

LESSONS LEARNED AT THE INTERFACE OF MEDICINE AND PSYCHIATRY

The Psychiatric Consultation Service at Massachusetts General Hospital (MGH) sees medical and surgical inpatients with comorbid psychiatric symptoms and conditions. Such consultations require the integration of medical and psychiatric knowledge. During their thrice-weekly rounds, Dr. Stern and other members of the Psychiatric Consultation Service discuss the diagnosis and management of conditions confronted. These discussions have given rise to rounds reports that will prove useful for clinicians practicing at the interface of medicine and psychiatry.

Dr. Edersheim is an attending physician on the Law and Psychiatry Service at MGH and an instructor of psychiatry at Harvard Medical School. Dr. Stern is chief of the Psychiatric Consultation Service at MGH and a professor of psychiatry at Harvard Medical School.

The authors report no sources of financial or material support for this article.

Corresponding author and reprints: Judith G. Edersheim, J.D., M.D., Massachusetts General Hospital, Wang Ambulatory Care Center 812, Boston, MA 02114 (e-mail: jedersheim@aol.com).

© Copyright 2009
Physicians Postgraduate Press, Inc.

Liability Associated With Prescribing Medications

Judith G. Edersheim, J.D., M.D.,
and Theodore A. Stern, M.D.

Have you ever wondered whether you might be found liable for something you do or do not do in the course of your medical practice? Have you wondered whether or when you need to warn a patient, a patient's family member, or someone responsible for the patient about his or her use of medication? If you have, the following clinical vignette and analysis may be useful to help manage these situations in your clinical practice.

Case Report

Mr. A, an 80-year-old man with coronary artery disease, chronic obstructive pulmonary disease, and hypertension, presented to his primary care physician with complaints of anxiety and insomnia. The primary care physician prescribed a low dose of an atypical antipsychotic medication. One week later, Mr. A was the driver in a motor vehicle accident; both he and a bystander were injured.

How Is Liability Defined and Determined in the Legal Arena?

Liability for unintentional harm is governed by tort law, and for medical professionals, the specific subset of tort law is known as professional negligence law. To be found negligent and responsible for harm resulting from your professional activities, courts generally require the presence of 4 conditions, often referred to as "The Four Ds" of malpractice.¹

First, the physician must have a "duty" to the patient, which means that he or she must have undertaken this patient's treatment. Duty is easily demonstrated in the presence of an established treatment relationship and is only controversial when the relationship is not clearly established or the setting is not professional.

Once the presence of a duty is established, the person asserting professional malpractice must demonstrate that the physician was "derelict" in this duty or in some way acted below the standard of care expected of physicians practicing in the same field. While the language used to determine the standard of care varies by state, such substandard care may take many forms, including dispensing poor-quality care or failing to offer appropriate and necessary treatments. This dereliction of duty must "directly" cause damage to the patient or third parties. By this, the courts mean that the injury must bear a causal relationship to the physician's actions and cannot be caused by intervening actors or conditions.

Finally, the dereliction of duty must have directly caused "damages" or compensable harm to the patient. While some poor medical practices might directly cause minor discomfort or inconvenience to the patient, the law generally confines itself to compensating serious harms, whether physical or psychological in nature.

Can the Prescribing Physician Be Held Liable for the Injuries and Losses That Resulted From His or Her Patient's Motor Vehicle Accident?

As a general matter, the case study presents a scenario in which the physician might have liability for both the injuries to the patient and the downstream harm caused by the motor vehicle accident. The appropriate analysis follows "The Four Ds" set forth previously. In this case, the physician had a clear treatment relationship with Mr. A, giving rise to a duty to practice up to reasonable standards of medical care.

The next step in the inquiry is to determine whether the decision to prescribe an atypical antipsychotic medication was in keeping with good medical practice. If the physician can demonstrate that the choice of this medication was within the standard of care, including the standard of care for informed consent regarding medications, there would be no dereliction of duty; therefore, there would be no negligence. The physician might use authoritative texts, professional association treatment guidelines, scholarly articles, and the testimony of experts in the field to establish that the prescription was appropriate for this patient with his underlying medical conditions. Keep in mind that prescribing appropriately in this case would have included a determination that the antipsychotic medication was appropriate and would not combine unfavorably with medications already prescribed for coronary artery disease, hypertension, and chronic obstructive pulmonary disease.

