Preventing and Reducing Professional Liability Risk Related to Psychopharmacology

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Several significant factors have converged to impact and heighten concern about the potential for malpractice litigation related to psychopharmacology. Current influences as well as frequent sources of professional liability risk related to psychopharmacology are reviewed and suggestions for preventing and reducing risk are made.

Four significant issues have converged to impact and heighten concern about the potential for more malpractice litigation related to psychopharmacology:

- Psychiatric malpractice lawsuits frequently include allegations of negligence related to the use of psychotropic medications because these drugs are vital to the treatment of mental disorders.
- A host of controversies about the safety of psychotropic medications has been widely publicized, debated and considered in various realms (e.g., regulatory, research, clinical, drug industry, medical profession, patient advocacy).
- Adverse drug events (ADEs) are a focus of attention by the patient safety movement in an effort to decrease medical errors.
- Historically, advances in medical treatment tend to increase medical malpractice litigation.

This article will review sources of professional liability risk related to psychopharmacology and make some suggestions for preventing and reducing risk. **Background**

Advances in psychopharmacology have provided therapeutic options that were unavailable just a short time ago. This has resulted in an increase in the use of psychotropic medications in all age groups. The efficacy and safety of psychotropic medications, especially in pediatric patients, is an ongoing issue in clinical practice and psychopharmacological research (Curtis et al., 2005). Specific concern about the off-label use of psychotropic medications has been voiced by consumers and, in some instances, by experts.

These issues have received more attention lately. This is due in part to the March 22, 2004, Public Health Advisory from the U.S. Food and Drug Administration about worsening depression and suicidality in patients treated with antidepressants and with the FDA's directive for a black box warning about this risk on the package labeling of antidepressants (FDA, 2004). Moreover, research findings and reports in the media about various serious side effects and risks of psychotropic medications often emphasize the problems and not the benefits of these drugs. Announcements such as the FDA Public Health Advisory of April 11 (FDA, 2005) regarding increased mortality in elderly patients with behavioral disturbances prescribed atypical antipsychotics have added to the escalating national debate about post-approval safety of prescription medications.

Patient safety research and initiatives, in large part stimulated by the 1999 Institute of Medicine report "To Err Is Human: Building a Safer Health System" (Kohn et al., 2000), point to the prevalence of adverse medication events in causing patient injuries. In a 2002 study, Rothschild and colleagues found that "[a]dverse drug events associated with malpractice claims were often severe, costly, and preventable." Prevention of ADEs is one of four priority areas approved by the American Psychiatric Association Board of Trustees for patient safety activities to be directed in psychiatric practice (APA, 2002). Increased awareness of the problem at the early stages of the patient safety movement may prompt more attention to ADEs with a subsequent impact on litigation. However, in the longer-term, patient safety initiatives hold the promise of decreasing ADEs and related malpractice actions. (See Liang [1999] for a discussion on the impact of tort and contract law on patient safety efforts.)

High-profile legal actions against physicians related to prescribing scheduled controlled substances periodically cause concern for physicians about professional liability risk and even criminal risk in this heavily regulated area of practice. Historically, innovations in medicine have often been followed...
by an increase in medical malpractice lawsuits. These innovations usually add to the complexity of treatment and may simultaneously increase patients' unrealistic expectations for positive treatment outcomes (Sage, 2003). Against this background, psychiatrists' prescribing decisions will be scrutinized more than ever, increasing the risk of professional liability. Sources of Liability

Medical malpractice actions involving psychopharmacology usually allege negligence in prescribing, administering and monitoring medication(s), and/or failure to obtain informed consent or adequate informed consent (Table 1).

**Prescribing.** Allegations about negligent prescribing encompass the adequacy of assessment/evaluation of the patient (including history-taking, physical findings, obtaining past treatment history/records), diagnostic formulations and the decisions regarding medication(s) (including which to prescribe, dosage, frequency of dose and management of refills) (Table 1). Off-label prescribing is a widespread and well-accepted part of medical practice and is not, in and of itself, a professional liability risk. Off-label uses range from the clearly controversial to those considered the established standard of care. Typical off-label uses include prescribing for a condition not indicated on the FDA-approved labeling, prescribing at a different dosage than indicated or a different patient population.

Physicians are entitled to prescribe FDA-approved medications for off-label use (Arbitblit and Fleishman, 2005; FDA, 1982; O’Reilly and Dalal, 2003). The American Medical Association (AMA, 2004) (emphasis added) confirms its strong support for the autonomous clinical decisionmaking authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an unlabeled indication *when such use is based upon sound scientific evidence and sound medical opinion.* Critical issues in the evaluation of professional liability risk associated with off-label prescribing are: 1) whether the decision to prescribe off-label is evidence-based; and 2) whether supporting documentation reflect the psychiatrist's clinical judgment and decision making for prescribing this drug in this instance for this patient. Should a lawsuit arise with allegations that the off-label use injured a patient, these two elements provide evidence that will help defend the case.

