boards, as opposed to federal agencies. The practice of therapeutic interchange as a component of a formulary system is widely recognized and legally authorized within institutional pharmacy practice under the laws enforced by state licensing boards.<sup>6</sup> The parameters of those rules are generally consistent with those of organizations such as ASHP, and may incorporate those standards by direct reference.<sup>18</sup> Regulatory compliance is straightforward, either through adherence to the details of the rule itself or by use of the principles contained in the organizational standards incorporated by reference within the rule.

## Liability Issues

The perception of loss of control by individual physicians when drug choice is determined by formulary management has led to speculation that serious litigation "may arise from professional activities associated with this practice."<sup>19</sup> This speculation is based on traditional notions of legal responsibility for harm caused by negligent care.

For a patient to recover in a negligence action against a health care provider, three elements must be proven:

- (1) that the patient suffered an injury,
- (2) that the health care provider breached a legal duty not to expose the patient to an unreasonable risk of harm, and
- (3) that the provider's breach of duty caused the patient's injury.<sup>20</sup>

**Question of harm.** The first of these elements is a straightforward issue of fact. One cannot be liable for negligence if no harm has occurred. Thus, no patient will succeed in a negligence claim

for harm due to therapeutic interchange if no harm can in fact be shown.

**Breach of duty.** The other two elements are more problematic as applied to therapeutic interchange. Breach of duty to not expose a patient to unreasonable risk of harm can be proven only by showing failure to meet the applicable standard of care. Patients must be exposed to some level of risk for there to be any benefit from drug therapy. The relevant question in a negligence case is whether the risk to which a patient was exposed was offset by the benefit expected from the drug. This question is addressed through expert testimony and evaluation of that testimony by a jury. There may be two or more standards to which expert witnesses are willing to testify, leading to a "battle of the experts." Juries are faced with the daunting technical task of sorting through and assessing competing medical opinions and the bases for them.

As a practical matter, the defendant health care provider need only show compliance with a single appropriate standard of care to escape liability. The plaintiff must show that the defendant's conduct failed to meet any standard of care. This requirement is a significant obstacle to any claim that therapeutic interchange is the basis of liability. When done appropriately, therapeutic interchange is an activity endorsed by a P&T Committee. The P&T Committee necessarily sets the standard; that is why the committee exists. Compliance with formulary guidelines is a virtually impenetrable shield to liability. It would not matter that in another institution the guidelines were different, because all that is required is compliance with a single standard. Proof that two institutions conducted therapeutic interchange in different ways does not mean one institution fell below the standard of care, because there are many ways to meet the standard of care. An institution that ignored all relevant guidelines for therapeutic interchange and focused on profitability only, to the exclusion of patient safety, could fall below the standard of care in its formulary activities. But this would hardly surprise anyone. In an appropriately designed and managed formulary system, the standard set by the P&T Committee would be the standard of care for mal-

practice liability. Because there is malpractice only when the standard has not been met, any therapeutic interchange approved by the P&T Committee, based on appropriate review of all relevant evidence, has met the standard of care.

**Causation.** The third element of negligence involves causation, which is another significant obstacle to a successful lawsuit for negligence based on therapeutic interchange. Any claim of liability would have to prove that it was the interchange, not the drug, that caused harm to the patient. Thus, if Drug A had been ordered for a patient and Drug B had been interchanged pursuant to the formulary system, it would

---

In an appropriately designed and managed formulary system, the standard set by the P&T Committee would be the standard of care for malpractice liability.

---

have to be shown that harm caused by Drug B would not have occurred if Drug A had instead been dispensed and used. It is unlikely that causality could be thus shown to a reasonable degree of scientific certainty. Usually the two drugs are so similar that their adverse effects are essentially the same and it is difficult, if not impossible, to prove that one caused harm that the other would not have caused. Of course, if the facts showed that Drug B had been administered incorrectly, then there could be liability. But harm would have been caused by incorrect administration, not by therapeutic interchange.

