# Pharmacy Malpractice

## The Changing Standard of Care

By GERALD A. SCHWARTZ


### *Estate of John Jones vs. Smith Pharmacy*

*Alex Smith, owner of Smith Pharmacy, graduated from pharmacy school in 1965. Pharmacist Smith works a 12-hour day, dispensing over 200 prescriptions daily. He has not yet begun to maintain patient medication profiles and has little time to read, attend meetings, or participate in continuing education programs.*

*For the past five years, Smith Pharmacy has dispensed all of the Jones family's prescriptions. John Jones, a 40-year-old corporate executive with three children, suffers from depression. He was first treated with amitriptyline hydrochloride by his family physician. The drug was discontinued because of cardiotoxic side effects, including palpitations and tachycardia.*

*After a 14-day interval, John Jones was given a prescription for phenelzine 15 mg, one tablet four times a day. He responded well to the phenelzine therapy, and his dosage was decreased four weeks later to a maintenance level of 45 mg daily in divided doses.*

*Three months later, Jones accidentally fractured his large toe and was given a prescription for relatively high doses of meperidine to relieve "excruciating pain" at the hospital emergency room. The prescription was filled at Smith Pharmacy.*

*Within 24 hours, John Jones lapsed into a coma and died, according to the medical examiner, as a result of a drug interaction between the phenelzine and meperidine.*

*The widow and children of John Jones brought a malpractice action against Smith Pharmacy for wrongful death.*

*Should the law allow the loss of John Jones to lie upon his widow and children—or should the law place the burden of loss on Pharmacist Smith through a court-ordered award of monetary damages? Did Smith run a "medical red light" and commit professional negligence by failing to keep up with the state of the art on drug interactions, and not maintaining patient medication profiles which would have prevented dispensing meperidine to a patient on phenelzine maintenance therapy?*

*To answer these questions, the court would compare Smith's conduct with the standard of care required of a "reasonable, prudent pharmacist" acting under the same circumstances. If Smith's conduct fails to measure up to this standard of care, he is professionally negligent and answerable for the consequences of John Jones' death.*

The standard of care that society demands is an external and objective standard defined as that amount of care and caution which a "reasonable, prudent person" would exercise under the same circumstances. Who is this "reasonable, prudent person" against whom our hypothetical Pharmacist Smith would be compared? He or she is an imaginary person, set up by the courts as a prototype, whose conduct represents that which society and the law expect of a person acting under the same circumstances as those facing the defendant. The "reasonable, prudent person" is a personification of a community ideal of reasonable behavior, determined by the court's sense of social judgment.

The high standard of care required of a pharmacist is described in *American Jurisprudence* as "... that degree of caution and care called for by the peculiar and dangerous character of the business, that is the highest degree of care and prudence for the safety of customers known to practical men." The rationale for holding pharmacists to such a high standard of care is stated by *American Jurisprudence* to be self-evident:

"People trust not merely their health, but their lives to the knowledge, care and prudence of druggists, and a slight want of care may prove fatal."

The courts have required the pharmacist to exercise the highest degree of care to advise the patient of the injurious effects produced by combining two drugs, where each drug by itself would not be harmful.

### 'Locality' vs. 'Accepted Practice'

What standards of care must society's fictitious "reasonable, prudent" pharmacist exhibit? Is Pharmacist Smith's conduct measured against the standard of care required of a "reasonable, prudent" pharmacist in a small rural community, a factory town, a major metropolis, or nationwide?

Generally, there are two standards that the courts apply in measuring a health practitioner's professional conduct: a local community standard of care, referred to as the "locality rule," and a nationwide standard of care, referred to as the "accepted practice" standard.

Developed in the "horse and buggy" days, the locality rule allowed for marked geographic differences in medical education and training. The country doctor, because of inadequate transportation and communication facilities at the time, could not be expected to keep abreast of advancements in the profession as well as his city counterpart. Under the locality rule a practitioner's conduct is compared to the standard of care customarily practiced by reasonable, prudent practitioners in the same or similar locality.