Despite some recent high-profile media reports, criminal prosecution of physicians based on allegations of prescribing controlled substances for other than legitimate purposes is rare. Becoming the subject of a malpractice lawsuit and/or administrative (i.e., medical licensure) action alleging inappropriate prescribing is the greater risk. Examples of cases involving scheduled controlled substances include: 1) a patient death with allegations that the amount of methadone (Dolophine, Methadose) prescribed caused methadone toxicity and; 2) a patient death with allegations that methadone was prescribed for narcotic addiction treatment outside a specialized opioid treatment program in violation of federal and state law. Sometimes these cases are brought with allegations that the patient became addicted to the controlled substance due to the physician's prescribing practices.

All aspects of prescribing and dispensing controlled substances are highly regulated. Knowledge of and compliance with the federal, state and local laws and regulations, and applicable state medical board guidelines and position statements about prescribing scheduled controlled substances, along with utilizing the standard medication safety practices used for prescribing any drug, are critical to avoiding professional liability risk when prescribing scheduled controlled substances. (For more information and resources, see Federation of State Medical Boards [2005, 2002]).

**Administering.** Lawsuits alleging negligent administration of medications are not often seen against psychiatrists. Allegations usually involve ordering and/or administering a medication by the wrong route (e.g., giving the drug intravenously instead of intramuscularly). Such problems are more likely to occur in crisis or emergency practice settings and often involve possible negligence of the nursing staff or other hospital staff in the administration of the drug ordered by the psychiatrist.

**Monitoring.** Liability claims based on alleged failure to properly monitor a prescribed medication may be particularly difficult to defend because of well-established standards and guidelines for the monitoring of many psychotropic medications (e.g., clozapine [Clozaril], lithium [Eskalith, Lithobid], antidepressants). Furthermore, ongoing monitoring of drug treatment is a basic tenet of medical treatment. Any failure to monitor will be characterized by a plaintiff's attorney as a virtual abandonment of the patient's care. It is recommended that psychiatrists set up a system for regularly monitoring medications prescribed as well as documenting the results of monitoring (Table 2).

Some of the most serious cases involving negligence in monitoring psychotropic drugs are those in which patients develop tardive dyskinesia or neuroleptic malignant syndrome. These cases also typically include allegations of lack of informed consent or inadequate informed consent.
Informed consent. Informed consent allegations are prevalent in medication-based malpractice claims. Physicians have a duty to disclose to patients the information necessary for them to make informed decisions about treatment recommendations, including psychotropic medications. The specific legal standard regarding a physician's duty to disclose information varies from state to state. Regardless of a jurisdiction's disclosure standard, the law of informed consent requires that the basic content of the disclosure include (Rozovsky, 2004):

- The nature of the proposed treatment
- The risks and benefits of the proposed treatment
- The alternatives to the proposed treatment
- The risks and benefits of the alternative treatments
- The risks and benefits of doing nothing

In certain lawsuits involving psychopharmacology, both the psychiatrist and the drug manufacturer are sued by the patient/plaintiff. In some of these cases the intended target is the drug company and the defendant doctor is subsequently dismissed from the litigation. When the case proceeds against both, the drug company may rely on the "learned intermediary doctrine" in an attempt to place liability on the physician (O'Reilly and Dalal, 2003). The learned intermediary doctrine operates to shield the drug manufacturer from liability if the company proves that adequate information and warnings about the drug were available to the prescribing physician. The prescribing doctor, the "learned intermediary," then has the duty to disclose the information about the medication so the patient may make an informed decision about the risks and benefits of drug treatment (O'Reilly and Dalal, 2003).

Other, less common sources or theories of liability related to psychotropic medications are beyond the scope of this article. Regardless of the theory of liability that is alleged, the determination of whether medical malpractice occurred requires an analysis of the applicable standard of care.

Standard of care. A plaintiff must establish that a physician's actions or omissions were a departure from the accepted standard of care in order to prove a claim of negligence. A physician who deviates from the standard of care has the burden of proving that there was a justification for that deviation. Although there is variation among jurisdictions, generally, the standard of care is the degree of skill, care and diligence exercised by other physicians practicing in similar situations and in light of the present state of medical science. This is a "reasonableness" standard. The standard of care is established primarily by psychiatrists in the role of the expert witness. In providing an opinion about the applicable standard of care, the expert witnesses for the plaintiff and for the defense will rely on their own clinical experience, education and the clinical record, as well as a variety of legal and professional standards and resources that are indicative of and can be used as evidence to establish the applicable standard of care in a given case (Table 3). Reducing Risk

Key risk management strategies for reducing professional liability risk related to psychopharmacology include:

- **Information-gathering** about the medication and about the patient. Be knowledgeable about the medications prescribed and stay up-to-date with emerging research and safety information (Table 4). Know the patient through proper assessment and ongoing monitoring.
- **Communication** with the patient, family and other involved health care professionals about medications prescribed and the patient’s response to them. Use the informed consent process to support effective ongoing communication with the patient.
- **Documentation**, at least of the informed consent process, the basis for clinical decisions, the patient assessment, ongoing monitoring and response to treatment, medications prescribed, and changes to prescriptions.

As one researcher stated, "Psychiatric care relies heavily on medications, which are relatively toxic, although highly beneficial overall" (Bates et al., 2003). Many lawsuits against psychiatrists include allegations involving medications. It is imperative that psychiatrists engage in thoughtful decision making with regard to prescribing, communicate effectively with patients about medications, and be cognizant of the probable sources of liability and the factors involved in a standard-of-care analysis.

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psychiatric nursing with a focus on child and adolescent psychiatry.

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