Perhaps the technical and theoretical difficulty of proving breach of duty and causation of harm is why there have been no successful lawsuits involving therapeutic interchange despite the frequency of the practice.

### Institutional Liability

At one time, when hospitals and clinics were charitable establishments run without thought to profit, they were afforded charitable immunity from mal-

practice litigation. Although the physicians who had privileges at such a hospital could be sued for malpractice, the hospital itself could not be.<sup>21</sup>

Times have certainly changed. Many modern hospitals are openly for-profit, and those that maintain not-for-profit status are keenly aware of the need to at least minimize losses. Marketplace realities and the mandates of legal and quasilegal organizations have placed hospitals in the position of controlling, to a degree, the quality of care provided by the physicians to whom they extend privileges. A hospital is now a primary health care provider, with a legal duty to monitor the care provided to its patients.

**Corporate responsibility.** The principle of "corporate responsibility" was first recognized in 1965 by the Supreme Court of Illinois in *Darling v Charleston Memorial Community Hospital*.<sup>22</sup> Since then, a clear trend in the law has emerged, recognizing corporate responsibility as a doctrine under which a hospital owes a duty to its patients to adequately monitor both the quality of care and the competence of health care providers in the hospital.<sup>23</sup>

Corporate responsibility was directly applied to the realm of medication use in *Thompson v Nason Hospital*,<sup>24</sup> decided in 1991 by the Supreme Court of Pennsylvania. According to this case, a hospital has four important duties with regard to the provision of patient care: (1) maintenance of safe and adequate facilities; (2) selection and retention of competent physicians; (3) oversight of all health care professionals practicing within its walls; and (4) formulation, adoption, and enforcement of adequate policies to ensure quality care for patients. Under this legal mandate, a hospital cannot "play it safe" by failing to have policies concerning pharmaceutical care, because it is legally necessary to have such policies.

The patient in the Thompson case died as the result of an intracerebral hematoma due to her anticoagulation therapy not having been correctly monitored. The hospital attempted to lay blame entirely with the attending physician, who had not ordered the appropriate laboratory tests. The court concluded, however, that when an attending physician is practicing below the standard of care, a hospital

employee has a duty to notify the attending physician; if the attending does not respond appropriately, there is a further duty to notify hospital authorities.

In 1997, this responsibility was expanded in *Voorhees v The Hospital of the University of Pennsylvania*<sup>25</sup> to include the failure to use medication as well as the inappropriate use of medication. In the *Voorhees* case, a patient undergoing bilateral hip replacement was supposed to have received either warfarin or low-molecular-weight heparin, yet neither drug was administered in a timely fashion. The patient died from a pulmonary embolism. Noting that this same result had occurred twice before in this hospital, the court recognized a duty of the hospital to develop a system for assuring that patients for whom drugs are indicated receive the drugs they need.

The Thompson and *Voorhees* cases,<sup>24,25</sup> and others like them, show that hospitals are not merely passive observers of care provided by attending physicians. They are active participants in care, and their participation occurs primarily through the formulation, adoption, and enforcement of policies.

**P & T Committee role.** The primary mechanism through which a hospital can meet its corporate responsibility in the area of medication use is the formulary system managed by the P & T Committee. Decisions made by the P & T Committee concerning therapeutic interchange and other formulary management activities must be evidence-based, but they need not rely solely on the high level of evidence produced by randomized controlled trials. In fact, other hospital committees can provide useful, relevant, and valid information for P & T Committee consideration. For example, the Drug Utilization Evaluation Committee or the Quality Improvement Committee frequently conduct internal studies that are done not only to meet accreditation standards or legal requirements but also to provide data on the hospital's particular patient mix or unique characteristics. It is fully appropriate to use data from these committees as the basis for formulary decisions. To fail to do so would unnecessarily squander investigative efforts to improve care within the institution.