**'The local standard was merely a mirror image of the customary practice in the locality.'**

The locality rule came under vigorous attack as fostering substandard health care practices, since the local standard was merely a mirror image of the customary practice in the locality. In *Shilkret v. Annapolis Emergency Hospital Association* the court criticized the rule because "it effectively immunizes from malpractice liability any doctor who happened to be the sole practitioner in his community. He could be treating bone fractures by the application of wet grape leaves and yet remain beyond the criticism of more enlightened practitioners from other communities."

With the development of standardized medical training, modern transportation and communication facilities, and the availability of quality continuing professional education, modern courts have abandoned the locality rules holding that the standard of care should not vary from locality to locality. Patient safety demands that health care practitioners "measure up" to a nationwide standard of care.

Under this nationwide standard—the "accepted practice" standard of care—a practitioner's professional conduct would not be judged almost exclusively on customary practices, but instead would be based on the reasonable expectations of the profession as a whole of what constitutes sound professional practice.

In ascertaining what is reasonably expected of a competent pharmacist under the "accepted practice" standard, the courts would look to the Standards of Practice for the Profession of Pharmacy; to the current level of professional practice; to current practices being taught in the nation's pharmacy colleges; to the availability and content of continuing pharmacy education; to professional developments reported in pharmacy journals; and to authoritative texts such as *USP Dispensing Information* and APhA's *Evaluations of Drug Interactions*.

### Standards of Practice

The professional consensus as to what is expected of a reasonably competent pharmacist is found in the AACP/APhA Standards of Practice for the Profession of Pharmacy (see March 1979 *American Pharmacy*, p. 21). According to these standards of practice, the responsibilities of a reasonably competent pharmacist include:

- Interviewing the patient to obtain information for entry into a patient profile, including the task of obtaining a history of prior and present medical problems and drug usage;
- Checking the prescription against patient profile data for the presence of drug-drug interactions before dispensing medication;
- Determining whether the potential exists for a significant drug interaction.

Under the "accepted practice"

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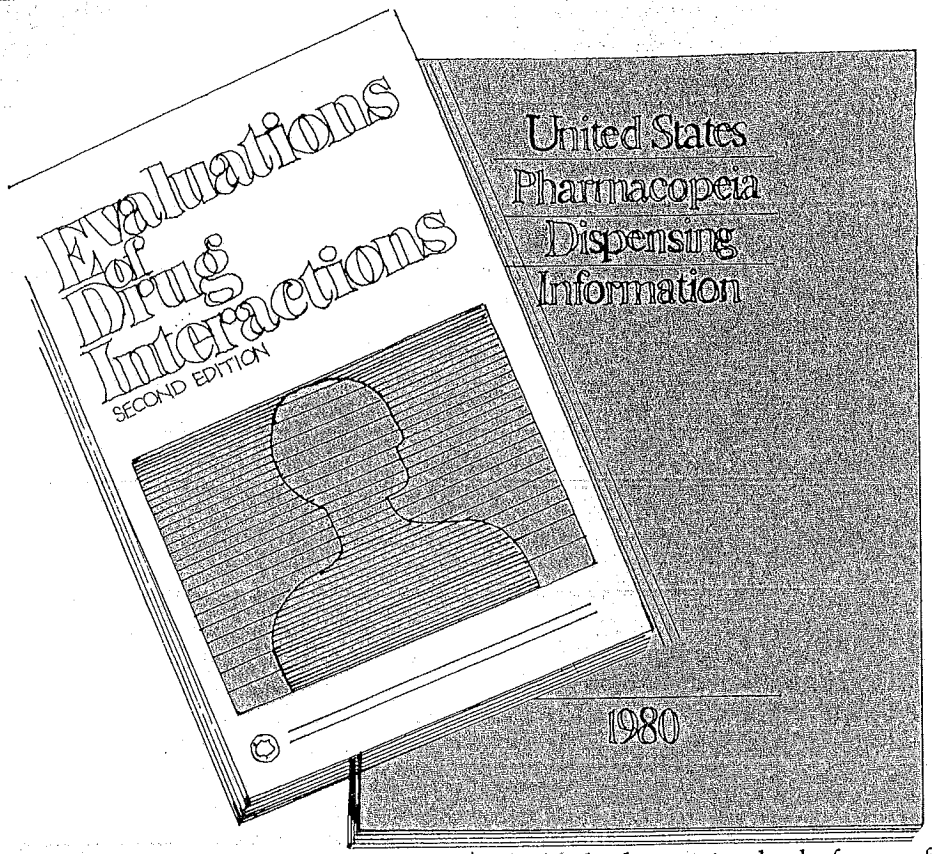