If the court determines that the physician's choice of medication fell below the expected standard of care, the claimant would still have to demonstrate the third "D," namely that taking the medication "directly" caused the motor vehicle accident. If, for example, the facts clearly established that, prior to starting the medication, Mr. A was alert and able to operate a motor vehicle safely, but that immediately after starting the medication he had failures of attention, concentration, and alertness, a court might find that the medication was the cause of a change in mental status that resulted in the accident. If, however, a second intervening event unrelated to the prescription altered his mental status, the prescriber would not be held responsible. This intervening event might be, for example, sedation caused by taking an over-the-counter medication not revealed to the physician, contemporaneous substance use by the patient, or even weather conditions so severe that they were deemed the "proximal" or ultimate cause of the accident.

In the vignette presented here, the final inquiry would be whether the claimants suffered compensable damages. If the patient in this case suffered significant bodily injury or psychological injury, liability might rest with the prescriber. In many states, the liability of the prescriber does not end with the damages to the patient and may extend to all of the untoward consequences of the accident, whether

to the patient or to a third party. These damages might include compensation for physical and emotional harm, medical bills, legal bills, and lost wages. Unless intervening factors were responsible for the consequences to third parties, the liability chain might well extend to others affected by the accident.² For example, in *Coombes vs. Florio*,² a primary care physician was held liable for failure to warn a patient of the dangers posed by medication side effects and failure to warn the patient not to drive. Liability extended to persons who were foreseeably put at risk by the doctor's failure to warn.²

Can a Physician Other Than the One Who Prescribed for a Patient Be Found Responsible for the Downstream Consequences of a Motor Vehicle Accident?

While a treatment relationship is a prerequisite for a professional liability claim, this concept is interpreted broadly, as a physician may have direct liability for a patient he or she treats or indirect liability through a shared practice or supervisory relationship with another physician. A physician who supervises other providers is often found legally responsible for the substandard practices of those he or she oversees.³ There are 2 legal bases for this liability; one is based in tort law with a claim of professionally negligent supervision, and the other is based in agency law alleging *respondeat superior* or asking that the "master reply for the servant." Supervisory liability may be proportionate to the degree of oversight and control the supervisor has over the clinician being supervised⁴; this is of particular concern to physicians who oversee several clinician prescribers in managed care organizations. Agency liability, or liability for those deemed to be a physician's agent, is generally determined along hierarchical lines without regard to the professional competence of the superior.

How Can Physicians Mitigate These Commonly Encountered Risks?

Ensure that prescribing practices meet current standards of medical care. Providing high-quality medical care is always the best defense against professional liability and claims of medical malpractice. In the area of prescribing medications, this means choosing a medication tailored to the clinical needs of each patient (e.g., to minimize adverse side effects and adverse interactions with other medications or conditions). At the outset, clinicians should maintain an updated list of all current medications prescribed for the patient, including those prescribed by other physicians. This list should also include over-the-counter medications or homeopathic remedies used by the patient. With the increasing number of known drug-drug interactions, many physicians use computerized drug interaction databases to screen medication combinations for unfavorable interactions and then place the results of this inquiry in the

medical record. Physicians should make sure that prerequisite blood tests are obtained and checked prior to starting certain medications. If follow-up blood levels are required, the practice should have an automatic mechanism for obtaining and checking them at appropriate intervals.

Risks can also be minimized by keeping up with the latest clinical prescribing information and U.S. Food and Drug Administration (FDA) regulations concerning the medications prescribed.⁵ Physicians should be cognizant of the treatment recommendations and medication algorithms promulgated by professional organizations (e.g., the American Medical Association [AMA], the American Psychiatric Association, or other subspecialty groups). These guidelines are commonly used in court as evidence of the standard of care associated with prescribing medications, and they are helpful resources for determination of current prescribing practices. Clinicians should stay current with the literature on medications prescribed in their field by reading authoritative texts and peer-reviewed journals. Finally, clinicians should obtain continuing medical education credits, which are required by all state licensing boards and are helpful in maintaining up-to-date prescribing skills. In the legal arena, continuing medical education can also demonstrate an ongoing commitment to provide cutting-edge clinical excellence if this is challenged in a malpractice action.