**Pharmacist exposure.** Pharmacists are of course the providers whose efforts are most directly oriented toward medication use. Legal requirements of individual pharmacists have expanded, paralleling the expansion of institutional liability. The expectation of unwavering accuracy in order processing continues to be a legal standard for institutional pharmacists. Despite recognition that systems often create circumstances that make it impossible to practice completely error-free pharmacy, the reality is that any mistake in order processing is considered negligence as a matter of law.<sup>26</sup> Pharmacists also have a responsibility to detect mistakes made by a prescriber and to notify both the prescriber and the nursing service of the need to rectify any such mistake.<sup>27</sup>

---

Today, a hospital is at risk for failing to have a policy, as well as for having a policy and failing to follow it.

---

Courts have recently begun to recognize pharmacists as responsible for anticipating bad patient outcomes and to require that they collaborate with physicians to assure optimal care.<sup>28</sup>

However, all of the expanded responsibilities of pharmacists are collaborative responsibilities. There is no trend toward requiring pharmacists to countermand physician orders based on a difference in judgment. There is likewise no trend that would require pharmacists to refuse to obey a P & T Committee policy. This is not to say that pharmacists are not free to disagree with a physician or with a committee; in fact, such disagreement is permitted, if not encouraged, in most institutions. But the law has not evolved to the point that failure to refuse an order, based on a difference in judgment, is malpractice. A pharmacist who complies with a formulary system can feel secure that the applicable standard of care has been met.

**Implications.** The conclusion reached by Liang et al in 1988—that a formulary system, including therapeutic interchange, is a liability-reducing factor for health

care institutions—appears to be valid for contemporary practice. In fact, the added legal responsibilities recognized since 1988 argue even more strongly for such a conclusion. The legal requirements for institutions, under the principle of corporate responsibility, should stimulate adoption of comprehensive policies for medication use, whereas previously there may have been safety through inaction. Today, a hospital is at risk for failing to have a policy, as well as for having a policy and failing to follow it. The formulary system, along with the P & T Committee's role in monitoring it, provides necessary evidence that an institution's corporate responsibilities have been met.

### Prescriber Liability

The choice of an appropriate drug for a patient, and the decision of how to use that drug, are responsibilities of the attending physician. Physicians have been held liable for failure to use due care in prescribing.<sup>29</sup> However, data suggest that only a small percentage of patients who are victims of medical malpractice actually file a legal claim against their physician.<sup>30</sup> A physician is not liable to a patient simply because a bad outcome occurred. There must be satisfactory proof that the physician violated the standard of care, and this proof is a challenging one.

**Evidentiary challenges.** The traditional process for offering evidence that a physician has committed malpractice has been expert witness testimony. Far from an exact science, expert witness testimony relies on a lay jury's ability to sort through complicated and conflicting evidence to discern a standard of care, as well as compliance or noncompliance with that standard. The potential arbitrariness and unreliability of this approach has led to rules such as the "honest error in judgment" or "two schools of thought" rules, which forgive some decisions by physicians that seem ill advised with the benefit of hindsight, but cannot legitimately be second-guessed by those not responsible at the time a decision had to be made.<sup>31</sup> "Hindsight bias" is a significant threat to valid appraisal of conduct that occurred in the past, because evaluators tend to consistently exaggerate what could have been anticipated in foresight.<sup>32</sup>

**Advice for managing liability risk**

The risk of legal liability cannot be eliminated, but it can be managed. Health care institutions should consider the following risk management strategies in meeting their medication use management responsibilities:

- Formulate, adopt, and enforce comprehensive policies for medication use within the institution.
- Thoroughly educate the medical staff on the content and process of therapeutic interchange so that there are no surprises and resulting disappointments.
- Base decisions concerning appropriate medication use on relevant literature review and/or pertinent institutional data. The package insert for a product is an important piece of information, but it should not necessarily guide a formulary decision in the face of newer or more specific knowledge.