court test, professional conduct that does not measure up to the standards of practice would be strong, if not prima facia, evidence of professional negligence. Even in jurisdictions following the "locality rule," professional standards of practice are admissible as evidence to indicate the level of standard care—Standards of the American Psychiatric Association, the American Medical Associations's Principals of Medical Ethics, and even the Chiropractic Oath have been applied by the courts in ascertaining the standard of care.

### Levels of Practice

Several surveys described in early 1970 pharmacy journals reported that a majority of responding pharmacists maintained patient medication profiles. A study conducted in 1975 in three mid-Atlantic states by Joseph L. Fink III and co-workers found that over 54% of the responding pharmacists kept patient records and concluded:

"... Acceptance of patient medication records at the levels found in all three states could indicate that maintenance of such records is now established as a standard of care of pharmacy practice in these states."

With respect to professional liability for failure to maintain patient medication records, Fink reported (see September 1975 *JAPhA*, p. 496):

"Thus, one who fails to maintain PMR's will be leaving himself open for a lawsuit. With articles documenting the effectiveness of PMR's in the professional literature, as well as their low cost, and even beneficial economic effects, an astute attorney could well argue that a pharmacist was negligent for not maintaining PMR's. An entire industry, by adopting such careless methods to save time, effort or money, cannot be permitted to set its own uncontrolled standards."

### Pharmacy Education

The undergraduate pharmacy curriculum has changed drastically during the last 15 years. Clinical pharmacy, as a central concept of the professional curriculum and as a major course, was almost nonexistent in 1965 when our fictitious Alex Smith graduated from pharmacy school. Then the emphasis was on drug products, whereas today's emphasis is on patient care.

Gerald E. Schumacher, dean of the Northeastern University College of Pharmacy and Allied Health Professions, described the new role of pharmacy education:

"Our role is to assist students to understand disease states and to deal with drug profiles, drug interactions, and disease recognition. We're seeing more and more emphasis in pharmacy on the patient than on dispensing."

A prerequisite for graduation for today's pharmacy student is demonstrated basic competency in varied areas of clinical practice. Colleges such as Northeastern require that their graduating baccalaureates be competent in a number of categories of practice, including:

**'Clinical pharmacy has become the core of pharmacy practice...'**

- Recognizing drug-drug interactions and their potential for toxicity;
- Developing and implementing a patient profile system as an adjunct to rational drug therapy in both ambulatory and institutional settings;
- Monitoring patient profiles to determine the occurrence of problems such as drug-drug interactions, drug disease contraindications, and prescription errors or discrepancies;
- Assessing drug therapy with regard to adverse drug reactions, therapeutic incompatibilities, and drug-drug, drug-laboratory tests, and drug-food interactions;
- Suggesting specific changes in drug therapy based on clinical response to the drug regimen, intolerance by the patient of adverse reactions, or change in renal or hepatic function resulting in altered metabolism or excretion of drug(s);
- Providing to the patient cautions for drug use as well as information on probable or potential side effects and correct storage procedures.