Maintain accurate and thorough documentation of prescribing practices. The legal adage, "If you don't write it down, it didn't happen," holds sway in the courtroom.¹ Proper documentation of clinical interactions is critical in the defense of a malpractice claim. Physicians must document what service was provided, must document when and by whom it was provided, and must document the medications prescribed, including the dose, directions, and number of refills provided. In our vignette, for example, a malpractice action might have turned on the appropriateness of the dose of antipsychotic medication prescribed and what instructions were provided to the patient concerning its use. If the patient was prescribed a very low dose of medication and instructed to take the medication only immediately before going to bed, behavior contrary to these instructions might release the physician from liability. Similarly, instructions to refrain from concomitant use of alcohol or to refrain from driving would make the patient's failure to adhere to treatment recommendations the proximate cause of the accident. Some physicians dispense written instructions regarding the appropriate use of each medication prescribed and obtain the patient's signed acknowledgement of the receipt of these written instructions. While this level of risk management is not required in order to document appropriate prescribing practices, the minimum level of documentation is a chart note that reflects the instructions given to the patient.

Finally, special care should be taken with regard to the documentation of prescriptions that are so-called "off-label" uses.⁶ Off-label prescribing refers to the prescribing of a medication for a use that has not been approved by the FDA. Off-label use of medications is a common practice and consists of prescribing for a nonapproved indication, prescribing doses outside an approved range, or prescribing for a different clinical population. The FDA, the AMA, professional medical organizations, and the federal courts have explicitly sanctioned off-label use, and off-label prescribing per se does not indicate that a physician has practiced below the applicable standard of care.⁷ While prescribing off-label is at the physician's discretion, FDA approval and the resultant prescribing guidelines in the *Physician's Desk Reference*⁸ may be used in a malpractice case as evidence of the standard of care, and the physician may be in the position of defending this off-label use in court. Therefore, it is prudent to maintain a file that provides the clinical rationale for such off-label uses, which might include reprints of scholarly articles, continuing medical education materials, or other sources that show that the use chosen was within the acceptable standards of medical care.⁹

In our vignette, the use of an atypical antipsychotic medication was a so-called "off-label use," as the atypical antipsychotics are currently FDA-approved for the treatment of schizophrenia and bipolar disorder but not for insomnia.¹⁰ In addition, in 2005, the FDA required the manufacturers of atypical antipsychotics to include a "black box warning" in package inserts concerning the increased risk of death among elderly patients with dementia treated with antipsychotic medications.¹¹ While this "off-label use" for an elderly patient with insomnia is a permissible course of action, this choice will come under greater scrutiny in the courtroom because of cautions regarding the use of this class of medications in elderly patients, many of whom take other medications that may also impair attention and alertness. This is not to suggest that atypical antipsychotics should be avoided in this clinical context, but rather that the choice must be undertaken with a conscious weighing of the risks, the benefits, and the alternatives. Most physicians have been careful to weigh the reasons for choosing one medication over another; unfortunately, they frequently neglect to record these reasons in the patient's medical record. A well-reasoned choice on the part of the physician goes to the heart of proving that he or she performed up to the standard of care and is invaluable as evidence against professional negligence.