- Avoid decisions that are driven primarily by financial considerations such as product promotions or preferential prices.

- Permit prescriber choice of alternatives other than a primary formulary alternative, based on sound clinical judgment and other valid evidence. Committee review of some physician-chosen alternatives may be necessary in a manner similar to the prior authorizations that occur in managed care environments to permit prompt overrides of interchanges when circumstances warrant.

- Conduct drug utilization evaluations for specific critical drugs in order to evaluate the effect of therapeutic interchange on the quality of care.

- Update the formulary system on a continuous basis and invite interdisciplinary participation in the update process.

rational and that the expense of care provided is justified by the expected results. Increasingly, consumers have expressed a willingness to attribute poor outcomes to managed care decisions rather than to health care provider judgments.<sup>37</sup>

Therapeutic interchange is an activity that could very well be subject to critical scrutiny in cases where an MCO stipulates that only certain drugs are paid for under its plan, without physician override and/or medical necessity provisions. A therapeutic interchange program would not likely stand up to scrutiny if the facts showed it was designed solely to increase profitability, and if the need to safeguard quality by maintaining comparable patient outcomes had not been given serious consideration. While technically it could be argued that MCOs do not make medical decisions but only establish rules for payment, the reality is that few patients have the resources to pay for drugs their plan will not cover.

The potential pressure from MCOs for physicians and health care institutions to limit prescription drug costs has led to suggestions that any cost-related decision to use a medication other than the one ordered should thoroughly consider the importance of full disclosure by the MCO to its enrollee and should show respect for physician autonomy in patient care decisions.<sup>6</sup> Some MCOs have oversimplified reimbursement issues by ruling that any off-label use of a medication is “investigational” and thus not reimbursable because it does not meet the medical necessity requirement of the contract. This approach has been harshly criticized as overbroad and unnecessary. It is entirely inconsistent with the approach of the FDA as described above. The FDA has never contended that all off-label use is investigational. Critics of managed care nevertheless admit that some sort of control of prescription drug expenditures is appropriate.<sup>38</sup>

**PBMs.** Most activities of pharmacy benefit management companies (PBMs) occur in the outpatient setting, but the concerns they’ve prompted may be relevant to some institutional practices. Foremost among these concerns is the possibility that pharmaceutical manufacturers will artificially create demand for their products through vertical integration with

Jurors may also be affected by the “fundamental attribution error,” which causes them to blame bad outcomes on an actor’s perceived personal inadequacies rather than on situational factors beyond his or her control.<sup>33</sup>

**Need for a standard.** To overcome these kinds of threats to validity and reliability, it is important to have an objective standard with which to compare the conduct of the prescriber being evaluated. Clinical practice guidelines, policies and procedures, decision-assistance algorithms, and other consensus-approved descriptions of appropriate practice can serve nicely as objective standards with which to compare allegedly substandard conduct. Obviously, objective standards are a double-edged sword. Those who have complied with them are in a favorable position, while those who have not may have explaining to do.<sup>34</sup> The formulary system, including the decisions made through it concerning therapeutic interchange, falls within the category of explicit standards that can facilitate the defense of malpractice by rebutting the vague standards on which the legal system might otherwise rely.<sup>35</sup> For prescribers who have followed the formulary system, and have either initiated

or consented to a therapeutic interchange, there is solid support for a determination that the standard of care has been met. There is security for individual practitioners in the expert consensus of the P&T Committee.

Departure from indications or directions in FDA-approved product labeling does not increase a physician’s exposure to liability.<sup>36</sup> The package insert has consistently been held to be only some evidence of appropriateness in prescribing. It is not an irrelevant document, but it does not define the standard of care because it is intended to describe risks to populations, and physicians treat individuals. Certainly any use of a medication that is off-label and also carries an unnecessary risk to the patient would be considered substandard. But the decision that it was substandard would be based on the unnecessary risk, not on the departure from labeling. It is fully appropriate for a physician to depart from labeling if the departure is consistent with the best interest of the patient.