### Continuing Education

The past several years have witnessed a nationwide explosion of continuing education programs offered by pharmacy colleges which enable pharmacy practitioners to keep up with recent developments in clinical pharmacy practice. For example, year-round continuing education programs are sponsored by the faculty of the Medical College of Virginia School of Pharmacy, who travel throughout the state holding full-day professional educational seminars on clinically related topics such as drug interactions. If the pharmacist is unable to attend continuing education seminars, the seminars can come to the pharmacist in the form of self-instructional handbooks or cassette tape courses, which are readily available at relatively low cost.

The literature of pharmacy has kept pace with the clinical state of the art developments. All major pharmacy journals regularly publish on pertinent topics in clinical pharmacy. The *FDA Drug Bulletin*, which is sent to all practicing pharmacists, also contains drug warnings. A June 1979 *Bulletin* was devoted entirely to alcohol-drug interactions, and the December 1979 issue of *American Pharmacy* contained a special feature on the subject. In addition, scores of publishing houses make available each year a wealth of new information about subjects such as drug-drug and drug-alcohol interactions.

The impact of pharmacy education will play a major role in ascertaining the level of the standard of care for the profession of pharmacy, since the courts emphasize the current state and availability of professional education.

### Authoritative Texts

Authoritative medical and scientific texts and journals also have been used by the courts in ascertaining the standard of care. With the publication of the *USP Dispensing Information* the pharmacist's responsibility to counsel patients on the safe use of medication has been authoritatively recognized by the United States Pharmacopeial Convention. Joseph G. Valentino has indicated that although *USP-DI* alone would not establish a legal standard of care, it would be regarded as "authoritative evidence of what the standard of care is."

In the area of drug interactions there are several authoritative texts available to assist the practicing pharmacist. For example, if Alex Smith had consulted pages 142-144 of APhA's *Evaluations of Drug Interactions*, he would have been alerted to the following precaution and recommendation:

*Concurrent administration of meperidine and phenelzine or other monoamine oxidase inhibitors may result in excitatory and depressant effects on the central nervous system (CNS) leading to deep coma and death.*

*Recommendation: Meperidine should not be administered concurrently with monoamine oxidase inhibitors.*

Had Pharmacist Smith maintained patient medication profiles and checked for harmful drug-drug interactions, John Jones might still be alive today.

**'Patient safety demands that health care practitioners "measure up" to a nationwide standard of care.'**

### Evolving Standards

The standard of care for pharmacy practice is never stationary; it evolves with changing times and changing practices. Significant advances have been made in the content of pharmacy curriculum, continuing education, and contemporary pharmacy practices.

Pharmacy education, which now emphasizes patient care, has influenced contemporary standards of care. Clinical pharmacy has become the core of pharmacy practice, and the profession reasonably expects today's pharmacist to be knowledgeable about drug interactions and to maintain patient medication profiles to prevent harmful injury to the patient. Failure to do so will result in substandard care—and professional negligence. Pharmacists are now considered to be important members of the health care team in monitoring the safe use of medication. They no longer merely serve a customer—every pharmacist gains a patient with each prescription dispensed.

The assumption of professional responsibility carries with it the corresponding assumption of legal liability.

At the trial of the Estate of John Jones v. Smith Pharmacy the defense will search for pharmacists from the local community who can testify that they, too, do not maintain patient medication profiles nor check for harmful drug-drug interactions. The courts will not allow these practitioners, who adopt methods to save time and effort at the expense of patient safety, to set the standard of care. As one court stated, "To hold otherwise is to exempt one from even willful negligence on the patently unsound ground that others in the same profession do likewise."

Only by continued learning and sensitivity to professional responsibility can the practicing pharmacist maintain competency and thus avoid the legal liability imminently facing the profession. □

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*A copy of the original manuscript including a complete list of footnotes and references is available from the editor of* American Pharmacy.