Engage in informative and interactive informed consent discussions that allocate appropriate responsibility between physician and patient. Most physicians are aware that they must obtain the informed consent of their patients before starting a treatment or medication. Many do not know, however, that the failure to obtain and

Table 1. Obtaining and Documenting Informed Consent^a

1. Engage in an individualized and reciprocal discussion with the patient regarding consent to medical treatment
 - (a) Set aside time to discuss the treatment with the patient and/or guardian
 - (b) Maintain open and active lines of communication with the family and other caregivers regarding the patient's response to treatment
 - (c) Understand that a change in treatment plan, a change in the labeling of the medication, or a change in the patient's health state may require revisiting the informed consent discussion
2. Inform the patient of the following
 - (a) The nature of the proposed treatment
 - (b) The risks and benefits of the proposed treatment
 - (c) The alternatives to the proposed treatment
 - (d) The risks of failure to treat
3. Verify that the patient has the mental capacity to give a competent, voluntary consent; seek an indication that the patient understood the information provided and freely consented to treatment
4. If prescribing off-label, inform the patient that the drug being prescribed is not approved by the FDA for the particular use in question
 - (a) Discuss the rationale for off-label use
 - (b) Discuss why an FDA-approved medication was not selected
5. If prescribing a medication with a black box warning, explain the nature of the warning, the increased risks posed by the medication, and any attendant increase in physician and patient monitoring required
6. Document numbers 1–5 above in the patient's chart; if the informed consent process was conducted with the assistance of consent forms, obtain a signed copy of the form to include in the patient's chart

^aBased on Bradford and Gupta¹⁶ and Simon.¹⁷

Abbreviation: FDA = U.S. Food and Drug Administration.

document high-quality informed consent or informed treatment refusals can give rise to a claim of professional negligence. Each state has its own requirements for what constitutes appropriate informed consent, and it is prudent to check the standard in the state in which you practice. As a rule of thumb, however, a patient must make a knowing, voluntary, and competent decision regarding his or her medical care, and that includes the decision to accept or to decline a medication.¹² With respect to knowledge, a prescriber is typically charged with disclosing to his or her patient what a reasonable person would need to know in order to make the decision, or what a reasonable practitioner would disclose to a patient in similar circumstances. Whichever standard applies, the prescriber is usually guided to disclose the patient's diagnosis, the proposed treatment, the consequences of accepting or declining the treatment, and existing alternatives to the treatment proposed.¹³

One should take the time needed to engage in a mutual discussion with the patient regarding the risks and benefits of treatment. During this discussion, the practitioner should have a mental "checklist" regarding whether or not his or her patient is demonstrating the ability to engage in the process and to understand the nature of his or her choices. These abilities include the capacity to understand the treatment options, to reason through available courses of action, to understand the impact of treatment for the particular situation, and to express a consistent choice in this regard. One should be candid and careful about possible side effects of medications and about what course of action the patient should take if these side effects occur. With respect to alliance building, this mutual discussion of realistic expectations and pitfalls can strengthen the patient's understanding and commitment to treatment, while minimizing surprise and misunderstanding.¹⁴ With respect to

risk management, appropriate informed consent shifts some of the responsibility for undesired outcomes to the patient, who has been forewarned of the risks of treatment.

Many physicians engage in high-quality informed consent discussions, but fail to record them in the patient's chart. Undocumented discussions offer little protection in the legal arena. Indeed, some courts have gone so far as to say that failure to document the patient's informed consent for, or refusal of, a recommended procedure constitutes evidence that the discussion never occurred.¹⁵ All discussions of informed consent should be noted in the patient's record. Some physicians use printed forms that provide boxes to check regarding the information imparted to patients. While a preprinted disclosure may be adequate for generic advice, such as the requirement that patients notify the physician of any changes in symptoms, side effects, or medications, it is less useful for demonstrating that the patient in question understood the scope of the risks. Courts expect a discussion that engages the specific risks presented to the patient in question and look for an indication that the discussion was tailored to the individual (Table 1^{16,17}). For example, in our vignette, the discussion should have included identifiers specific to the patient, such as the possibility of additive sedation with his other medications. Clinicians can show evidence of an individualized discussion by augmenting a checklist form with a small narrative. Some risk management experts recommend asking the patient to sign the informed consent document and inserting the original form in the patient's chart.