**Managed Care Considerations**

In response to rising health care costs, MCOs have implemented strategies to assure that decisions made about care are

PBMs.<sup>39</sup> Economic influences have the potential to bias cost-effectiveness decisions made through the formulary process, threatening the independence and objectivity of the system. This concern might apply with equal force to the institutional setting if a P&T Committee were asked to approve a therapeutic interchange based on a market share issue concerning an entirely different therapeutic category. While an interchange based on cost-effectiveness evidence should be relatively easy to defend, the same action based on purchasing rewards could be far more difficult to justify to patients who believe their health was placed at risk in exchange for financial preferences.

**Patients' bills of rights.** Concerns over managed care have consistently produced proposals to change laws that make it difficult to sue an MCO for medical malpractice.<sup>40</sup> The "Patients' Bill of Rights" movement is directed toward opening up the courtrooms to solve the problems caused by restrictive managed care decisions. However, there is legitimate fear that this solution may be worse than the problem. Permitting lawsuits against MCOs may increase the costs of health care and decrease access to it. If MCOs were held liable for medical malpractice, they might begin to make real medical decisions, as opposed to just coverage decisions; after all, there would be no sense in holding back when one is going to be held accountable for the consequences. Patients might begin to insist on only the "best" treatment, believing that the best is always the most expensive, when the reality may be otherwise.

These and other concerns make it unlikely that the responsibility for outcomes of drug therapy will shift significantly away from the health care institutions and professionals who are responsible for patient care. Cost is a significant factor in medication use decisions, but quality is the overriding concern.

### Conclusions

The prospect of legal liability may be intimidating, but it should not be used as a reason for choosing one drug over another. As a general rule, good decisions about patient care are good decisions about liability as well. Any suggestion that fear of legal liability should form the

basis of therapeutic decisions must be challenged. Formulary systems, including therapeutic interchange, have shown themselves over the decades to be cost-effective and beneficial for patients without increasing liability. Health care providers, not lawyers, should determine what care is appropriate for patients.

### REFERENCES

1. Bollinger KA, Vermeulen LC, Davis SN, Geurink EA. Comparative effectiveness of low-molecular-weight heparins after therapeutic interchange. *Am J Health-Syst Pharm* 2000;57:368-72.
2. Carroll NV. Formularies and therapeutic interchange: The health care setting makes a difference. *Am J Health-Syst Pharm* 1999; 56:467-72.
3. American Society of Hospital Pharmacists. ASHP guidelines on formulary system management. *Am J Hosp Pharm* 1992;49:648-52.
4. Liang FZ, Greenberg RB, Hogan GF. Legal issues associated with formulary product selection when there are two or more recognized drug therapies. *Am J Hosp Pharm* 1988;45:2372-5.
5. Blum JD. Hospitals, new medical practice guidelines, CQI, and potential liability outcomes. *Saint Louis Univ Law J* 1992;36:913-45.
6. American Medical Association, Council on Ethical and Judicial Affairs. Managed care cost containment involving prescription drugs. *Food and Drug Law J* 1998;53:25-34.
7. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm* 1990;47:533-43.
8. Shuman DW. The standard of care in medical malpractice claims, clinical guidelines, and managed care: Towards a therapeutic harmony? *California Western Law Rev* 1997;34:99-113.
9. Shapiro SA. Limiting physician freedom to prescribe a drug for any purpose: The need for FDA regulation. *Northwestern Univ Law Rev* 1979;73:801-73.
10. Wilsker JA. One-half phen in the morning/one fen before dinner: A proposal for FDA regulation of off-label uses of drugs. *J Law and Policy* 1998;6:795-851.
11. Kessler DA. Regulating the prescribing of human drugs for nonapproved uses under the Food, Drug, and Cosmetic Act. *Harvard J on Legislation* 1978;15:693-760.
12. Hutt PB, Merrill RA. *Food and Drug Law. University Casebook Series*; 1991:616-631.
13. *Washington Legal Foundation v Henney*, 56 F Supp 2d 81 (DDC 1999).
14. *Western States Medical Center v Shalala*, 69 F Supp 2d 1288 (D Nev 1999).
15. *Managing the Risks from Medical Product Use: Creating a Risk Management Framework*. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration; May 1999.
16. FDA seeks help in evaluating consequences of therapeutic interchange. *Am J Health-Syst Pharm* 1997;54:1149.
17. *Approved Drug Products with Therapeutic*