Evaluate split treatment arrangements and supervisory settings to ensure that your supervisees have the training, ability, and resources to provide high-quality medical care. Supervisory liability generally takes 2 forms: one most often alleged when senior clinicians

supervise trainees (negligent supervision) and the other when supervisors are held responsible for the acts of other clinicians in a medical hierarchy (vicarious liability). In managed care or other corporate practice settings, functioning as a medical backup or medical director may incur both forms of liability.¹⁸ For example, in our vignette, if the prescribing physician for Mr. A was supervised by a more senior physician or residency supervisor, or by someone who held a position of contractual responsibility, such as the medical director, the supervisor might also be held legally responsible for the damages caused by negligent prescribing.

In order to avoid downstream liability that results from the poor practice of physicians under your supervision, make sure that the split-treatment arrangement or managed care contract provides for the delivery of quality medical care, with appropriately trained staff who have adequate levels of resources to provide good clinical care. One should examine managed care contracts to determine whether they allow for appropriate patient contact, visit frequency, and formularies. Such contracts should allow you to have direct communication with the clinicians who treat your patient and should outline the licensure and credentials expected of the prescribers who are under your supervision. Finally, the contract should provide for appropriate coverage during your absences and for the absences of treating clinicians.⁴

REFERENCES

1. Behnke SH, Hilliard JT. *The Essentials of Massachusetts Mental Health Law: A Straightforward Guide for Clinicians of all Disciplines.*

- New York, NY: WW Norton & Company; 1998
2. *Coombes v Florio*, 877 NE 2d 567 (Mass 2007)
3. Sederer LI, Ellison J, Keyes C. Guidelines for prescribing psychiatrists in consultative, collaborative, and supervisory relationships. *Psychiatr Serv* 1998;49(9):1197-1202
4. Gutheil TG. Risk management at the margins: less familiar topics in psychiatric malpractice. *Harv Rev Psychiatry* 1994;2(4):214-221
5. Index to drug-specific information. Available at: www.fda.gov/cder/drug/DrugSafety/DrugIndex.htm. Accessed May 13, 2009
6. O'Reilly J, Dalal A. Off label or out of bounds? prescriber and marketer liability for unapproved uses of FDA-approved drugs. *Ann Health Law* 2003;12(2):295-324
7. Beck JM, Azari ED. FDA, Off-label use and informed consent: debunking myths and misconceptions. *Food Drug L J* 1998;53(1):71-104
8. *Physician's Desk Reference*, 2008. 62nd ed. Montvale, NJ: Thomson Healthcare; 2007
9. Melonas JM. Some practical pointers for off-label use of an approved drug. *Rx for Risk* 2005;13(2):3, 8
10. Rochon PA, Normand SL, Gomes T, et al. Antipsychotic therapy and short term serious events in older adults with dementia. *Arch Intern Med* 2008;168(10):1090-1096
11. FDA Talk Paper: FDA issues public health advisory for antipsychotic drugs used for treatment of behavioral disorders in the elderly. T05-13, April 11, 2005. Available at: <http://www.fda.gov/bbs/topics/ANSWERS/2005/ans01350.html>. Accessed May 13, 2009
12. Grisso T, Appelbaum P. *Assessing Competence to Consent to Treatment.* New York, NY: Oxford University Press; 1998
13. Appelbaum PS, Gutheil TG. *Clinical Handbook of Psychiatry and the Law.* Philadelphia, Pa: Wolters Kluwer/Lippincott, Williams & Wilkins; 2007:126-127
14. Gutheil TG, Bursztajn HJ, Brodsky A. Malpractice prevention through the sharing of uncertainty: informed consent and the therapeutic alliance. *N Engl J Med* 1984;311:49-51
15. *Amos v Louisiana Med Mut Ins Co*, 936 So. 2d 875 (LA App 2006)
16. Bradford F, Gupta S. Psychotropic medications and informed consent: a review. *Ann Clin Psychiatry* 2008;20(2):87-95
17. Simon RI. Hot spots in clinical practice. In: Lifson LE, Simon RI, eds. *The Mental Health Practitioner and the Law.* Cambridge, Mass: Harvard University Press; 1998:118-130
18. Gutheil TG. Supervisor, supervisee and medical backup. In: Lifson LE, Simon RI, eds. *The Mental Health Practitioner and the Law.* Cambridge, Mass: Harvard University Press; 1998:140-152