- Equivalence Evaluations. 19th ed. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration; 1997:viii.
18. Fla Stat 465.019 (1999).
19. Plumeri PA, Crane VS. Legal and medical issues in therapeutic interchange: Implications for pharmacists, physicians, and P & T Committees. *Hosp Formulary* 1992;27:1040-50.
20. Kinney ED, Wilder MM. Medical standard setting in the current malpractice environment: Problems and possibilities. *Univ Cal Davis Law Rev* 1989;22:421-45.
21. Mulholland DM. The corporate responsibility of the community hospital. *Univ Toledo Law Rev* 1986;17:343-62.
22. *Darling v Charleston Memorial Community Hospital*, 211 NE2d 253 (Ill 1965).
23. Butler KA. Health care quality revolution: Legal landmines for hospitals and the rise of the critical pathway. *Albany Law Rev* 1995;58:843-70.
24. *Thompson v Nason Hospital*, 591 A2d 703 (Pa 1991).
25. 1997 Phila Cty Rptr, LEXIS 16 (June 3, 1997).
26. *DeCordova v State of Colorado*, 878 P2d 73 (Colo Ct App 1994).
27. *Gassen v East Jefferson General Hospital*, 628 So2d 256 (La Ct App 1993).
28. *Horner v Spalitto*, 1 SW3d 519 (Mo App 1999).
29. Farrell MJ. Medication malpractice: Claims, culprits and defenses. *Am J Trial Advocacy* 1992;16:65-107.
30. Shuman DW. The psychology of deterrence in tort law. *Kansas Law Rev* 1993;42:115-66.
31. Hall MA. The defensive effect of medical practice policies in malpractice litigation. *Law and Contemp Problems* 1991;54:119-31.
32. Fischhoff B. Hindsight does not equal foresight: The effect of outcome knowledge on judgment under uncertainty. *J Exp Psychol* 1975;1:288-99.
33. Fiske ST, Taylor SE. *Social Cognition*. Reading, MA: Addison-Wesley; 1984.
34. Hyams AL, Brandenburg JA, Lipsitz SR, et al. Practice guidelines and malpractice litigation: A two-way street. *Ann Intern Med* 1995;122:450-5.
35. Havighurst CC. Practice guidelines as legal standards governing physician liability. *Law and Contemp Problems* 1991;54:87-117.
36. Henry V. Off-label prescribing: Legal implications. *J Leg Med* 1999;20:365-83.
37. Noah BA. The managed care dilemma: Can theories of tort liability adapt to the realities of cost containment? *Mercer Law Rev* 1997;48:1219-47.
38. Raiford DS, Shulman SR, Lasagna L. Determining reimbursement for prescription drugs: Off label uses and investigational therapies. *Food and Drug Law J* 1994;49:37-79.
39. Mitchell EL. The potential for self-interested behavior by pharmaceutical manufacturers through vertical integration with pharmacy benefit managers: The need for a new regulatory approach. *Food and Drug Law J* 1999;54:151-83.
40. Brasel CE. Managed care liability: State legislation may arm angry members with legal ammo to fire at their MCOs for cost containment...but could it backfire? *Capital Univ Law Rev* 1999;27:449-82. **F**